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September 6, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1654–P
P.O. Box 8013
Baltimore, MD 21244–8013

RE: CMS–1654–P – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Federal Register (Vol. 81, No. 136), July 15, 2016

Submitted electronically via www.regulations.gov

Dear Mr. Slavitt:

UnityPoint Health ("UPH") appreciates the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the 2017 Physician Fee Schedule and Part B reimbursement. 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 committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Health Partners is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UnityPoint Health Partners 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.

MEDICARE TELEHEALTH SERVICES

CMS has proposed that telehealth service reimbursement be extended to (1) ESRD-related services CPT codes 90967 through 90970 and (2) Advance care planning services CPT codes 99497 and 99498.

- ***Comment***: We applaud the continued expansion of the list of telehealth services eligible for reimbursement. In last year's comment, we specifically advocated for the transition of the specified advance care planning (ACP) service CPT codes to active status. Telehealth reimbursement aligns with our past recommendation for CMS to embed flexibility within ACP standards and processes. A significant portion of such internal patient discussion occurs between

the patients and registered nurses or allied health professionals functioning as care coordinators, care navigators or similar roles and a growing proportion of these discussions are being performed within the patient's home. We urge CMS to go even further and enable care coordinators and navigators to bill for these ACP codes (either within the definition of 'other qualified health professionals' or under the 'incident-to' billing criteria).

While the services targeted for this year's expansion impact a relatively small proportion of Medicare beneficiaries, a telehealth service delivery option recognizes the high risk status of these individuals and the importance of service convenience to their quality of life. We encourage CMS to consider eliminating the requirement that the "originating site" for telehealth services must be located in a rural HPSA or a county outside of a MSA. 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. We recommend that CMS tie the removal of this rural limitation to providers participating in risk-bearing arrangements.

APPROPRIATE USE CRITERIA (AUC) FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

CMS has proposed requirements and processes for specification of qualified clinical decision support mechanisms (CDSMs) under the Medicare AUC program; an initial list of eight priority clinical areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

- ***Comment***: UPH comments are based upon our experience evaluating the CDSM marketplace as well as selecting and implementing a CDSM within an EHR order entry workflow throughout our enterprise – inpatient, outpatient, and emergency department settings.

  First, we strongly recommend that CMS require that a structured indication be entered into a qualified CDSM for every advanced imaging examination. Presently, there is considerable provider frustration with the current environment of varying and non-transparent criteria and processes for pre-authorization to order imaging exams imposed by health plan companies and radiology benefit managers. Providers need clear direction to properly implement a qualified CDSM and undertake necessary workflow changes. Using a simple, streamlined workflow that is the same in all cases is desirable and achievable with a successful implementation of PAMA.

  Within the CDSMs, we suggest that a structured indication be selected and recorded for each exam, whether an AUC exists or not. Meaningful statistical analysis of imaging utilization data for population health management requires reliable complete data. Having large data subsets with "no indication selected" or "other" seriously distorts any conclusions, weakens precision, and undermines efforts to alter provider behavior and engage in quality improvement efforts. In addition, the absence of structured indication for every exam will not facilitate the addition of AUCs to qPLE libraries to capture these omissions.

  Specifically, we recommend the following minimum qualified CDSM functional requirements:

  1. Accept a reasonably clinically specific structured indication for every exam
  2. Identify whether an AUC exists for that indication
     a. If an AUC exists, (i) record that an AUC was consulted and (ii) provide a mechanism to communicate that a consultation occurred to the CMS in a valid payable bill

b. If an AUC does not exist, i) identify those indications and (ii) provide a mechanism to communicate such deficiencies to the qPLE for further AUC development

Second, we support the use of Priority Clinical Areas (PCAs) solely as a measurement tool. We strongly believe that PCAs should be used for analysis of provider utilization behavior, but not as a limiting set of indications for CDSM use. Limiting CDSMs to the proposed eight PCAs adds confusions and complexity to a provider's work. We anticipate that this limitation will result in gaming of the system by some providers routinely selecting "other" or another indication not related to the PCA which will undermine the statistical basis for population health management, statistical analysis validity, and physician engagement efforts as discussed previously. We encourage CMS to apply PCAs in subsequent years to evaluate provider performance and involvement in stage 3 and 4 requirements. This assumes that qualified CDSMs contain indications and AUCs that fully cover all PCAs. In support of this, we recommend that a qualified CDSM must provide the following evidence:

1. Contractual relationships with at least 2 qPLE to demonstrate that all AUC applicable to each PCA are reasonably provided
2. Operational capability to provide effective CDSM support to the ordering provider at the point of care
3. qPLE (with a contractual relationship to provide AUCs) have specified an intent and timeline to deliver AUCs covering the entire scope of all PCAs

The written intent of a CDSM to develop relationships with potential qPLE for a full panel of AUCs is not sufficient evidence to become a qualified CDSM.

Finally, we recommend that CMS establish January 1, 2018 for the use of CDSMs. Given these new requirements and the need to coordinate vendors and train providers, we believe that this implementation date is both reasonable and achievable.

IMPROVING PAYMENT ACCURACY FOR PRIMARY CARE, CARE MANAGEMENT SERVICES, AND PATIENT-CENTERED SERVICES

CMS proposed coding and payment revisions intended to improve payment for care management services provided in the care of beneficiaries with behavioral health conditions; cognition and functional assessment and care planning for beneficiaries with cognitive impairment, including behavioral health integration; routine visits to beneficiaries whose care requires additional resources due to their mobility-related disabilities; non-face-to-face prolonged E&M services; and complex CCM services.

- ***Comment***: UPH supports separate payments for collaborative care by specialists and inter-professional teams or intensive PCMH services. The proposed payment structure facilitates the development of a medical neighborhood in situations where internists are co-managing patients or supporting the PCMH but are not within the entity employing the PCP. Among disease states for which specialist collaboration is behavioral health and cognitive impairment.

PHASE-IN OF SIGNIFICANT RVU REDUCTIONS

When Relative Value Units (RVUs) are proposed to be reduced by 20% or more, CMS has offered a phased-in reduction to be applied in which no more than a 19% reduction occurs on an annual basis.

For these significant reductions, CMS suggested reevaluating codes with assigned phased-in values for the subsequent year. This yearly reevaluation would continue until the value does not meet the threshold in excess of 19%.

- ***Comment***: UPH generally supports an extended phase-in period for significant reductions in RVUs. While the 19% annual limit appears reasonable when single codes are targeted for reduction, we urge that this percentage be examined and lowered to extend over a greater duration when entire code groupings are impacted. A lowered percentage and extended phase-in timeframe should also be considered when multiple codes are identified within a code grouping and they significantly impact revenue to a specific provider or specialist. The rationale for this request is to assure provider/practice sustainability and enable patient access to required care. If the RVU reduction annual percentages are too high and timeframes are too short to absorb cost reductions, a likely result will be providers and practices leaving the local market entirely or even selectively for Medicare beneficiaries. We urge CMS to re-evaluate these requirements for significant reductions in code groupings.

CCM AND TCM SUPERVISION REQUIREMENTS IN RHCs AND FQHCs

To enable RHCs and FQHCs to enter into third-party contracts for aspects of CCM and TCM, CMS has proposed to permit services and supplies furnished incident to TCM and CCM services to be furnished under general supervision of a RHC or FQHC practitioner.

- ***Comment***: UPH has more than 30 associated stand-alone RHCs located throughout Iowa and Illinois. 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. We support this proposed rule, which provides service delivery flexibility and enables greater use of these services for vulnerable populations.

  To encourage greater use of these codes, we urge CMS to eliminate the co-payment and deductible for these services in all sites of service. Despite the overall merits of these services, their nature as non-face-to-face billable services creates beneficiary confusion and patient dis-satisfaction when patients receive these bills. This patient dis-satisfaction results in a reluctance from providers to order these services. Even without a co-payment or deductible, CCM and TCM will raise revenue through cost savings to CMS attributable to the avoidance and reduction in preventable readmissions or transfers to higher care levels. We believe these services should be provided without a beneficiary charge.

ACO PARTICIPANTS WHO REPORT PQRS QUALITY MEASURES SEPARATELY

For purposes of the 2018 PQRS payment adjustment, EPs that bill under the TIN of an ACO participant may report separately if the ACO fails to report on behalf of the EPs. Specifically, CMS has proposed that the informal review period for these EPs would occur during the 60 days following the release of the PQRS feedback reports for the 2018 PQRS payment adjustment.

- ***Comment***: UnityPoint Health Partners, the ACO arm of UPH, has participated in the MSSP from July 2012 to December 2015 and in the Next Generation ACO Program since January 2016. Our UPH senior affiliate in Fort Dodge, Iowa – Trinity Pioneer ACO – was one of two rural ACOs that

participated in the CMMI Pioneer ACO Model. We appreciate this reporting adjustment to address the 2018 PQRS payment adjustment.

We are also concerned with a similar reporting misalignment for the 2019 MIPS payment adjustment, which will have ramifications for 2018 and subsequent reporting periods. To become an Advanced APM Qualified Professional, 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.

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. To allow providers confidence related to quality payment adjustments and reporting, we request that the 2018 PFS for MIPS payment adjustments in 2019 and subsequent years contain a long-term solution to address this situation. 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's thresholds.

PROPOSED EXPANSION OF THE DIABETES PREVENTION PROGRAM (DPP) MODEL

CMS proposed to expand a CMMI Health Care Innovation Award Round 1 demonstration project effective on January 1, 2018. This is the first of at least two opportunities to comment. For this comment period, CMS seeks input on the: (1) DPP benefit description; (2) enrollment of new Medicare suppliers; (3) expected DPP reimbursement; (4) IT structure and capabilities; (5) DPP eligible beneficiaries; (6) learning activities; (7) quality monitoring and reporting; and (8) timing of DPP expansion.

- ***Comment***: Given the pervasiveness of diabetes and pre-diabetes, we generally support efforts aimed at diabetes prevention and management. Prior to mandating a demonstration pilot project, we applaud the CMS approach of instituting a multiple-step comment process over a period of years with a delayed implementation date. Despite this prolonged comment process, we have concerns that CMS has not provided adequate financial information to inform our initial input. Of particular concern, CMS cites to an actuarial study to support national dissemination based on the CMMI demonstration, yet CMS indicates that it is "premature" to provide an impact statement for this rule. In particular, "comments received from this proposed rule will inform key design parameters of the MDPP [and] modifications to the proposed MDPP could result in changes to our current financial projections and therefore affect economic impact estimates of MDPP." This implies that CMS does not know what key design elements are necessary to make this program effective. The absence of an economic impact prevents commentators from taking this into effect when offering input. The lack of financials also does not explain how a grant project with a three-year award of $11,885,134 and an estimated savings of $4,273,807 has been factored into the success of this program. These figures suggest that there are upfront costs associated

with implementation that need to be better understood by providers aside from projected long-term Medicare savings.

We defer detailed comment on this program until a financial impact is provided. As a general comment, we encourage the use of quality monitoring and reporting that is consistent with other CMS programming and reporting mechanisms and balance administrative burden with anticipated benefits.

MEDICARE SHARED SAVINGS PROGRAM

CMS proposed changes related to (1) ACO quality reporting, including measures to assess ACO quality performance, quality validation audits and their impact on sharing rate, alignment with the MACRA proposed rule, and quality assessment terms such as ''quality performance standard'' and ''minimum attainment level;'' (2) conforming to regulatory text; (3) voluntarily beneficiary alignment; (4) beneficiary protections within the SNF 3-Day Waiver; and (5) technical issues concerning merged and acquired TINs and the minimum savings rate (MSR) and minimum loss rate (MLR) for low-volume ACOs.

- ***Comment***: UnityPoint Health Partners is a Next Generation ACO and is comprised of former MSSP and Pioneer Model ACO participants. We appreciate and wholeheartedly support CMS' recommendations to implement best practices from the Pioneer ACO and Next Generation ACO into the MSSP. Benefits and program flexibility features should be afforded to providers that enter into these risk-bearing arrangements.

  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. We want to reiterate our support for Section 101 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) that 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). Since MIPS is a stepping stone to Advanced APMs, UPH applauds CMS' 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.

  Lastly, 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.

PHYSICIAN SELF-REFERRAL (Stark Law) UPDATES

The Stark law serves the noble purpose of deterring over-utilization and fraud and abuse. 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. While UPH is supportive of reform efforts that include clarification of substantive terms and technical corrections, we believe more dramatic change is needed in Stark Law reform in light of movement from a fee-for-service system to one of risk-based provider payment.

Stark contains numerous ambiguities in its substantive terms that unfairly create hurdles and barriers for health care providers, impeding physician alignment, network growth and integrated care delivery. As healthcare providers continue to assume more risk and transition toward value-based payments, fixing the impediments created by enforcement of the Stark law has become critical. Physicians who seek to participate in Alternative Payment Models ("APMs") need to know their efforts will not result in violations of the Stark law. While violation of the Stark law is avoided through waivers that exist for existing APMs, there is no language in the SGR repeal legislation that addresses Stark in light of APMs created in the future.

Any effort to reform Stark will need to retain adequate protections against fraud and abuse, particularly in the fee-for-service setting. However, there needs to be recognition that broad flexibility is needed with Stark regulations that are solely predicated on a fee-for-service based payment regime. We are advocating with the agency and our congressional delegations that a broad Stark exception should be established where providers are participating in innovative payment models that assume financial risk and contain appropriate quality measures.

- ***Arrangements Involving the Rental of Office Space or Equipment*:** CMS has proposed an exception to permit the per-unit of service rental charges for the rental of office space or equipment, but only in those instances where such referral did not come from the lessor.
  - ***Comment***: UPH welcomes this per-unit clarification for rental/leasing of equipment. We support rental arrangements in which both licensor and licensee may utilize the equipment (such as an x-ray machine) without the necessity of a minimum block amount of time. We have found that such block lease arrangements are not generally conducive to either the licensor's or licensee's delivery of services to their respective patients.

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
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UnityPoint Health