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 electronica 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.
CY 2020 REVISIONS TO PAYMENT POLICIES

CMS is proposing a number of revisions to relative value units (RVUs), Geographic Practice Cost Indices (GPCIs), potentially misvalued services and specific code valuations. The proposed CY 2020 PFS conversion factor is $36.09, a slight increase above the CY 2019 PFS conversion factor of $36.04.

Comment: Clinicians are the face of medicine and we are discouraged with the relatively small magnitude (0.05) of the conversion factor. We are particularly disappointed in the payment inequity being perpetuated for internal medicine and mature family practices.

EVALUATION & MANAGEMENT (E/M) VISIT PAYMENTS

CMS is proposing a number of coding and payment changes with the intent of reducing administrative burden and improving payment accuracy. CPT coding changes retain five levels of coding for established patients, reduce the number of levels to four for office/outpatient E/M visits for new patients, and revise the code definitions. These changes also revise the times and medical decision making process for all of the codes and require performance of history and exam only as medically appropriate. The AMA RUC-recommended values for the office/outpatient E/M visit codes for CY 2021 and the new add-on CPT code for prolonged service time are proposed for adoption. CMS is consolidating the Medicare-specific add-on code for office/outpatient E/M visits for primary care and nonprocedural specialty care. While global surgery codes are not being revised, CMS is seeking input on three RAND reports related to these codes.

Comment: We appreciate the deliberative process that CMS has engaged in that resulted in this proposed rule. We are hopeful that CMS will continue to examine the merits of further collapsing E/M codes in the future with stakeholder input and allowing for multiple year implementation. This proposed rule starts that journey. We applaud the proposed emphasis for E/M payments that recognize time, medical decision making and additional codes reflecting prolonged time ordered or performed by providers in coordination of care for patients. We believe these changes have the potential to positively impact workflows through a templated note format and use of the EHR as a data aggregator and repository to be referenced for medical decision making.

Although we recognize the potential value, we also support the delayed implementation date of January 1, 2021 to allow our organization and providers across the country to fully digest the rules, make workflow changes, revise EHRs as needed and institute training. There are real and potentially significant short-term costs related to development, training and implementation. This proposal will require revisions to our current EHR documentation. Provider training will now focus on adequately describing and documenting time and decision making, including change management on access and plan documentation. We anticipate that documentation will be less intensive for separate acute short visits and more intensive for complex primary care visits. We will also need to engage in outreach that aligns our clinicians with our revenue cycle team and auditors.

Aside from internal efforts aimed at our organizational readiness, we would encourage CMS to proactively work with its MACs to assure consistency in rule interpretation. Any ability to release guidance or other sub-regulatory directives well in advance of the January 1, 2021 implementation date would be appreciated.

MEDICAL RECORD DOCUMENTATION

CMS is proposing to allow the physician, physician assistant or advanced registered nurse practitioner
who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team. The changes do not modify the scope of, or standards for, the documentation that is needed in the medical record to demonstrate medical necessity of services.

Comment: UnityPoint Clinic appreciates CMS’s continued efforts to remove redundant documentation. When furnishing professional services, this change allows clinicians to review and verify (sign/date) notes in a patient’s medical record made by other physicians, residents, nurses, students, or other members of the medical team, including notes documenting the practitioner’s presence and participation in the services, rather than fully redocumenting the information. This change will positively impact our workflows and reduce time and effort related to physician documentation. We wholeheartedly support this change.

CARE MANAGEMENT SERVICES
CMS is continuing ongoing work through code set refinement related to Transitional Care Management (TCM) services and Chronic Care Management (CCM) services. CMS is proposing new coding for Principal Care Management (PCM) services for beneficiaries with one chronic condition and addressing chronic care Remote Physiologic Monitoring (RPM) services. In addition, CMS is seeking comment on the framework for consent for communication technology-based services – frequency and scope of consent as well as the potential for program integrity concerns. Payment rates for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs) care management services HCPCS code G0511 is proposed to be set at the average of the national, non-facility payment rates for HCPCS codes GCCC1 and GCCC3 and CPT code 99484.

Comment: At first blush, it would appear that care management services would be an ideal fit for our service areas. In general, our beneficiaries are older than the national average, have multiple chronic conditions, and live in more rural settings with less access to healthcare providers. To date, these services have not been fully realized due to regulatory barriers instituted by CMS. While we appreciate CMS efforts to reduce barriers and encourage more use of these services, there is still more work needed.

For TCM services, CMS is proposing to allow concurrent billing for 14 services (Table 17) and certain payments. This proposed rule is intended to provide service delivery flexibility and enable greater use of these services for vulnerable populations. We support payment updates and believe that concurrent billing is complementary and not duplicative. For CCM services, CMS is implementing a new set of G codes and streamlining care plan reporting. While the intent behind these changes is to encourage greater use of these services, it is questionable whether temporary G-codes are the answer and encourage CMS to hasten its adoption of appropriate CPT codes.

To encourage greater use of both TCM and CCM services, 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 dissatisfaction when patients receive these bills. This patient dissatisfaction 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 and UnityPoint Clinic will not be robustly furnishing until cost sharing is removed.
CMS is proposing a new PCM service. At face value, this appears to be a win, particularly for patients with a single condition like ESRD. As with other care management codes, this will enable workflows for all patients regardless of comorbidities to build the necessary team to coordinate care, including medication reconciliation activities and office time surrounding a follow-up visit. We do not believe this code would lead to duplicative care management by focusing on disease-specific, rather than larger population health objectives. In fact, we believe that this code is an on-ramp for treating single diagnosis patients under a broader lens. We would encourage CMS to monitor the use of this code to identify potential overlap.

CMS is also seeking comment on the consent process for communication technology-based services. Practitioners have indicated that the current process is a barrier to care for service intended as brief check-ins and interprofessional services for an initial consultation. Although CMS is seeking comment on whether the process could be streamlined through a single advanced beneficiary consent or reduced consent frequency, it is the content of the consent that we would like to comment on. As proposed, the practitioner is responsible for informing patients of associated cost sharing obligations. In general, we believe cost sharing should be the responsibility of the insurer and that, if required, CMS and not providers should compose standard language on cost-sharing to include within the consent form.

**TELEHEALTH SERVICES**

*CMS is proposing to modernize Medicare payment by expanding telehealth reimbursement for specific services. In particular, CMS is proposing to reimburse face-to-face portions of services related to office-based treatment for opioid use disorder (HCPCS codes GYYY1, GYYY2, and GYYY3). In addition, CMS is proposing to define opioid use disorder treatment services by Opioid Treatment Programs to include use of two-way interactive audio-video communication technology, as clinically appropriate, in furnishing substance use counseling and individual and group therapy services, respectively.*

**Comment:** We support the addition of these three codes as well as the inclusion of a telehealth modality within the definition of opioid use disorder treatment services. We would also encourage CMS to remove current regulatory barriers to enable access to services for patients with distance or transportation barriers, mobility issues and/or provider shortages. We would recommend that CMS:

- **Authorize telehealth reimbursement for Rural Health Clinic providers** to offer remote service to their own patients. While patients may travel to their RHC for a specialist telemedicine visit (i.e. the RHC remotes to a distance specialist from their clinic), the RHC provider themselves cannot provide a home-based telemedicine visit.

- **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.

**COINSURANCE FOR COLORECTAL CANCER SCREENING**

*For beneficiaries scheduled for a colorectal screening procedure to which coinsurance does not apply, coinsurance does apply when they receive a diagnostic procedure because polyps were discovered and removed. CMS is seeking comment on whether advance notice should be required that a screening procedure could result in a diagnostic procedure (and accompanying coinsurance) if polyps are discovered and removed as well as the form of such advanced notice.*

**Comment:** UnityPoint Clinic appreciates the desire of CMS to avoid surprise billings; however, we are not convinced that physicians should be the source of truth for Medicare coverage information and conditions/circumstances that trigger coinsurance. **We believe that ultimately this messaging lies with the insurer and, in this instance, CMS and medical supplement plans.** The appropriate role of practitioners could be to provide the patient with a CMS-prepared consent form that details coverage differences for screening versus diagnostic procedures. A standardized form produced by CMS would help to assure that messaging is consistent regardless of setting or practitioner.

**INTENSIVE CARDIAC REHABILITATION (ICR)**

*CMS is proposing to expand coverage of ICR to beneficiaries with chronic heart failure and provide for modifications to covered cardiac conditions for ICR, as specified through a National Coverage Determination.*

**Comment:** We support this expanded coverage for ICR. Additionally, we would request that CMS revisit the Ejection Fraction (EF) percentage required for phase II Cardiac Rehabilitation generally. On November 21, 2013, CMS announced the decision to cover phase II Cardiac Rehabilitation for people with chronic heart failure who have an EF of 35% or less and NYHA class II — IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, and who have not had recent (less than 6 weeks) or planned (less than 6 months) major cardiovascular hospitalization. While this announcement was encouraging, approximately 50% of all HF patients have HFpEF (Heart Failure with preserved Ejection Fraction) with an EF of more than 50% and are disqualified from the program according to CMS guidelines. We believe this is a missed opportunity. In fact in 2013, AACVPR/ACC/AHA/HFSA had made a formal coverage request to include HFpEF patients with an EF of 40% or less, but this was postponed by CMS pending larger patient trials.

**OPEN PAYMENTS**

*For data collected beginning in CY 2021 and reported in CY 2022, CMS is proposing to: (1) Expand the definition of a covered recipient to include the categories specified in the SUPPORT Act; (2) expand the nature of payment categories; and (3) standardize data on reported covered drugs, devices, biologicals, or medical supplies.*
**Comment:** While we understand the desire for transparency and the need for data collection to monitor payments, open payment reporting does not necessarily imply that payments are improper or unethical. Given the expanded definition of “covered recipient,” we support the delayed implementation for data collection and reporting.

**PHYSICIAN SUPERVISION OF PHYSICIAN ASSISTANTS (PAs)**

*To align with current regulations on physician collaboration with advanced registered nurse practitioners (ARNPs), CMS is proposing to align the regulation on physician supervision for PA services. This proposal defers to state law and state scope of practice and enables states the flexibility to develop requirements for PA services that are unique and appropriate for their respective state.*

**Comment:** UnityPoint Clinic employs PAs. As part of an integrated health system within a largely rural geography, advanced practice healthcare professionals are vital to provide access to high quality healthcare in our communities. We have been a proponent for CMS to recognize State laws to permit top of practice licensure and we support this proposal. That said, UnityPoint Clinic is a multi-state organization and our licensing boards require varying degrees of supervision or collaboration in response to legal risk. While we will revisit our internal governing documents with an eye towards collaborative practice environments, UnityPoint Clinic will always require some form of monitoring for PAs to assure knowledge transfer and shared decision making.

In addition to this proposal, we would encourage CMS to consider expansion of ARNP and PA practice altogether to include:

- For skilled patients with Physical Therapy / Occupational Therapy / Speech Therapy orders, authorize ARNPs and PAs to sign orders;
- For cardiac and pulmonary rehabilitation, authorize ARNPs and PAs to sign orders and individualized treatment plans;
- For diabetes education (Medical Nutrition Therapy), authorize ARNPs and PAs to sign orders without physician co-signature;
- For diabetic shoes, authorize ARNPs and PAs to sign orders; and
- For home care, authorize ARNPs and PAs to sign home care orders.

**STATE SCOPE OF PRACTICE**

*CMS is proposing to permit advanced practice providers (APPs) or non-physician practitioners (NPPs) to provide services in Medicare-certified facilities within the extent of their scope of practice as defined by state law. Specifically, this enables certified registered nurse anesthetists (CRNAs) to perform the anesthetic risk and evaluation on the patient they are anesthetizing for the procedure and permits hospices to accept drug orders from certain physician assistants, along with physicians and nurse practitioners. CMS is also seeking additional information on the role of physician assistants in hospice care.*

**Comment:** We have been a proponent for CMS to recognize State laws to permit top of practice licensure and we support this proposal.

CMS is also seeking information on the current and future role of NPPs in hospice care. UnityPoint Hospice is affiliated with 5 Medicare certified agencies in Iowa and Illinois. In addition, UnityPoint Hospice is a CMMI Medicare Care Choices Model awardee in three Iowa regions. While we currently have ARNPs serving as attending providers for our hospices in both states, regulatory restrictions have limited potential relationships with PAs.
• **NPP Role**: There are beneficiaries, particularly in rural communities, who have a PA as their primary care provider and have developed a strong relationship / connection that is beneficial to the beneficiary and their family and to the provision of safe, quality clinical care. When the beneficiary elects the hospice benefit, the PA can now be considered the attending provider, but the hospice agency is prohibited from accepting medication / treatment orders from the PA under current regulations. As a result, care is often fragmented as the attending provider from the hospice agency, who may not know the beneficiary, has to start providing orders for the hospice patient. If a PA can be the attending provider on paper, we believe that they should be able to follow their patient through the hospice journey, providing the medical orders for care / treatment at end of life.

• **Core Service Classification**: We believe if the PA is the acting “attending” provider, they should be a core service, similar to the physician. Currently, we have ARNPs that provide the face-to-face visit and then recommend to our medical director that the patient should be recertified. If they are able to provide that level of assessment, they should also be able to be attending provider, sign the certification of terminal illness (CTI) and recertifications, and attend Inter-Disciplinary Team (IDT) as a provider and member of the core hospice team. In our experience, NPPs are usually more informed than many physicians that sit on the IDT and sign CTIs and recertifications.

• **NPP Supervision**: In Iowa, an ARNP is licensed independent of any supervising physician. In Illinois, an ARNP does require some level of supervision, but it is not prescriptive. We have not had issues with NPP competency or skill level, and they enable us to provide timely and thorough hospice care and services. We are generally supportive of NPP independent practice or minimal supervision requirements in every state.

• **NPP Orders**: In Iowa, ARNPs can practice independently and do not require physician supervision of the medical record. This ability enables timely workflows and care, and we would support this function being performed by NPPs.

**HOME INFUSION THERAPY BENEFIT**  
*Beginning January 1, 2021, home infusion therapy is a Medicare covered benefit. CMS is soliciting comments regarding the appropriate form, manner and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy under Medicare Part B.*

**Comment**: This benefit is limited to home infusion drugs, which are included under Part B and not Part D, and therefore restricts the relative magnitude of this coverage. In terms of the physician notification under the home infusion therapy benefit, we appreciate that CMS is seeking stakeholder input and we recommend a streamlined notice at the beginning of treatment to avoid any associated service delays. Since in many instances the physician may not be the most appropriate resource to know what place of service beneficiaries can get their home infusion drugs from, we would encourage CMS to embed sufficient time for physicians to research place of service. We would also recommend that CMS develop a single form for this notice to standardize its format and avoid benefit denials. Lastly, only one notice should be required at the start of therapy, since many of these therapies have a duration for the life of the beneficiary.
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 rescue 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 setup 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 differ 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.

o **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).

o **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 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.

o **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,

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