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October 5, 2020

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1734–P
P.O. Box 8016
Baltimore, MD 21244–8016

RE: CMS-1734-P: Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy published in Vol. 85, No. 159 Federal Register 50074-50665 on August 17, 2020.

Submitted electronically via www.regulations.gov

Dear Administrator Verma:

UnityPoint Clinic appreciates the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the 2021 Physician Fee Schedule and Part B reimbursement. UPC is comprised of more than 1,200 physicians and advanced practice providers at over 280 clinics in communities throughout Iowa and Illinois. UPC provides services in family medicine, internal medicine, obstetrics/gynecology, pediatrics, and a wide variety of specialty services, and is the ambulatory arm of UnityPoint Health. UnityPoint Health is the nation's 13th largest nonprofit health system and the fourth largest nondenominational health system in America, providing care to both metropolitan and rural communities across Iowa, western Illinois and southern Wisconsin.

UnityPoint Clinic (UPC) respectfully offers the following comments to the proposed regulatory framework.

CY 2021 REVISIONS TO PAYMENT POLICIES

CMS is proposing a number of revisions to relative value units, Geographic Practice Cost Indices, potentially misvalued services and specific code valuations. The proposed CY 2021 PFS conversion factor is $32.26, a 10.61 percent net decrease from the CY 2020 PFS conversion factor of $36.09.

Comment: This overall 10.61 percent net decrease sends a tone deaf message to frontline health care providers during a Public Health Emergency (PHE).

EVALUATION & MANAGEMENT (E/M) VISIT PAYMENTS

In addition to the AMA RUC-recommended values for the office/outpatient E/M visit codes for CY 2021 that were finalized in last year's rule, CMS is proposing to reevaluate several services that are closely tied to office/outpatient E/M visits, but is not reevaluating global surgical codes. Among the E/M proposals, CMS is revising the amount of time associated with E/M visit levels for the purpose of rate setting and limiting the use of the prolonged visit add-on code (99XXX). Also, CMS received feedback that the definition of the visit complexity add-on code (GPC1X) is unclear and is seeking comment.

Comment: **We applaud CMS for its acknowledgement that E/M payments have been undervalued** and support the delay in implementation until January 1, 2021, as provided in last year's final rule. As indicated in our 2019 comment letter, these changes have entailed time and effort related to workflow changes, EHR revisions and provider training. The additional "E/M-like" codes that are being added through this rule will need similar time and effort for provider education and training. With the shortened timeframe from final rule until January 1, 2020, as well as its late Fall / early Winter timing (i.e. flu season combined with the COVID-19 response), our providers will be challenged to prioritize E/M education and training over direct patient care. Although we intend to go live with E/M changes for the January 1 deadline, we request a grace period from CMS compliance and enforcement activities through March 31, 2021, or the end of the federal PHE, whichever is later. This grace period will enable a cushion timeframe that supports internal testing and workflows for implementation.

Overall, while we appreciate that E/M reimbursement has been increased and has been long overdue, we are disappointed that budget neutrality forces CMS to balance this increase from other providers.

TELEHEALTH AND OTHER COMMUNICATIONS TECHNOLOGY-BASED SERVICES

CMS is proposing to add nine services to the Medicare telehealth list on a Category 1 basis as well as to add 13 services to a newly created Category 3 telehealth list for the duration of the PHE. Other telehealth proposals include revising the frequency of telehealth visits for nursing facilities, including smartphones as telehealth equipment, enabling other practitioners to furnish Communications Technology-based Services (CTBS), and clarifying separate locations for billing. CMS is extending the PHE flexibility for direct supervision by interactive telecommunications technology and soliciting input on additional guiderails. CMS is also seeking comment on the continued payment for audio-only visits.

Comment: **The gains made in telehealth during the COVID pandemic and under the waiver flexibilities granted under the PHE have been transformative to health care delivery**. Aside from safety precautions, these flexibilities have enabled access to services for patients with distance or transportation barriers, mobility issues and/or provider shortages. Just in the first 60 days for our organization alone, telehealth visits increased by more than 1000 percent, the number of telehealth specialties increased from six to 54, and participating providers climbed from 15 to 902. Our virtual care platform "right sized" care by getting patients to the right level of care, at the right time, and reducing emergency room visits and other higher cost settings. These telehealth visits replaced urgent care (62 percent); doctor's office (20 percent); no treatment (10 percent); emergency room (6 percent); and retail health clinic (2 percent) and are associated with cost savings while maintaining a 4.85 star rating out of 5 stars.

Legislative Action. Before commenting on the specific regulatory proposal, we must acknowledge that **Congressional action will be required for beneficiaries to obtain the upmost benefit**. To inform this decision, **we urge CMS to provide Congress with data on the following points**:

- **Provider / Patient Location (i.e. originating site and geographic restrictions - §1834(m) of the Social Security Act)**. The rural 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 addition, limiting originating sites outside physician offices and hospitals ignores the population health and safety benefits of including patient homes, schools, long-term care hospitals, hospice centers, and employer work sites.
- **Eligible Providers and Facilities (§1834(m) of the Social Security Act)**. Flexibilities for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) reimbursement that permit RHC or FQHC providers to offer remote service to their own patients. While patients may travel to their RHC or FQHC for a specialist telemedicine visit (i.e. the RHC/FQHC uses a remote service for a telemedicine visit by a distance specialist from their clinic), the RHC or FQHC provider themselves cannot provide a home-based telemedicine visit. We also encourage CMS to consider additional practitioners beyond physicians and a limited set of non-physician practitioners, including encounters by dieticians, physical therapists, occupational therapists and speech language pathologists, as well as additional facilities, such as Hospital Outpatient Departments.

Medicare Telehealth List Additions. **We support the nine codes being added to the Medicare telehealth list on a Category 1 basis. We also support the addition of Category 3 and its 13 codes**. This new category allows clinicians and health care systems to determine efficacy and collect supporting data and information to justify a permanent addition to Category 1 or 2. Table 11 contains numerous services not elected by CMS to be placed in Categories 1, 2 or 3. We respectfully request the temporary continuation as Category 3 services of certain physical and occupational therapy services in CPT codes 97161, 97162, 97163, 97164, 97165, 97166, 97167, 97168, 97110, 97112, 97116, 97535, 97750, 97755, 97760, and 97761. In terms of the remainder of codes in Table 11, we are hopeful that CMS still intends to evaluate the use of these codes, including a public report, with outcomes and associated data for potential future additions to the list.

The Table 11 list also provides an opportunity to examine the future broadening of Medicare telehealth service offerings. **We firmly believe that Participant Providers and Preferred Providers in two-sided Medicare ACO models should be enabled to use and be reimbursed for a broader scope of telehealth waivers, including reimaging what telehealth services should encompass devoid of CMS modality, frequency and cost-sharing limitations.** Two-sided ACOs are charged with total cost of care for a beneficiary and present the ideal testing ground for telehealth innovation and case studies. Two-sided ACOs have (1) reduced incentives for ACOs to increase unnecessary costs, (2) an emphasis on holistic care and management of underlying conditions, not just the acute episode, to trigger early interventions that reduce ED use and avoidable admissions, and (3) protocols to monitor and evaluate utilization trends through claims files to review avoidable utilization and identify efficiencies.

Furnishing Telehealth Visits in Nursing Facility Settings. During the COVID pandemic, CMS waived the requirement for physicians and nonphysician practitioners to personally perform required visits for nursing home residents. **We support the use of two-way, audio/video telecommunications technology when the treating clinician based on the independent medical judgment determines an in-person visit is not necessary.** Rationale can be documented if required; however, we urge flexibility and do not believe clinicians should be confined to a laundry list of circumstances, such as continued exposure risk, workforce capacity, etc. **We are also concerned about the imposition of any frequency limitations.** While we would support the revision from 30 days to three days, we are concerned that any limit is arbitrary and should not be imposed absence a showing of fraud or abuse. Even then, we believe that CMS has the regulatory authority to address this potential on an individual basis, particularly given the recent Category 1 and Category 3 additions are each anticipated in this rule to be furnished, on average, less than 0.1 percent of the time overall.

Furnishing Telehealth Visits in Inpatient Settings. In the CY 2019 PFS final rule, CMS stated that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth to ensure that hospitalized patients have frequent encounters with their admitting practitioner. The provision of subsequent hospital care services through telehealth is limited to once every three days. **We support the use of telehealth in the inpatient setting but do not agree that arbitrary frequency limitations should be imposed**, rather we believe frequency of the telehealth modality should be left to the medical judgment of the provider and must take into account individual circumstances. Case in point, our hospitals often serve as a domicile for beneficiaries with mental health diagnoses who are awaiting more permanent placement. In some instances, lengths of stay for these beneficiaries are described in months, not days or even weeks. The use and frequency of telehealth versus in-person visits should rely on medically necessity and appropriate level of care protocols, not reimbursement rules.

Communication Technology-Based Services (CTBS). **We fully support top of practice licensure and the ability to have workflows that appropriately utilize physician time**. This proposal would allow billing of CTBS by certain nonphysician practitioners consistent with the scope of their benefit categories. We believe that nonphysicians should be able to practice/treat within the same scope as they would in-person. By engaging more practitioners, this may result in an increase in care plan adherence and general access to care. Additionally, **we support the following services and request that they be available to both new and established patients**:

- **E-visits** (Online Digital Evaluation and Management Services, CPT codes 99421, 99422, and 99423).
- **Virtual check-in services** (HCPCS codes G2010 and G2012), which includes asynchronous discussion or exchange of information.

Continuation of Payment for Audio-Only Visits. Audio-only payments are authorized as a CTBS and, as such, are not considered a telehealth service or eligible for inclusion within the Medicare telehealth list. **We have found value in audio-only visits and would support their limited continuation, particularly for established patients, patients without access to telehealth technology (such as a smartphone or broadband), and patients with complex conditions (such as behavioral health diagnoses)**. It has been helpful as a follow-up communication tool with patients. We urge CMS to

place audio-only on a "Category 3 like" status in order to collect data on the beneficiaries who are utilizing these services to identify trends in access to care. We believe CMS will find this service associated with vulnerable populations and an increase in access to services.

Clarification of Existing PFS Policies for Telehealth Services. CMS has clarified that services billed "incident to" may be provided via telehealth "incident to" a physician's service and under the direct supervision of the billing professional. **We appreciate this clarification**. In addition, CMS has clarified that if audio/video technology is used in furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in-person, and the service would not be subject to any of the telehealth requirements. **We would request that CMS consider an exception for public safety/protection, when a provider should be physically separated within the same facility/office to prevent contagion spread, preserve Personal Protective Equipment (PPE), etc.**

Direct Supervision by Interactive Telecommunications Technology. CMS is proposing to allow direct supervision to be provided using real-time, interactive audio and video technology through the later of the end of the calendar year in which the PHE ends or December 31, 2021. The presence of the physician (or other practitioner) may include virtual presence through audio/ video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising physician or (other supervising practitioner). **We support this proposal as long as discretion remains with the supervising physician/practitioner.** CMS is also seeking input on whether additional ''guardrails'' on interactive telecommunications technology should be considered. **We do not believe that additional requirements outside the physician's/practitioner's clinical judgment is needed.** Clinicians have the discretion to use or not, and some clinicians are already engaging in this practice. Adding more requirements mid-stream will add confusion and potentially expense as platforms, workflows, and training may be required.

CARE MANAGEMENT SERVICES AND REMOTE PHYSIOLOGIC MONITORING SERVICES

CMS is proposing 15 additional HCPCS codes to be billed currently with Transitional Care Management (TCM) services. A new HCPCS code GCOL1 is proposed (30 minutes by a behavioral health care manager on psychiatric collaborative care management) to be billed during the same month as TCM and/or Chronic Care Management (CCM) services. For Remote Physiologic Monitoring (RPM) services, CMS is proposing to allow consent for RPM services to be obtained at the time the services are furnished and to allow auxiliary staff to furnish RPM services under general supervision. After the PHE, RPM services will be restricted to established patients and limited to durations of 16 days or more of data within a 30-day period.

Comment: We continue to be supportive of expanded and more flexible TCM and CCM service delivery. As our beneficiaries are older than the national average, have multiple chronic conditions, and live in more rural settings with less access to health care providers, ideally these codes should be beneficial. That said, **we believe these services should be provided without a beneficiary charge**, and UPC will not be robustly furnishing these until cost sharing is removed. 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. **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. 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.

RPM services are a valuable tool not just for safely providing access to needed care during the COVID pandemic but generally to manage the health of beneficiaries with chronic conditions in the least restrictive and most convenient setting. As an example, during a significant COVID-19 surge in a rural part of Iowa, the hospital was overwhelmed by patient volume. We were able to use RPM to maintain beneficiaries in their homes, and RN case managers under general supervision have been able to effectively manage a greater caseload overall through RPM. With the shortage of and longer hours by health care workers, this efficiency has been timely. During the pandemic, RPM was also crucial to our strategy to conserve PPE. **We support the proposed continuation of RPM flexibilities, but would urge CMS to remove the arbitrary 16-day limitation.** We also believe that Participant Providers and Preferred Providers in two-sided Medicare ACO models should be enabled to use and be reimbursed for a broader scope of RPM services.

PRINCIPAL CARE MANAGEMENT (PCM) SERVICES FOR RURAL HEALTH CENTERS

CMS is proposing to add two HCPCS codes (G2064 and G2065) to G0511 and to be included in the payment rate calculation for PCM services for RHCs and FQHCs starting January 1, 2021.

Comment: Our comments are limited to RHC implications. While the combination of the codes reduces the overall cost by a negligible 27 cents per visit, we believe it is a stand-alone code and does not entail a time study, which streamlines implementation. **We seek clarification as to whether RHCs would be able to bill more than one code comprising the G0511 payment rate and, if so, we would request that the calculation use weighted rates as opposed to an average weight**.

SCOPE OF PRACTICE

CMS is proposing several changes intended to assist health care professionals to practice at the top of licensure and professional training. Proposed changes include supervision of diagnostic tests by certain advanced practice providers, pharmacist ability to provide "incident to" physicians' services, therapy assistants ability to provide maintenance therapy, and teaching physician and residency moonlighting flexibilities. Additionally, medical record documentation is clarified so that physicians and advanced practice providers can review and verify documentation entered into the medical record by members of the medical team for their own services that are paid under the PFS.

Comment: **We have been a long-standing proponent for CMS to recognize State laws to permit top of practice licensure as feasible. To promote practice flexibility and enable timely and appropriate allocation of human resources, we also support the concept of interstate licensure compacts**. Many of our service areas contain geographies classified as Health Professional Shortage Areas, Medically Underserved Areas, or Medically Underserved Populations and have caseload ratios for specialists which exceed national averages. It is critically important to utilize every member of our health care team to their fullest potential on behalf of patients. We support:

- Supervision of diagnostic tests by nurse practitioners (ARNPs), clinical nurse specialists, physician assistants (PAs) and certified nurse-midwives;

- "Incident to" services, such as medication management, being provided by pharmacists under appropriate levels of supervision; and
- Maintenance therapy being delegated to (1) a physical therapist assistant from a physical therapist; or (2) an occupational therapy assistant from an occupational therapist.

We also support as proposed the flexibility for reviewing and verifying documentation within the medical record.

Additionally, **we urge CMS to consider additional expansion of ARNP and PA practice when authorized under state laws 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; and
- For diabetic shoes, authorize ARNPs and PAs to sign orders.

Currently Medicare requires orders to be signed by a physician, which creates an unnecessary workflow funnel, particularly for beneficiaries who consider an ARNP or PA to be their primary care provider.

CLINICAL LAB FEE SCHEDULE (CLFS)

As required by the CARES Act, the next CLFS data reporting period is delayed until January 1, 2022 through March 31, 2022, which will not impact the private payer laboratory data collection period (January 1, 2019 through June 30, 2019). Additionally, the phase-in of payment cuts for CLFS services is extended through CY 2024. As a result, there is a zero percent reduction for CY 2021, and payment may not be reduced by more than 15 percent for CYs 2022 through 2024.

Comment: Given the COVID pandemic and additional related testing and reporting, **we agree that the data reporting period and the phase-in of payment cuts should be postponed**. It is our hope that this delay will allow a more representative share of laboratories to report private market data and will provide valuable time for stakeholders and policymakers to ensure that PAMA data collection reflects a market-based system that will protect Medicare beneficiary access.

We urge CMS to assure that all laboratory types are represented within the private payer-based rate setting methodology. The initial PAMA data collection was vastly incomplete and represented less than one percent of laboratories nationwide. With large independent reference labs being over-represented, the resulting fee schedule contained significant cuts to a range of laboratory services. Significantly impacted were laboratories serving hospitals, nursing homes, and rural communities that are on the frontlines of care delivery for the most vulnerable patients. These labs often provide rapid test results on a daily basis in order to triage health conditions and inform clinicians of any necessary changes to treatment regimens. According to a survey by the Infectious Disease Society of America related to PAMA changes, over 79 percent of respondents are unable to provide the full range of testing needed to rapidly diagnose infectious diseases. Approximately one-third of

respondents have changed their test menu, and nearly 40 percent now refer more tests to another laboratory, which can cause life-threatening delays in diagnosis and care.

Instead of promoting access to Medicare, we fear that PAMA is providing less access to quality laboratory services with a decrease in locally available laboratory services. These significant decreases in revenue will force difficult decisions, including:

- Inability to retain staff;
- Less investment in equipment and new technology; and
- Less testing performed in hospital labs with more tests sent to external reference labs, resulting in increased delays in diagnosis and treatment of patients and increased lengths of stay.

Local laboratories also impact the local economy. As high-paying, technical jobs or even whole service lines are shifted to national reference labs, local economies suffer.

SPECIMEN COLLECTION FOR COVID-19 CLINICAL DIAGNOSTIC TESTS

CMS is requesting comment on whether HCPCS codes G2023 and G2024 should continue to be payable to support COVID–19 testing beyond the conclusion of the COVID–19 PHE.

Comment: During the PHE, CMS established HCPCS codes G2023 (specimen collection for severe acute respiratory syndrome coronavirus 2, any specimen source); and G2024 (specimen collection for severe acute respiratory syndrome coronavirus 2, from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source). **We support the continuation of these codes to maintain their payment streams**. The COVID-19 virus will not cease to exist once the PHE terminates, and specimen collection will be ongoing.

HOME INFUSION THERAPY SERVICES

Beginning January 1, 2021, home infusion therapy is a Medicare covered benefit. The 21st Century Cures Act (Cures Act) provided that the Secretary determine, as appropriate, the form, manner and frequency of beneficiary notification of service delivery options. In this rule, CMS is clarifying required beneficiary notification requirements.

Comment: This benefit is limited to home infusion drugs, which are included under Part B and not Part D. Under the benefit, these services will need to be provided and billed by a home infusion therapy supplier under Medicare Part B, whether or not the home infusion therapy supplier is also the Medicare-certified Home Health Agency (HHA). Prior to the furnishing these services, the physician who establishes the plan of care must notify the beneficiary of service delivery options, such as home, physician's office, or hospital outpatient department. CMS is proposing for physicians to continue with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. **We support the spirit of this proposal but would encourage CMS to provide additional sub-regulatory guidance on documentation sufficiency**.

While the request for public comment was limited to the physician notification, we continue to believe that CMS has established a complex, costly and inefficient process for a very limited benefit.

Instead, we would encourage CMS to revisit this process and relaunch as a full comprehensive, all-inclusive home infusion therapy supplier benefit after seeking input from providers, beneficiaries and other stakeholders. **Our continued concerns are**:

Beneficiary Impact: This benefit structure disadvantages beneficiaries in terms of cost-sharing implications, limiting entitled benefits and fragmenting care.

- *Cost-Sharing*: Currently under the home health benefit, eligible beneficiaries are able to receive the professional services associated with infusion without incurring out of pocket costs. **The new Part B home infusion therapy benefit will require a 20-percent beneficiary co-payment for the professional services that are otherwise covered in full under the home health benefit**.
- *Benefit Limitations*: Current eligible beneficiaries who qualify for the home health benefit due to the receipt of home infusion therapy services may also be entitled to receive dependent home health services, such as occupational therapy, home care aide, or social worker services. **Under the new proposal, these beneficiaries will receive services under the home infusion therapy benefit, which includes skilled service but does not include other support services**. As a result, these beneficiaries will not be covered under the home health benefit for these support services and will simply forego this care or be forced to seek private-pay arrangements for this care.
- *Fragmented, Inefficient Care*: Currently under the home health benefit, eligible beneficiaries receive coordinated care from HHAs for skilled services, including home infusion therapy services. The responsibility for HHAs to coordinate this care remains unchanged in the HHA conditions of participation. Under the new proposal, **the home infusion therapy benefit and the home health benefit operate concurrently and may require two distinct service providers in the home under separate plans of care during the same episode of care**. For example, a beneficiary that requires skilled nursing for wound care and infusion services could potentially be required to receive skilled nursing for the wound care from the HHA and receive skilled nursing for the infusion from the home infusion therapy supplier. This fragmentation of care poses a clear risk to the quality of care provided to the beneficiary. It also imposes additional time constraints on beneficiaries and caretakers due to multiple appointments.

Scope: In general, since most home infusion drugs are included under Part D, we believe the scope of this benefit (as evidenced by Table 12) will be very narrow in relation to this extensive new regulatory framework. **We encourage CMS to include Part D under this new framework for consistency.**

UPDATES TO CERTIFIED EHR TECHNOLOGY

For the Promoting Interoperability (PI) Program and the Quality Payment Program (QPP), CMS is proposing that health care providers use technology that is certified to either the current 2015 Edition certification criteria or the 2015 Edition Cures Update. After August 2, 2022, PI and QPP technology must be certified to the 2015 Edition Cures Update. For the Hospital Inpatient Quality Reporting (IQR) Program, CMS is proposing that hospitals use technology certified to either the 2015 Edition certification criteria or the 2015 Edition Cures Update. These IQR program requirements are effective beginning with the CY 2020 reporting period/FY 2023 payment determination and for subsequent

years.

Comment: Increased interoperability is an ongoing focus of the QPP and CMS as a whole. We likewise agree that a bidirectional exchange of data with our health care trading partners as well as sharing claims and quality data to enhance care management are laudable goals. The Cures Act and the Interoperability and Patient Access Final Rule further these goals for all health care providers, not just those participating in QPP to receive Medicare Part B payment adjustments. In fact, the Cures Act has created an overall sea change for EHRs everywhere. Essentially, the Cures Act shifted to locust of EHRs from internal record keeping that was maintained for providers to being patient-focused records that are maintained for patients. As a result, EHR documentation and processes must and will look significantly different.

While we are aligned with interoperability goals, **the 18-month timeline for the broad expansion of data sharing is proving to be quite burdensome**. The magnitude of this task and the burden of mapping and data integration is multiplied by the numerous means data can be exchanged. Adding to the complexity is that UPC is part of a large integrated health care system spanning several states and our internal EHRs reside on multiple platforms not to mention those provider platforms for which we exchange records.

November 1, 2020 marks the first milestone, which is the effective date for the information blocking provisions. This looming deadline has required software builds, workflow revisions, provider training and countless hours from a large multidisciplinary team to assure a flawless "go live". These are resources that have been diverted from other projects as well as the COVID pandemic response. While we appreciate the phased approach to interoperability, the six-month implementation period for expanded data sets is woefully inadequate. The United States Core Data for Interoperability (USDI) provides an exceptional starting point regarding the expectations for data that should be sharable to patients, across health care organizations and, over the course of the next two years, with payers and other identified sources. Unfortunately, **the current interoperability data set as defined in the Stage 2 Meaningful Use rule (and expanded/clarified during subsequent releases) does not match the robust USCDI requirements**. To meet USCDI requirements for data sharing with patients in a thorough and consistent manner, a six-month guide path is not ideal. More time is required to identify gaps, create an approach to mitigate gaps, and establish processes, policies and procedures to document data requests and to transfer and monitor data.

As work continues, we have found that HHS requirements ignore and often negate professional judgment and lessons learned related to patient communication. In particular, these requirements:

- Recreate problems that have been solved over time through reporting and software fixes;
- Disregard communication timing and cadence that have been honed over years; and
- Force a paradigm shift from one in which providers decide to share or unlock data to a future state in which providers will proactively block data.

As providers put forth best efforts to comply, **we request that HHS provide dedicated FAQs and guidance documents. Among the issues requiring clarity is the scope of records implicated** – for

instance, what is the timeframe (i.e. day forward data versus legacy data); and what is included (i.e. internal data versus external / converted data). As rules are further refined, we seek to partner with CMS, ONC and HHS and request clear guidance and an adequate runway with implementation phases to make this possible.

MEDICARE SHARED SAVINGS PROGRAM (MSSP) QUALITY MEASURES

CMS is proposing to reduce the number of measures in the ACO measure set from 23 measures to six measures to align with Merit-based Incentive Payment System (MIPS). CMS is proposing to eliminate the Web Interface as a means to report quality measures. In terms of the quality performance standard, the minimum threshold is increased from 30 percent to 40 percent and the comparison group includes most other MIPS participants as opposed to only ACOs. Extreme and uncontrollable circumstances are proposed for CY 2020 and subsequent years, the definition of primary care services is revised for alignment purposes, and the amount of repayment mechanisms is reduced.

Comment: UPC participates in the Next Generation ACO Model through UnityPoint Accountable Care. As such, Next Generation ACOs use the MSSP quality measure set. Historically, UPC has been supportive of the Meaningful Measures initiative and has applauded CMS efforts to streamline data collection and reporting. **Although we appreciate efforts to reduce reporting burden, the drastic change in the measure set without a pay for reporting period is ill conceived**. We are very concerned that the emaciated Alternative Payment Model (APM) Performance Pathway measure set is comprised of just six measures – thee eCQM measures, one patient survey measure, and two claims-based measures. Theoretically, a very small measure set risks over-emphasizing certain metrics and underlying patient conditions and potentially creates more clinical disruption when the measure set is revised. Practically, the measure set as proposed under-emphasizes the complexity of holistic care through the limited suite of preventive care measures. For providers in risk-bearing arrangements, this small measure set heightens the risk with little transition time for learning.

CAHPS Survey: **We continue to have concerns about the CAHPS survey methodology used for the totality of the Patient's Experience Meaningful Measure Area**. Foremost, this survey is very subjective (being based on the patient's 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 reviewing our own CG-CAHPS data comparing Next Generation ACO patients to non-Next Generation ACO patients, Next Generation ACO patients consistently scored 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 are unable to supplement with more accurate contact information in an effort to reach more of the sampled patients); and (4) surveys are administered once annually with results usually received midway through the performance year.

GPRO, Web Interface Quality Reporting Option: The elimination of this reporting option is devastating for our large ACO with nearly 5000 providers. **We request that CMS retain the Web Interface reporting option for at least 24 months to allow health care organizations to transition to other methods of reporting**. A change in reporting is not as simple as flipping a switch and we need time to complete a third-party vendor assessment, CEHRT assessment and, if possible, implementation of APM Performance Pathway measures within the EHR, assessment of APM Entity

needs, organizational redesign and implementation regarding reporting methodology changes, validation of individual TIN software capabilities, and testing of file creation for ACO submission. As we are approaching our sixth and final year in the Next Generation ACO Model, timing is not ideal to learn a new reporting system in the waning days of this at-risk contract.

CMS has not adequately considered provider cost and overall burden. We do appreciate the general program costs associated with the upkeep of Web Interface reporting and respect the idea of streamlining reporting methods to reduce burden of cost on the overall program; despite this and with the extension of advanced APM models, the burden of cost will be allocated to health care providers who were previously required by program standards to utilize Web Interface reporting as a sole methodology for submission to the ACO model. For an ACO participating in Medicare models in CY 2021, these ACOs must overhaul their entire reporting structure, research and identify other reporting options for each TIN under the ACO entity, and identify a means to merge and submit data for all TINs associated with their ACO Entity. For our ACO, a third-party data vendor was selected to perform data integration from multiple CEHRT software within the APM Entity. This selection was made in part due to the vendor's ability to create Web Interface reports for ACO submission. **Notice timeframe of this sunset leaves us challenged to find another vendor appropriate for this task.**

We are also concerned with decentralized reporting. While we appreciate the ability of individual TINs under an ACO Entity to submit their own data, the ACO entity is not guaranteed access to TIN level data or results associated with that data submission. This **lack of transparency of Participant TIN data when submitted individually hampers the ability of the ACO Entity to predict ACO outcomes, identify mid-year concerns for select measures, and ensure that all beneficiaries are included in the data submission**. Basically, individual reporting adds a layer of complexity that is not conducive to ACO shared learnings and best practice identification.

QUALITY PAYMENT PROGRAM (QPP)

CMS is proposing two participation pathways: a revised MIPS Value Pathway (MVP) and a new APM Performance Pathway (APP). MVP implementation has been delayed until 2022 or later, and guiding principles and processes are set forth. The APP is proposed to launch in 2021. In addition, quality benchmark periods are established, scoring flexibilities are set forth, and multiple revisions to the various performance categories and their weighting are proposed.

Comment: For MIPS reporting, **we are supportive of**:

- **Establishing a 90-day minimum for the Promoting Interoperability performance period** for payment year 2024 (CY 2022) and each subsequent payment year;
- **Retaining the "Query of PDMP" measure** as optional for 2021 with bonus points for reporting;
- Refining the name for the **"Electronic Referral Loops" measure** to better describe the measure; and
- **Doubling the complex patient bonus** due to COVID treatment complexities.

MIPS Value Pathways (MVP): **We have not changed our position from last year and do not support**

the MVP proposal in concept. Instead, 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, but it does divert resources and rewards from providers who have been early adopters of care delivery innovation. Nonetheless, we appreciate the delay of the MIPS Value Pathways implementation as well as an implicit understanding that MVP success will be dependent upon a thoughtful and phased approach.

The current updates to the MVP Guiding Principles illustrate the increased reporting burden for multispecialty organizations, such as UPC and our parent organization, UnityPoint Health. Together we have roughly 68 specialty fields. Requiring measure sets for each specialty could result in upwards of 400 different eCQMs for reporting purposes, given the request to submit six measures per MVP. Although there are currently only 200 measures in the eCQM library, providers are struggling to keep up and do not have the resources to support the ever changing 200 eCQMs data set. We implore CMS to decide whether it is seeking measurement in support of population health or volume-based and episodic care. **We do not support a data set tailored to every subspecialty**, because in part:

- It is a slippery slope. Within a designated specialty, there are often subspecialties. It is questionable whether each subspecialty level should align to dedicated MVP measures instead of focusing on population health measures.
- The greater the number of measures, the more complexity is embedded and the more difficult it is to perform cross-comparisons.
- Many software vendors are not CEHRT approved to report all 200 measures currently. These designated measures sets for subspecialties become theoretical instead of operational.
- There are resource constraints. Software technology lacks an efficient way to set up specialty specific measures for an individual provider without touching each provider record separately. Along with software limitations, time and effort expended to create workflows, map data elements, and maintain updates per measure would be exorbitant. We spend roughly 20-40 hours per eCQM measure each year for updating mappings, validating, and continuing maintenance. If we had 100 measures, that is upwards of 4000 resource hours for just eCQM support without estimating training, issue research, and the development of multiple attestation files for reporting.

Quality Measure Benchmarking: Benchmarks are used to configure visual cues for providers to recognize at a glance how they are doing in MIPS category reporting. For the CY 2021 performance period, CMS is proposing the benchmark to be based on the actual data submitted during the CY 2021 performance period. We do not support use of the 2021 data for the shortcomings described by CMS in the preamble. **We recommend that CMS repeat the 2020 benchmarks using the CY2018 data for PY2021 benchmark settings**. This enables providers to have predetermined benchmarks prior to the start of the calendar year to establish goals against an external benchmark. If using the proposed method based on data submitted during CY2021, providers would be forced to evaluate internal benchmarking scores without having national comparisons in advance.

Health Information Exchange (HIE) Bidirectional Exchange Measure: CMS is proposing a new measure within the Promoting Interoperability performance category to allow an eligible clinician to attest to participation in bidirectional exchange through an HIE using CEHRT functionality. The intent is to demonstrate engagement that supports robust HIE without placing burden on the clinician or the patient to be individually accountable to facilitate exchange via multiple (and potentially unknown) point-to-point connections.

To fully comply with the HIE alternative measure, providers would avoid sending patients to providers and health care facilities that do not have the capability to send and receive data electronically in CCDA format. Because the Cures Act does not specify content for data exchange, providers and health care organizations may be able to bidirectionally exchange data by other methods. **We request that the definition of electronic data sharing within the Promoting Interoperability category include methods outside of CCDA or FHIR API structures to align with the Cures Act**. If expansion is not possible, clarification regarding the need for CCDA and FHIR structures to be utilized during transitions of care is important to offer guidance to providers and health care organizations related to the current HIE measures.

Inclusion of Telehealth Encounters in Blood Pressure Measure. We reiterate our support of the rapid adoption of telehealth services and accompanying expansion of telehealth reimbursement during the COVID pandemic. We also support use of patient reported data, when feasible, and are encouraged that telehealth encounters are poised to be included within quality measurement. **We request that CMS reconsider the proposal to include telehealth encounters within the denominator of the 2020 CMS Web Interface HTN-2: Controlling High Blood Pressure measure.** While we understand the importance of telehealth encounters and value the functionality to keep patients safe, inclusion of these encounters in the denominator mid-year poses a challenge to meeting benchmark percentiles that did not contemplate the lack of equipment available when performing services via telehealth. We agree that inclusion of home health monitoring within the numerator for those with other encounters is appropriate, but raise concerns regarding its sudden inclusion within the denominator.

Furthermore, we raise concerns regarding the mid-year inclusion of telehealth encounters for various other measures using similar rationale. Due to the COVID pandemic, many of our high-risk patients have selected to utilize telehealth services to receive appropriate follow-up care. In some instances, we have been unable to collect biometric data outside the clinic setting during a telehealth encounter, such as vitals monitoring and important lab work including hemoglobin A1c for diabetic monitoring. Similar to the blood pressure measure, this inability to collect information during the telehealth encounter may also prove to negatively impact other denominator values. We request that CMS also similarly consider removing telehealth encounters from quality measure denominators where special equipment is needed to collect biometric data.

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 Scores 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 two months (and more likely one month this year) 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 or the Medicare Advantage Call Letter (Proposed Rule in the spring and Final Rule in the summer).

QUALIFYING APM PARTICIPANT (QP) THRESHOLD SCORE CALCULATION

CMS is proposing that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

Comment: As referenced in this letter, UPC participates in the Next Generation ACO Model through UnityPoint Accountable Care (UAC). UAC submitted a separate comment letter[1] on behalf of its participants in the Next Generation ACO contract. **In alignment with the UAC position, UPC supports this proposed revision to the Threshold Score calculation and respectfully requests that it be expanded to include all Advanced APMs – both APMs with prospective and retrospective attribution.** This flawed calculation has had real implications for our Next Generation ACO Model contract and impacts more than 1600 specialists with no ACO attribution but who contribute to care coordination, quality outcomes and quite frankly overall cost management efforts. While the regulatory text would suggest that this denominator fix applies to any other APM entity where the beneficiary would be ineligible to be added to their attribution list, the preamble appears to limit the plain language to Advanced APMs with retrospective attribution. The limitation is arbitrary and not within the plain language of the regulation.

We also respectfully request that CMS consider holding the MACRA threshold for patient count at the 2020 level (35 percent) due to the COVID pandemic. CMS has ample authority to maintain the threshold, particularly given that threshold scores will be dependent upon beneficiary attribution reflecting periods when patient volume was intentionally depressed due to concerns with maintaining patient and provider safety and preserving levels of PPE.

Finally, should CMS act to revise the Threshold Score calculation and/or maintain the MACRA threshold, we would request an additional flexibility – provide that CMS and its Innovation Center

[1] UnityPoint Accountable Care letter dated October 2, 2020 and submitted via www.regulations.gov. Comment tracking number is 1k4-9jbp-96p3.

(CMMI) reopen Participant List submission timeframes for the limited purpose of restoring Participant Provider status to impacted non-attribution providers. Next Generation ACOs were required to submit their Participant List on September 4th. The decision of UAC to move non-attribution specialists from Participant Provider status to Preferred Provider status was made based on the flawed calculation and the rising threshold, and a Participant List excluding these providers was submitted for CY 2021.

We are pleased to provide comments on this proposal. To discuss our comments or for additional information, please contact Cathy Simmons, Government and External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

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