UnityPoint Clinic

1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
Office: (515) 471-9200
unitypoint.org

September 13, 2021

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1751–P
P.O. Box 1850
Baltimore, MD 21244–1850

RE: CMS-1751-P: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements, published in Vol. 86, No. 139 Federal Register 39104-39907 on July 23, 2021.

Submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure:

UnityPoint Clinic appreciates the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the 2022 Physician Fee Schedule (PFS) and Part B reimbursement. UnityPoint Clinic is comprised of more than 1,165 physicians and advanced practice providers in communities throughout Iowa, Illinois, and Wisconsin. UnityPoint Clinic 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 one of the nation's most integrated health care systems. Through more than 33,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities, and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

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

CY 2022 REVISIONS TO PAYMENT POLICIES

CMS is proposing a number of revisions to relative value units, potentially misvalued services, and specific code valuations. The proposed CY 2022 PFS conversion factor is $33.58, a decrease of $1.31 from the CY 2021 PFS conversion factor of $34.89.

Comment: As in 2021, the decreased 2022 conversion factor continues to suppress frontline health

care providers during a multi-year Public Health Emergency (PHE). **UnityPoint Clinic encourages CMS not to decrease reimbursement to health care heroes during the COVID-19 pandemic**.

EVALUATION & MANAGEMENT (E/M) VISIT PAYMENTS

CMS is proposing a number of refinements to current policies for split (or shared) E/M visits, critical care services, and services furnished by teaching physicians involving residents. Under the 2021 PFS Final Rule, CMS limited incident to billing reimbursement available to health systems and provider practices for complex E/M services when provided by clinical pharmacists on their care team.

Comment:

Shared E/M Visits: **We applaud CMS for refining longstanding policies around split E/M visits better reflecting the current practice of medicine.** UnityPoint Clinic appreciates that CMS is acknowledging non-physician providers, including teaching physicians, as part of the medical team by allowing them to provide and bill for services within a shared visit. Non-physician providers play a critical role in care delivery and often times provide a substantive portion of a visit. In addition, UnityPoint Clinic is pleased to see critical care services furnished concurrently to the same beneficiary on the same day allowed under the proposed changes for split visits. **Overall, flexibilities and transparent reimbursement are a move in the right direction by recognizing the totality of services provided during a shared visit.**

Incident to Billing for Complex Care: Prior to 2021, providers and health systems utilizing E/M codes (not facility fee billing) were previously allowed to bill under "incident to" rules for E/M services provided by clinical staff on their care team, including pharmacists. In 2021, "incident to" rules were changed to require services provided by a clinical pharmacist incident to a physician to be billed at the lowest E/M code (99211), regardless of the complexity of the services provided. This undermines care delivery models that seek to integrate clinical pharmacists into the care team and also discourages top of licensure practice by physicians.

Along with the American Society of Health-System Pharmacists, **UnityPoint Clinic requests CMS to clarify that providers and health systems can bill complex E/M codes (99212-99215) when those services are provided, incident to the physician, by a clinical pharmacist on their care team**. If CMS determines that existing codes are inappropriate, we encourage CMS to establish a modifier or pharmacist-specific code to bill for these complex pharmacist services.

TELEHEALTH AND OTHER COMMUNICATIONS TECHNOLOGY-BASED SERVICES

CMS continues to evaluate the temporary expansion of telehealth services added to the telehealth list during the COVID-19 PHE, proposing to allow certain services added to the Medicare telehealth list to remain on the list until December 31, 2023. In addition, CMS has outlined several mental health telecommunication proposals.

Comment: **The gains made in telehealth during the COVID-19 pandemic and under the waiver flexibilities granted during the PHE have been transformative to health care delivery**. Aside from respecting safety precautions, these flexibilities have enabled access to services for beneficiaries with distance or transportation barriers, mobility issues, and/or provider shortages. For UnityPoint Clinic, Medicare beneficiaries were the highest utilizer of telehealth services during the pandemic.

Expanded Telehealth Services: Pursuant to the COVID-19 PHE, telehealth service restrictions were lifted to enable beneficiaries to be served without regard to urban versus rural distinctions as well as in their homes and other more convenient sites of service. **UnityPoint Clinic supports the continuation of flexibilities in the delivery of telehealth services and strongly recommends that CMS encourage Congressional action for permanency.** This includes lifting provider/beneficiary location limitations through 'originating site' and geographic restrictions in §1834(m) of the Social Security Act.

Category 3 Temporary Codes: During the pandemic, UnityPoint Clinic has utilized many of the temporary Category 3 codes which enable convenient and timely access to care. Frequently used Category 3 codes include: *96127 PR BEHAV ASSMT W/SCORE & DOCD/STAND INSTRUMENT; 99221 PR INITIAL HOSPITAL CARE/DAY 30 MINUTES; and 99222 PR INITIAL HOSPITAL CARE/DAY 50 MINUTES.* **UnityPoint Clinic supports the continuation of Category 3 codes through 2023 and strongly encourages CMS to transition these codes to a Category 1 or Category 2 status in 2024.**

Virtual Check-in Code: **UnityPoint Clinic supports the permanent adoption of G2252.** While instituted during the COVID-19 pandemic, there is continued merit for this check-in visit to perform an assessment when the acuity of a beneficiary's condition would not necessarily appear to warrant an in-person visit.

Mental Health Services:

- *Audio-Only Visits*: **UnityPoint Clinic commends CMS for providing access to services through audio-only means**, which has been advantageous for beneficiaries residing in rural areas with limited broadband access and/or beneficiaries with limited technical capabilities to receive care. UnityPoint Clinic has received positive feedback from beneficiaries that have had audio-only visits during the COVID-19 pandemic, and many would prefer to continue receiving services through audio-only means. **UnityPoint Clinic supports the general use of audio/video telecommunications technology as well as audio-only visits as needed and based on independent medical judgment.**

- *In-Person Visit Frequency*: UnityPoint Clinic agrees that audio-only visits should be paired with in-person visits to assure a more thorough evaluation and assessment. In terms of timing, CMS should not require prior in-person care before a beneficiary may receive audio-only services and supports the proposed six-month timeframe for in-person visits after an initial audio-only visit. By providing access to new beneficiaries through audio-only visits, beneficiaries may avoid seeking services at unnecessarily heightened levels of care, such as an emergency department. This also enables workforce efficiencies in areas where behavioral health providers are in short supply. While we understand the need for an in-person visit, we encourage CMS to continue to monitor the duration at which in-person services are needed, as we believe that the determination of audio-only versus in-person modality is beneficiary specific and should be left to a provider's medical judgment. **UnityPoint Clinic supports an in-person visit at a six-month interval post audio-only visit; however, we do not support an in-person visit as a prerequisite to accessing an audio-only visit**.

- *Eligible In-Person Visits*: **UnityPoint Clinic encourages CMS to expand the criteria of a**

qualifying in-person visit beyond the provider furnishing the audio-only services. Examples would include, but not be limited to, E/M visits that occur by providers in a home nursing setting, an emergency department, a hospital stay, or other ambulatory clinic or mental health care facility.

- *Location Requirements*: While we support the beneficiary's home as an eligible telehealth site, we urge CMS to consider a more expansive interpretation of a beneficiary's home or eligible location. For instance, a beneficiary could be located in any number of locations (e.g. caregiver or family home), which should not disqualify services provided by telehealth/audio-only. Additionally, tracking the exact beneficiary location may not be feasible for health care organizations and is an unnecessary administrative burden. **UnityPoint Clinic urges CMS to apply a loose definition of "home" to mental health beneficiaries to enable the use of audio/video telecommunications technology as well as audio-only visits as necessary and based on independent medical judgment.**

- *Modifier*: CMS is also proposing to require use of a new modifier for services furnished using audio-only communications. Rationale for audio-only visits can be documented if required and has proven useful in reporting both at a facility and agency level. **UnityPoint Clinic urges flexibility and recommends that CMS limit the underlying documentation burden for providers using this modifier.**

- *Preclusion of High-Level Services*: **UnityPoint Clinic does not support this proposal.** In an ideal world, we understand that high-level services should receive in-person services. This does not comport with reality as the level of services cannot always be established prior to a visit, and CMS should default to enabling providers to provide and bill for this service as opposed to either not providing the service or providing the service and not being reimbursed. **We encourage CMS to include Level 4 or 5 E/M or psychotherapy with crisis codes for audio-only visits**.

COINSURANCE FOR COLORECTAL SCREENINGS

CMS is proposing to provide a special coinsurance rule for procedures that are planned as colorectal cancer screening tests but become diagnostic tests when the provider identifies the need for additional services (e.g., removal of polyps). This rule, over time, reduces the amount of coinsurance a beneficiary will pay for such services (i.e., 20% for CY 2022, 15% for CYs 2023 through 2026, 10% for CYs 2027 through 2029, and zero percent beginning CY 2030).

Comment: The coinsurance policy update for colorectal cancer screenings is a positive move in the right direction and supports adherence efforts in preventative care. This proposal will shore up frequently voiced beneficiary grievances around unexpected bills for diagnostic testing confused as covered under a screening test benefit. While the Affordable Care Act attempted to make similar proposals for preventive services that were given a USPSTF grade recommendation of A or B, exceptions were made for colorectal cancer screening. **UnityPoint Clinic agrees with the substance of the proposal - that the screening test benefit should apply regardless of whether a tissue biopsy or polyp removal is performed. On process, we disagree with the proposed phased-in approach.** We

believe that the 80% coverage proposal for 2022 has little impact as many beneficiaries are currently billed 20% coinsurance for their screening test because a polyp is found. **UnityPoint Clinic strongly recommends CMS not delay full coverage for this screening test until 2030. Full coverage should begin in 2022 so beneficiaries are not deterred from completing this important cancer screening test.**

MEDICAL NUTRITION THERAPY (MNT) SERVICES

CMS is proposing to update the payment regulation for MNT services to clarify that MNT services are, and have been, paid at 100% (instead of 80%) of 85% of the PFS amount, without any cost-sharing, since CY 2011.

Comment: **UnityPoint Clinic supports telehealth for MNT and Diabetes Self-Management (DSMT) Services.** Both are critical but different services that support holistic health and wellness goals. **Additionally, UnityPoint Clinic requests that CMS align coinsurance obligation for these services.** Currently, the MNT benefit is covered 100% so beneficiaries have no copay for this service. We believe this is appropriate. For DSMT services, beneficiaries have a 20% coinsurance obligation. This discrepancy in coverage has behavioral effects – namely, MNT services are ordered for diabetic beneficiaries to avoid copayments when DSMT services are more appropriate. To better tailor service to beneficiaries, we encourage CMS to revisit this coinsurance policy and remove the 20% coinsurance obligation from DSMT services.

RURAL HEALTH CLINICS (RHC)

There are several provisions CMS is proposing aimed at bolstering the abilities of RHCs to furnish care to underserved Medicare beneficiaries including: mental health service furnished via telecommunication; RHC payment limit per-visit; payment for attending physician services to hospice beneficiaries*; concurrent billing for chronic care management (CCM) services and transitional care management (TCM) services; and payment for administering COVID-19 vaccines.*

Comment:

Tele-Mental Health Services – As part of an integrated health care system with a large rural footprint, we are pleased to see the inclusion of costs associated with telehealth services and visits in the cost report, aligning the payment structure more closely with the services provided at RHCs. **UnityPoint Clinic is supportive of the telehealth changes outlined in the proposal and encourages CMS to extend reimbursement for all telehealth visits, beyond mental health visits alone**.

Limit Per Visit: **UnityPoint Clinic supports the increase to the payment limit per visit.** RHCs enable access to fundamental preventative and maintenance care for rural beneficiaries, and heightened reimbursement will assist with keeping clinic doors open.

Services to Hospice Beneficiaries: Continuity of care and the importance of an established provider-patient relationship does not lessen in importance as beneficiaries elect a hospice benefit. Forcing beneficiaries to switch providers in order to elect a hospice benefit is counterintuitive, delays services, and unnecessarily delineates a provider workforce (i.e. hospice vs primary care) in rural areas. This is a no brainer, and **UnityPoint Clinic is pleased to see CMS recognizing that the gap in hospice care may be filled by rural providers**.

Concurrent Billing for CCM and TCM Services: UnityPoint Clinic continues 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 it proves difficult to robustly furnish 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 beneficiaries 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 copayment and deductible for these services in all sites of service**. Even without a copayment or deductible, CCM and TCM services will raise revenue through cost savings to CMS attributable to the avoidance and reduction in preventable readmissions or transfers to higher care levels.

ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES

CMS is proposing to implement the second phase of the SUPPORT Act requiring electronic prescribing of controlled substances (EPCS).

Comment: **UnityPoint Clinic agrees with the proposed changes.** At present, EPCS by UnityPoint Clinic providers ranges from 90%-97%. This deviation from 100% is due to extraordinary circumstances, such as emergencies or disasters, and a variety of information technology issues, including internet down time, cybersecurity breaches, program malfunctions, and loss of power. However, in recent years with more security (namely, two-factor authorization), electronic prescribing has become a standard practice. Overall, EPCS supports getting medication to beneficiaries both timely and efficiently.

PULMONARY, CARDIAC, AND INTENSIVE CARDIAC REHABILITATION

CMS is proposing to add coverage of pulmonary rehabilitation (PR) for beneficiaries who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for least 4 weeks after hospital discharge and to remove a PR direct physician-patient contact program requirement that is overly burdensome and unnecessary for all PR beneficiaries.

Comment:

Treatment Plans: **While UnityPoint Clinic is appreciative of reimbursement for treatment plans, there are operational concerns with the proposal as outlined.** First, the proposal adds administrative burden through use of an E/M code. Currently the physician receives the treatment plan from the rehabilitation facility and then reviews and signs the plan for a contracted amount or hourly charge. The majority of the treatment plan development is completed by the rehabilitation facility staff. In addition, there is the potential for negative impact to beneficiaries as often adjustments to billable services can trigger additional copayments or coinsurance, a potential dissatisfier to beneficiaries. **UnityPoint Clinic is pleased to see CMS reviewing reimbursement for treatment plans, and we encourage CMS to revisit the potential negative impact to beneficiaries and to further align reimbursement to work effort.**

Addition of CPT Codes: **UnityPoint Clinic is pleased to see 100% of PR services proposed to be billed under CPT 946X2.** At UnityPoint Clinic, both treatments are used and are individualized. Although

most beneficiaries rarely desaturate and require no oximetry monitoring; with the uptick of COVID-19 and due to certain disease states, some beneficiaries will require continuous monitoring of oxygen saturation.

COVID Diagnosis: **UnityPoint Clinic supports a new PR diagnosis code for beneficiaries with COVID-19 for more than four weeks.**

Virtual Direct Supervision: **UnityPoint Clinic encourages CMS to make permanent virtual direct supervision for cardiac and PR services**. This PHE flexibility has allowed vital access to high quality patient care particularly in rural communities. In addition, this flexibility has improved program adherence, helped address workforce shortages, and has been well received by beneficiaries. **UnityPoint Clinic also supports removing regulatory language around the frequency of direct beneficiary contact once every 30 days.** This will allow for efficiency and consistency between the cardiac and PR programs.

CLINICAL LAB FEE SCHEDULE (CLFS)

CMS is requesting comments regarding the nominal specimen collection fees for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital). CMS is also seeking comments related to the calculation of costs for transportation and personnel expenses for trained personnel to collect specimens from such beneficiaries. In addition, CLFS data reporting period under Protecting Access to Medicare Act of 2014 (PAMA) is scheduled from January 1, 2022 through March 31, 2022.

Comment: UnityPoint Clinic is pleased to see CMS allowing flexibility and reimbursement for collecting specimens from homebound patients. Historically the PFS contained significant cuts impacting laboratories serving hospitals, nursing homes, and rural communities that are on the frontlines of care delivery for the most vulnerable beneficiaries. These labs often provide rapid test results on a daily basis in order to triage health conditions and inform providers of any necessary changes to treatment regimens. Reimbursement often limits the access radius by which a laboratory can break even in providing services. Consideration of travel time in the reimbursement schedule, particularly in rural areas, would help promote greater access. Overall, we appreciate the ability to be reimbursed for specimen collection.

As the COVID-19 pandemic is still raging and the accompanying lab testing and reporting requirements with increasing demand from both the public and private sectors for COVID-19 testing remain, **we respectfully request that CMS further delay the PAMA reporting period for an additional year or the year following the end of the COVID-19 PHE**. 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.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

CMS is proposing to delay mandatory eCQM reporting, freeze the quality performance standard for an additional year, update the extreme and uncontrollable circumstances policy, and provide incentives for early eCQM reporting. CMS is also seeking comments on a number of additional policy issues related

to quality.

Comment: UnityPoint Clinic is currently a Medicare ACO Participant under the Next Generation ACO Model and has historically participated in the MSSP as well as the Pioneer ACO Model. As value-based Medicare ACO models share best practices and do not operate in isolation, UnityPoint Clinic is compelled to offer feedback on several MSSP proposals.

Consistent Measures and Reporting: As quality measures continue to evolve, **UnityPoint Clinic urges CMS to coordinate with CMMI to permit physicians to easily transition among models**. This will enable physicians to focus on quality care and not specific quality measures, which vary among models and require different and varied reporting structures. We encourage CMS and CMMI to consider a holistic delayed implementation of eCQMs as well as ability to use web interface reporting universally across all models.

Measure Set: UnityPoint Clinic has been supportive of the Meaningful Measures initiative and applauds CMS efforts to streamline data collection and reporting. That said, we want to recognize that CMS did not implement its proposed Alternative Payment Model (APM) Performance Pathway measure set from the 2021 PFS proposal, which was comprised of just six measures – three eCQM measures, one beneficiary survey measure, and two claims-based measures. This restraint did not carry over to CMMI and its Next Generation ACO Model nor to the Global and Professional Direct Contracting Model. **We caution that very small measure sets risk over-emphasizing certain metrics and underlying beneficiary conditions and potentially create more clinical disruption when measure sets are revised**.

eCQM Capture: The eCQM reporting methods evaluate quality performance based on all-payer data. These measures hold ACOs accountable for performance for beneficiaries and other patients outside the Medicare ACO. Not only is this over-broad but it creates reporting burdens. **We urge CMS to revisit these measures and restrict performance to attributed beneficiaries**.

CAHPS Survey: **We continue to have concerns about the CAHPS for MIPS survey methodology**. Foremost, this survey is very subjective (being based on the beneficiary'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 beneficiaries do not represent the full population ACOs serve; (3) providers cannot supplement response rates; and (4) surveys are administered once annually with results usually received midway through the performance year.

Calculating Historical ACO Benchmarks: CMS is seeking comment on considerations related to the use of regional fee-for-service (FFS) expenditures in establishing, adjusting, updating, and resetting historical ACO benchmarks. ACOs including UnityPoint Accountable Care (of which UnityPoint Clinic is an ACO Participant) have expressed concerns with CMS calculating regional FFS expenditures using a population of assignable beneficiaries that includes the ACO's own assigned beneficiaries. As a result, benchmarks are lower for ACOs with high market penetration. This issue is affectionately referred to as the rural glitch, given its disproportionate negative impact on benchmarks in rural service areas. **We wholeheartedly support the exclusion of an ACO's own beneficiaries and associated expenditures from the historical benchmark calculation**.

QUALITY PAYMENT PROGRAM (QPP)

CMS is proposing MIPS Value Pathways (MVP) implementation details intended to replace "traditional MIPS", adjustments to MIPS performance thresholds as well as an overhaul of the MIPS complex patient bonus.

Comment:

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 Alternative Payment Model (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.

The current updates to the MVP Guiding Principles illustrate the increased reporting burden for multi-specialty organizations, such as UnityPoint Clinic 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 seven 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 measure 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.

Measures Removed for CY 2022: **UnityPoint Clinic supports removal of *C.14 – Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented* as well as *C.11 – Falls: Risk Assessment***. That stated, we request additional clarity on measure C.11. Specifically, it is unclear if C.11. will be removed from eCQM reporting as the collection type is not specifically identified.

Promoting Interoperability: CMS proposes to make changes to the category's objectives and measures for CY 2022 that align with changes proposed for the hospital Promoting Interoperability Program.

- Public Health and Clinical Data Exchange Objectives: UnityPoint Clinic has a number of concerns with implementation of additional public health and clinical data exchange objectives:
    - Not all states are using the same configurations to receive data for each of the proposed categories, Electronic Case Reporting is an example.
    - Some states require fees to third-party vendors for implementation as many states do not have resources available to support or use a third-party vendor to report data.
    - Many states do not accept syndromic surveillance, such as Iowa. It is unclear if exclusion reporting will be allowed if states do not have capacity.
    - Concerns exist regarding maintenance around use of public health registries and clinical data registries for submission as those tasks could lead to an unproductive level of administrative burden.

  To reduce burden of reporting, UnityPoint Clinic recommends allowing required submissions for other programs such as National Healthcare Safety Network (NHSN) reporting under a clinical data registry. In addition, UnityPoint Clinic recommends not requiring all four measures rather increasing optional selection to three measures.

- Query of PDMP Measure: As a multi-state clinical enterprise, UnityPoint Clinic has experienced state variation in Prescription Drug Monitoring Program (PDMP) measure build and data submission. As such, **UnityPoint Clinic agrees the PDMP measure should remain optional and as bonus points.** Until there is standardization of the PDMP build across states and systems, updating this as a performance measure would be challenging to implement, especially for multi-state clinical practices. Therefore, **UnityPoint Clinic opposes making the PDMP a required measure.**

- Provide Beneficiaries Electronic Access to Their Health Information Measure: **UnityPoint Clinic has concerns with the CMS proposal** to have all data from 2016 to present available for a beneficiary's immediate access via a portal account. We have outlined our concerns below:
    - When providers move from old record systems to new, often times they do not convert all data discretely. In addition, for health care mergers and acquisitions over time, variation exists on data conversion and, in many cases such as small rural physician practices, legacy system data were not converted at all. For these cases, it becomes a financial burden to maintain legacy systems.
    - It is unclear if data can be in Common Clinical Data Set (CCDS) or if it must be in USCDIv1 format, which is not required to be used until 2023. In addition, clarification is needed on what data sets will be required from 2016. For example, with the implementation of OpenNotes, many hospitals did not include historical notes as it was not required under the CMS Interoperability and Patient Access rule. If required, this becomes additional work and requires substantial resourcing.

  - For security and resource concerns, many providers turn off access to a patient's portal if the account is not active for a set timeframe. While access can be reactivated, often times this requires additional administrative and security support.

- New HIE Bi-Directional Exchange Measure: **UnityPoint Clinic opposes this measure**. Given the current challenges in uploading content to the National Plan & Provider Enumeration System (NPPES) in a bulk fashion, the lack of availability and ease of sharing digital content poses additional challenges for large clinical practices to comply with this measure.
- Remove Attestation Statements Regarding Information Blocking: CMS is proposing to eliminate statements B and C. **UnityPoint Clinic is supportive** of this; however, we request that CMS provide information regarding the audit process and financial penalties associated with information blocking as set forth in the 21st Century Cures Act.

Other APM Flexibilities: We respectfully request CMS to consider the below recommendations to enable operational flexibility to promote innovation, physician 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 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 across ACO programs** to promote definition consistency, enable physicians to gauge QP status, and encourage further transition to value and risk-based arrangements.
- Timing of Annual QPP Proposed Rule. **We request that CMS consider moving the QPP proposed rule to a notice and comment period earlier in the calendar year**. By placing the QPP update within the annual PFS proposed rule, it is unlikely that the Final Rule will be released before November leaving only two 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 or the Medicare Advantage Call Letter (Proposed Rule in the spring and Final Rule in the summer).

REQUESTS FOR INFORMATION

A. HEALTH EQUITY

CMS is requesting information on several ways CMS is considering using the QPP to advance health equity. For example, CMS is considering physician and/or public-facing reports on MIPS quality measures to be stratified by dual-eligible status, race, and other factors. CMS also asks for comment on ways of increasing the collection of demographic and social risk data, including the collection of a "minimum set" of demographic elements (e.g., race, ethnicity, language, disability status) that could be used for a variety of tracking and quality measurement purposes. CMS is considering using EHRs as a data collection mechanism.

Comment: Included in **UnityPoint Health's comment letter to CMS-1752-P, Hospital Inpatient**

Prospective Payment System (IPPS), UnityPoint Clinic values health equity and focuses on reducing care variation with all patients no matter race, ethnicity, gender, sexual orientation, or other demographic or social risk characteristics. UnityPoint Clinic appreciate CMS's commitment to addressing health equity and looks forward to partnering with CMS in advancing this important focus. UnityPoint Health (inclusive of UnityPoint Clinic) is an active member of The Academy Advisors and generally supports comments provided in The Academy Advisors' comment letter to CMS-1752-P, which targets the health equity topic. We have provided additional comments as it relates specifically to UnityPoint Clinic below:

- Additional Measure Stratification: In order to accurately focus on driving palpable change in health equity, measure stratification becomes vital to the process. **Stratification must be robust to high variations in local market populations, including imbalanced race/ethnicity distributions or other identified equity attributes.** For less densely populated areas where imbalanced populations tend to exist, results can be disproportionately impacted by sentinel events to minority populations as compared to highly populated urban locations with greater balance. Existing quality measures serve well to define health care quality, but equity should be defined as gaps in these measures amongst attributes and targeted for improvements. UnityPoint Clinic recommends "descriptive" modeling using traditional predictive modeling techniques to study equity imbalance by only including equity attributes as model features with the health measure as the target, fitting a predictive model, and then examining the feature importance. Highly predictive features in this context suggest the type and magnitude of equity imbalance in a given population. In conclusion, **UnityPoint Clinic strongly discourages use of an algorithm to estimate race and ethnicity and recommends using existing quality measures utilizing predictive modeling techniques to study health disparities.**

- Expanded Demographic Data Collection/Reporting: In order to accurately measure data, the data itself must be of high quality. Challenges exist today in effectively capturing this type of information. Manual collection by physicians and health providers leads to high administrative burden and would require standardized data collection protocols, many of which do not exist today. However, UnityPoint Clinic agrees collection of self-reported data is the most precise method to capture current and accurate race and ethnicity information. Data lag can be significant between census surveys and performance periods and high variance, even at the census block level, may occur given social determinates of health (SDOH) factors. Using a proxy would still require beneficiary addresses to map to census locations identifiers. UnityPoint Clinic has a 55%-60% match rate when taking beneficiary addresses, geocoding to a census block, and joining results. While proxies are not ideal for capturing data, should CMS choose to continue development utilizing this method, it will be imperative for physicians and hospitals to have the opportunity to address self-identified inaccuracies as well as a process to appeal data and outcome results should they deem appropriate. **UnityPoint Clinic urges CMS to consider offering physicians financial assistance to develop and deploy health equity efforts, including funding support in addressing the capture of self-reported data,** a gold standard as noted by CMS**.**

UnityPoint Clinic is supportive of health equity and developing a framework for measuring so that providers can be transparent and accountable in closing the gap in health equity. As CMS considers this framework, **we strongly urge CMS to:**

- **Develop standard data definitions** as well as continue to partner closely with stakeholders in identifying measures that effectively and accurately measure health equity for diverse beneficiary populations and a variety of geographical regions.
- **Implement measures only after development and thorough testing** with stakeholders.
- **Standardize the use of "equity"** as defined in the Executive Order on Advancing Racial Equity and Support for Underserved Communities. In particular, "(a) The term "equity" means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. (b) The term "underserved communities" refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the preceding definition of "equity."[1] While UnityPoint Clinic supports a broader definition of health equity, we also support a consistent definition. An approach that phases in equity categories or social risk factors over time has the potential to penalize facilities early on that will perform better under a more comprehensive definition.

While UnityPoint Clinic appreciates the Administration's pervasive emphasis on health equity through the rulemaking process and its interest in closing disparity gaps, the measurement framework is still within the early development phase and its impact on reimbursement and operations is unclear. We encourage CMS to be thoughtful of these provider implications and to use a carrot approach, not a stick approach. We recommend that CMS study the large variation in defining health equity as well as additional ways in which to accurately collect and measure demographic and social risk factors. UnityPoint Clinic looks forward to partnering closely with CMS in future efforts driving health equity.

B. FAST HEALTHCARE INTEROPERABILITY RESOURCE (FHIR)

CMS is seeking feedback on its intention to align additional Promoting Interoperability performance category objectives with approaches utilizing HL7® FHIR® Standard Release 4-based API functionality.

Comment: With large clinical practices and health care systems historically being the first to implement electronic health records (EHRs) and FHIR, the biggest concerns lie within the variation of FHIR versions, lack of version requirements, and variation in industry timelines. With three different versions of FHIR and no version requirements, this puts limitations on a provider's ability to connect

[1] (https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/)

to certain application interfaces. There is no consistency in who is required to have FHIR, how to submit data, and when to submit data. This becomes a large challenge for providers who attempt to submit data utilizing these vendors and payors. Since 2017, four main FHIR versions have been released in addition to sub-versions released to correct errors or issues in technological builds, meaning vendors and providers have had to sort through up to six version updates to land at v4.1.0, the most recent "permanent home" version of FHIR. It should be noted that not all providers and organizations are at v4.1.0 yet because vendors and physicians are not required to meet ONC CURES Edition CEHRT.

While UnityPoint Clinic appreciates the attempt to align health care interoperability resources, providers and integrated health systems have competing information technology builds and priorities across care settings, which is true on a smaller scale for individual physicians and smaller organizations. **Overall, UnityPoint Clinic recommends slowing down the implementation and updates of new standards in health care interoperability, allowing all parties, including CMS' technology, to catch up and align as an industry**. Specifically, we urge CMS to consider:

- **A stair step approach to implementation**, first incentivizing milestones along the way and, at an appropriate point in the timeline, introducing a negative incentive to promote long-term adherence.
- **Biennial updates to FHIR for all providers**. If releases are consistent and across the board, providers can better plan for resourcing, allocations, and cost.
- **Incorporating SDOH as part of the standardized CCD documentation applicable to all providers**. This will allow the integration of such information into a patient's chart and ultimately promote transparency in health equity.
- **Standardized reporting requirements across all programs** to enable utilization of software and quality measures across all care settings allowing better continuity of care. This will facilitate vendors and providers to concentrate efforts universally and lessen the chances for some providers and/or care settings to be left behind.
- **Program incentives for stakeholders to partner with vendors in pilot programs and models**. Payment or flexibilities to participating providers would encourage a robust testing environment in which stakeholder input is included.

C. CLINICAL NOTES

CMS is desiring to support the goals of the OpenNotes movement and is seeking input on whether other program guidance is needed, whether quality points should be allocated for the use of ''clinical note'' types supported by certified health IT, and further information on types of clinical notes that are commonly sought, but not easily accessible to patients.

Comment: Overall, UnityPoint Clinic is very supportive of expanding OpenNotes for all our patients. We would like to offer thoughts for your consideration:

- Additional Changes or Program Guidance: While supportive of the OpenNotes movement, we request that CMS consider allowing the masking of portions of clinical notes. Case in point is the challenge of releasing teen notes to proxies while complying with state confidentiality /

privacy laws. It is very difficult to segregate which notes are appropriate to share versus which notes are not. Additional EHR development to better support the masking of a part of a note (rather than an entire note) could be very helpful. It would allow us to show as much information as legally possible without compromising patient privacy. For example, we currently have to mask the entire well child exam if we mention anything about sexual activity/drugs/alcohol/mental illness (which are standard questions in a teen well child exam).

- Development of a "Clinical Note" Use Measure: Without seeing the proposed measure, it is difficult to either support or oppose this measure. Based on the concept of a required and independently scored measure to allocate points for the use of ''clinical note'' types supported by certified health IT, we foresee operational challenges related to software builds and system redesigns as well as the potential temporary diversion of already scarce resources to implement. At minimum, we would urge that CMS involve stakeholders (providers and vendors) in the development of this measure, publicize the proposed measure via a usual public notice and comment period, establish a longer implementation run period, and provide an initial "pay for reporting" period.
- Other Clinical Notes: Another high value clinical note type to consider including in scope would be the operative note. Depending upon the provider and organizations, the operative note may be separate from a procedure note.

UnityPoint Clinic is pleased to provide comments on this proposed rule. 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,

Dr. Sanjeeb Khatua
President & CEO
UnityPoint Clinic

Dr. Dan Allen
Chief Medical Officer
UnityPoint Clinic

Cathy Simmons, MPP, JD
Executive Director, Government & External Affairs
UnityPoint Health