September 11, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1786-P
P.O. Box 8010
Baltimore, MD 21244-1810

RE: CMS-1786-P – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction; published at Vol. 88, No. 145 Federal Register 49552-49918 on July 31, 2023.

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

Dear Administrator Brooks-LaSure,

UnityPoint Health appreciates this opportunity to provide comments on this proposed rule related to the Outpatient Prospective Payment System (OPPS) for Calendar Year (CY) 2024. UnityPoint Health is one of the nation’s most integrated health care systems. Through more than 32,000 employees and our relationships with more than 370+ physician clinics, 36 hospitals in urban and rural communities, and 13 home health agencies throughout our 8 markets, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health agencies provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

UnityPoint Health appreciates the time and effort of CMS in developing this proposed rule. As a member of the American Hospital Association, UnityPoint Health supports their formal comment letter. Additionally, we respectfully offer the following input.

PAYMENT SYSTEM UPDATE

CMS proposes to update OPPS payment rates for hospitals that meet applicable quality reporting requirements by 2.8%. Additionally, CMS proposed to continue applying a 7.1% payment adjustment for rural Sole Community Hospitals.

Comment: UnityPoint Health generally supports increases to the OPPS base rate; however, a 2.8%
increase is grossly insufficient. As cost in health care supply and labor continues to grow, we recommend CMS continue to review and deploy rates that more accurately reflect the current health care financial landscape. UnityPoint Health does strongly support the proposed adjustment for rural Sole Community Hospitals, which are a vital safe entity provider.

### 340B DRUG PRICING PROGRAM

The 340B program, passed by Congress in November 1992 and signed into law as part of the Veterans Health Care Act by George H. W. Bush, requires pharmaceutical manufacturers to provide front-end discounts on covered outpatient drugs purchased by specified government-supported facilities that serve the nation’s most vulnerable patient populations. The 340B Drug Pricing Program allows safety-net providers “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

**Comment:** As a large nonprofit, integrated health care system in the Midwest, the UnityPoint Health network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals, and Rural Health Clinics provide vital access to health care services. The 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois, and Wisconsin. Not including our affiliated 20 critical access hospitals, we have 12 hospitals that participate as covered entities under the 340B Drug Pricing Program.

**340B Payment Rate**

For CY 2024, CMS proposes to continue the payment rate of Average Sales Price (ASP) plus 6% for drugs and biologicals acquired under the 340B program.

**Comment:** UnityPoint Health applauds the restoration of 340B payment rate back to ASP + 6%. Our hospitals are eligible to participate in the 340B Drug Pricing Program by virtue of high volume of Medicaid and low-income Medicare patients as well as rural locations. We rely on our 340B savings to meet the needs of low-income patients and rural patients in our communities. With thin operating margins, 340B savings often maintain vulnerable service lines (such as behavioral health, maternal and child health, and/or emergency services), enable preventive/outreach services (such as financial assistance for medications, medication therapy management, meds-to-beds programs, and/or dental clinics), and simply keep doors open (such as salaries for nurses and other frontline care staff).

**Claims Modifiers**

CMS continues to require use of the “TB” and “JG” modifiers to implement a Part B inflation rebate by manufacturers of single source drugs and biologicals with prices increasing faster than the rate of inflation (as authorized by the Inflation Reduction Act). Effective January 1, 2025, CMS proposes that all 340B covered entities report only the “TB” modifier when a drug is acquired under the 340B program. The “JG” modifier will remain effective through December 31, 2024, and providers will have the option to report either the “JG” or “TB” modifier during 2024.

**Comment:** UnityPoint Health is disappointed that ‘JG’ and ‘TB’ claims modifiers continue to be used and encourages CMS to use a different, less burdensome approach to collect Inflation Reduction Act information. The ‘JG’ and ‘TB’ modifiers are extremely burdensome. To ensure regulatory compliance of these claims modifiers, UnityPoint Health estimates 20–40 hours is expended monthly on administrative tasks from clinical staff documentation to supportive services for claims review. Alternatively, the
American Hospital Association suggests that CMS could exclude all units of separately payable outpatient drugs (identified using the claim status indicator “K”) that are billed by hospitals that participate in the 340B Program. Another suggestion would be for CMS to employ a retrospective approach that is used by Oregon’s Medicaid program, Oregon Health Plan. The Oregon approach requires a quarterly data file submission of 340B-eligible claims rather than a real-time approach using modifiers. Both alternatives would greatly reduce administrative burden.

**Manufacturer Restrictions on Contract Pharmacies**

An important way covered entities are able to get 340B drugs to beneficiaries is through contract pharmacy arrangements. Under these arrangements, covered entities purchase drugs at 340B prices and contract with pharmacies in the community to dispense the drugs to covered entity patients on the covered entity’s behalf. Since July 2020, 25 drug manufacturers have implemented policies refusing to provide or restricting 340B pricing to covered entities for drugs dispensed through contract pharmacies.

**Comment:** UnityPoint Health strongly encourages the enforcement of the 340B program requirements to stop unilateral action by drug manufacturers to establish or alter conditions of participation. During last year’s OPPS public notice and comment period, there were 18 major drug manufacturers engaging in actions to limit the distribution of certain 340B drugs by hospitals (up from eight in 2021); at the time this comment letter was submitted, there are now 26. In fact, Jazz is the most recent addition and announced contract pharmacy restrictions on September 11, 2023, with an effective date of October 9, 2023. In total, these manufacturers are AbbVie; Amgen; Astellas; AstraZeneca; Bausch Health; Bayer; Biogen; Boehringer Ingelheim; Bristol Myers Squibb; Eli Lilly; EMD; Serono; Exelixis; Gilead; GlaxoSmithKline; Jazz; Johnson & Johnson; Merck; Novartis; Novo Nordisk; Organon; Pfizer; Sanofi; Teva; UCB; and United Therapeutics. This number keeps growing (see timeline below) as there is no government reprisal.

### 340B Program timeline (9/1/2020 – 9/1/2023)

Meanwhile, the impact of these restrictions is devastating. First, as manufacturers step into the shoes of regulators and impose new rules, this increases administrative workload for hospitals just to access the drugs at 340B-acquired drug pricing. Each manufacturer has imposed different restrictions, such as mandating submission of claims data using 340B ESP (a specific vendor) to access 340B pricing for drugs dispensed at contract pharmacies, refusing 340B pricing for drugs dispensed at contract pharmacies unless a limited exception applies, or both claims reporting and limited exceptions. Effectively hospitals now have 27 340B drug pricing programs to administer, including the one authorized by Congress and administered by the Health Resources and Services Administration (HRSA). The 26 manufacturer programs are subject to frequent change with little notice, if any, and the frequency of changes is increasing as shown in the timeline above. This results in compliance chasing activities that detract 340B...
safety-net providers with extra administrative burdens and divert resources away from the program’s intent (“to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”) to administrative tasks. Second, this assault on the 340B program impacts beneficiaries and access to medications. These medications are needed to treat and manage chronic conditions and are not luxury items. Contract pharmacies enable outreach to beneficiaries at convenient locations and often with more extended hours. In an era when CMS is doubling down on telehealth to facilitate health care access and beneficiary convenience, the access to 340B-acquired drugs through community pharmacies seems similarly situated.

UnityPoint Health urges HHS and the Office of the Inspector General (OIG) to use current statutory authority in imposing civil monetary penalties against all drug manufacturers who have unlawfully overcharged safety-net health care providers. These manufacturers’ unlawful actions have undermined 340B hospitals’ ability to serve vulnerable communities, particularly in rural areas, where contract pharmacies are vital to providing access to more affordable medications.

340B Proposed Remedy for Underpayments


Comment: UnityPoint Health submitted a separate comment letter1 in response to the remedy proposed in CMS-1793-P resulting from the Supreme Court decision addressing the unlawful CMS reimbursement formula. In general, UnityPoint Health fully supports the proposed one-time lump sum repayment to hospitals, the inclusion of the additional beneficiary cost-sharing amount, and the methodology used to calculate what 340B hospitals are owed; however, we disagree with the proposed budget neutrality adjustment as this is neither statutorily required nor sound public policy.

In addition, the CMS remedy omitted two items that have significant impact to UnityPoint Health and other 340B covered entities.

- Medicare Advantage (MA) – While the Supreme Court decision, American Hospital Association v. Becerra, focused on CMS imposing unlawful reductions in 340B drug payments in Medicare fee for service, MA plans and other commercial payors followed suit, benefiting as well. For UnityPoint Health, MA plans comprise approximately 40 percent of the underpayments associated with the 340B payment rate reductions. We encourage CMS to take all possible measures to ensure Medicare Advantage Organizations compliance with the remedy, so they do not receive an inadvertent windfall.

- Medicare Accountable Care Organizations (ACOs) – Unlike MA plans, ACOs are being adversely impacted in that benchmark years include underpayments for 340B-acquired drugs, while performance years will now include expenses that reflect the restored 340B-acquired drug payment rate. We urge CMS to:
  - Develop a 340B remedy that holds ACOs harmless, including those ACOs participating in CMMI models;

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1 Submitted on September 11, 2023 – tracking number lmf-2d7j-f5ns
We reiterate our appreciation of CMS’ measured approach and use of criteria to remove and add services to the IPO list. The IPO list contains mostly surgical procedures that are majorly invasive, complicated, and require the care and coordinated services provided in the inpatient setting of a hospital. Until CMS can reference an ample evidence basis from the Medicare population to support a change in setting, we encourage procedures to remain on the IPO list. In tandem, UnityPoint Health also urges CMS to monitor procedures that are removed from the IPO list to determine if baseline Fee-For-Service payments should be readjusted to reflect heightened patient acuity and assure access to inpatient services. As procedures are removed from the IPO list, “healthier” patients are transitioned to outpatient settings leaving more complex, costly patients within inpatient settings. An unintended consequence of these policies is the perpetuation of a for-profit mentality and incentive for more infrastructure builds to cater to younger, healthier, and less costly patients. Ultimately these policies divert resources from existing inpatient settings threatening their financial stability and beneficiary access to high-acuity settings.

NONRECURRING CHANGES

Supervision of Cardiac, Intensive Cardiac, and Pulmonary Rehabilitation Services
To conform with supervision requirements in ambulatory clinic settings, cardiac rehabilitation services, intensive cardiac rehabilitation services, and pulmonary rehabilitation services may also be furnished under the direct supervision of a physician assistant, nurse practitioner, or clinical nurse specialist starting January 1, 2024. Temporary flexibilities also allow supervision to be remote via two-way, audio/visual communication technology through December 31, 2024.

Comment: UnityPoint Health supports these proposals providing supervision parity between care settings.
Site Neutral Policy and Intensive Cardiac Rehabilitation (ICR) Services
CMS proposes to pay for ICR in an off-campus non-excepted PBD at the full OPPS rate effective January 1, 2024. This policy would apply to the HCPCS codes G0422 and G0423 for ICR.

Comment: UnityPoint Health supports this proposal. The site neutral policy has produced an anomalous result where ICR services furnished in on-campus hospital departments, excepted off-campus provider-based departments (PBDs), and physician offices are paid at a higher rate ($120.47) than non-excepted off-campus PBDs ($48.03) – resulting in a significant barrier to beneficiary access for an already underutilized service.

Remote Services
CMS clarifies requirements for mental health services furnished remotely by hospital staff using communications technology to beneficiaries in their homes. To conform to CCA, 2023, CMS continues through December 31, 2024, to (1) delay periodic in-person visit for the remote mental health benefit and (2) allow remote benefits for outpatient therapy, Diabetes Self-Management Training, and Medical Nutrition Therapy.

Comment: Telehealth and remote services have been transformative for health care delivery. UnityPoint Health is pleased that CMS has provided greater clarity for billing of remote, in-home mental health services based on stakeholder input. UnityPoint Health supports the new untimed HCPCS C-code describing group therapy and the removal of the word “initial” from the descriptor of psychotherapy codes to make clear that the codes can be used for an initial or subsequent encounter. We also appreciate the care setting parity for telehealth extensions authorized by CCA, 2023.

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM
CMS proposes to refine three measures, readopt one measure with modifications, adopt two new measures, and remove one measure. CMS proposes to publicly report “Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate” on Care Compare. CMS is seeking comment on several areas for future measure development.

Comment: UnityPoint Health supports the ongoing development and improvement of quality measures within the OQR program. For measure updates, we offer the following:


COVID-19 Vaccination Coverage among Healthcare Personnel – UnityPoint Health supports alignment of this vaccination measure across all quality reporting programs and agrees that it should conform with up-to-date National Healthcare Safety Network (NHSN) standards. This proposal recognizes one source of truth and enables science to dictate standards for infectious disease management, which can change and should change related to an evolving disease state. To reduce duplicative reporting burden, we strongly encourage CMS to further recognize that NHSN data submission by hospitals for this measure meets all OQR Program requirements. Additionally, due to reporting lag, the recent roll-back of the federal mandate for vaccination of health care personnel, and the variance of state and local law governing vaccination requirements, we request that CMS continue to review this measure to determine whether to require public display by facility one-year in arrears.
OP-31: Cataracts Visual Function – **UnityPoint Health supports maintaining voluntary reporting status** for Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery.

OP-29: Colonoscopy Follow-Up Interval – **UnityPoint Health supports the modification** to Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients. This aligns with the United States Preventive Services Task Force recommendations for screening to begin at age 45.

**HOPD Procedure Volume** – This measure (Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures) was removed in the 2018 OPPS final rule based on lack of evidence to support its link to a facility’s overall performance or quality improvement with respect to surgical procedures. As payment is moving from volume to value, **UnityPoint Health is concerned that this measure is not an appropriate quality measure.** First, while we agree that volume indicators may show quality of care for procedures within larger facilities, results may vary for smaller facilities. This is particularly true in rural facilities, where patient access to certain procedures in the outpatient setting becomes challenging. Second, CMS only has access to Medicare/Medicaid claims populations, which will likely result in skewed data for surgical procedure volumes and outcomes. For example, some outpatient surgical procedures are more prevalent with advanced age, such as cataracts. Third, as with any measure utilizing claims data, reporting is delayed making it challenging for hospitals to identify gaps and improve performance.

**THA/TKA PRO–PM** – **UnityPoint Health reaffirms our general support for PRO-PMs but believes that this measure is overly complex.** While this measure has been modified slightly for the HOPD environment, Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty still has the attributes which gave us pause in the inpatient setting. As such, we reiterate our concerns from our IPPS formal comment letter.

This measure presents operational challenges when surveying patients pre- and post-surgical events and is overly burdensome. First, the patient could potentially be surveyed multiple times over the course of a year under the PRO-PM, which presents challenges for administering the survey pre- and post-procedure. In particular, who is responsible for documenting the post-acute survey? It does not seem appropriate to fall within the purview of the HOPD. Second, ownership of the PRO-PM measure needs further definition. While proposed for HOPD reporting, it is often the case that these surgeries are performed and under the auspices of independent physicians with HOPD serving as the site of service. Should HOPD be the reporting agent for locums? Third, the information regarding pre- and post-surgical outcomes for the PRO-PM is not centrally located. Often this data may not be housed in the same EMR or even be available across platforms. Last, gaps exist within the PRO-PM around addressing patient dissatisfaction through follow up care after the 300-day window. Given TKA and THA patients generally tend to be elderly, a survey on surgical outcomes of care requested a year after the procedure may pose confusion and result in inaccurate responses from patients as well as caregivers. In some cases, patients also receive CAHPS surveys mandated by CMS. Multiple surveys may lead to survey fatigue and frustration for patients. As such, UnityPoint Health encourages CMS to develop additional exclusion criteria to address these operational challenges.

Additionally, the PRO-PM measure includes four sources of data in the denominator: PRO-PM, claims
data, enrollment data, and Census Bureau survey data. Multiple data sources inherently create complexities and undue burdens to avoid potential mismatched patient information.

**Excessive Radiation eCQM** – Our feedback has not changed from our response to the similar measure proposed in the IPPS rule. **UnityPoint Health opposes the mandatory adoption of this measure** (Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults) as it is not ready for prime time. **We urge CMS to consult with HOPDs for additional input and testing prior to implementation.** At its core, this measure requires patient information to be integrated into electronic medical records (EMRs) to create a single patient eCQM file per encounter for all measures. While UnityPoint Health has an expert and experienced quality reporting team, we question how measure stewards envisioned measure implementation without the need for a sophisticated third-party tool to create a separate file from an external configuration system. Data capture challenges (i.e. the functionality of third-party software vendors) include:

- **Multiple Data Source Capture**: A solution limited to merging CT data for multiple hospitalizations from external sources would not allow for adequate tracking and control of patient exposure throughout the year.
- **Patient Complexity Capture**: A solution must consider the multiple and varied health issues that could arise during a single calendar year or for single treatment due to traumatic injury/illness monitoring.
- **Picture Archiving and Communication System (PACS) Integration Capture**: A solution cannot assume that all EMR systems use PACS as an integrated point of EMR software. For some, data capture will require data pulls from PACS system and a solution that matches these pulls with EMR encounter data. For example, data related to dosing or body habitus information may not be captured from PACS into EMRs.

**RURAL EMERGENCY HOSPITALS (REHs)**

*Rural emergency hospitals are a Medicare provider type that furnishes emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week and may elect to furnish other medical and health services on an outpatient basis.*

**Comment**: As is the case with all hospitals, care is local. This translates to each hospital being responsible for different community health needs and offering different services. This is particularly true in rural communities. As rural hospitals consider a conversion to REH status, there are programs / services outside of inpatient services that are needed in the community but are not contemplated in the REH model as it stands. UnityPoint Health requests that CMS continue dialogue with Congress to make recommendations related to the REH program flexibility and financial viability. As these have not lessen in importance from last year, we request that CMS continue to consider:

- **340B Drug Pricing Program** – REHs do not qualify as covered entities for the 340B program. Many critical access hospitals (CAHs) and other small rural hospitals have greatly benefited from the 340B program and would lose much needed funding with the conversion to a REH. **We strongly urge CMS to work with Congress to modify the statute to ensure that REHs are eligible for 340B Drug Pricing Program.** Similar to CAHs, we would recommend that that REH status is automatic
per this designation and, due to low patient volume, not tied to disproportionate share hospital percentages.

- **Distinct Unit Authorization** – The statute prohibits REHs from furnishing any inpatient services, except that skilled nursing services may be furnished in a separate and distinct unit of the REH. **We encourage CMS to work with Congress to expand the statute to allow REHs to furnish inpatient psychiatric and inpatient rehabilitative services if furnished in a separate and distinct unit.** This would enable rural communities with these needs to offer such services, and in the absence of inpatient services, facilities may be able to make these accommodations more readily.

- **Transport as a Core REH Service** – As REHs are charged with a focus on emergency treatment, the availability of timely Emergency Medical Services (EMS) is crucial. EMS is not only vital to getting patients to the REH timely but is necessary for timely transfers. Due to large geographic service areas and low population density, rural EMS providers often travel longer distances per run. The availability of rural EMS is often scarce and patchwork funding does not encourage stability in service providers. To assure access to EMS, **UnityPoint Health urges CMS to work with Congress to include EMS within the list of core REH services that receive enhanced reimbursement.**

- **OPD Services** – Subdivision (iv) of 1833(t)(1)(B) lists exclusions from the definition of “covered OPD services.” CMS should work with Congress to enable REHs to provide outpatient therapy services as well as screening and diagnostic mammography services. These are vital services for rural residents and should be available for REHs to offer.

### RURAL EMERGENCY HOSPITAL QUALITY REPORTING (REHQR) PROGRAM

**CMS proposes to (1) adopt and codify policies related REHQR implementation; (2) adopt an initial measure set beginning with the 2024 reporting period; and (3) codify requirements related to REHQR program participation. CMS seeks general feedback on electronic clinical quality measures (eCQMs), care coordination measures, and a tiered quality measure approach.**

**Comment:** UnityPoint Health supports CMS’ intent to adopt a concise set of important, impactful, reliable, accurate, and clinically relevant measures for REHs that would inform consumer decision-making regarding care and further quality improvement efforts in the REH setting. While the proposed measure set is concise with one chart-abstracted measure and three claims-based measures, it is not obvious that all are impactful or clinically relevant. REH core services are emergency department services and observation services, and it is uncertain if Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy (CBE# 2539) or Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery (CBE# 2687) will yield enough volume to be relevant. As the first cohort of REHs are designated, we recommend that CMS work closely with those facilities to understand services to guide appropriate quality measurement. We might also suggest that CMS delay any public reporting until at least two performance periods have lapsed to assure that measures appropriately reflect REH quality.

**Electronic Clinical Quality Measures (eCQMs) for Reporting Quality Data:** UnityPoint Health generally supports accurate measures that reduce reporting burden and prefers digital quality measures over chart-abstracted measures when feasible. We agree that eCQM adoption is a laudable goal, but it may not be operationally feasible in all cases due to interoperability concerns. This is evidence by the 81.5% success rate by CAHs reporting eCQMs under the Hospital Promoting Interoperability Program. It should also be
noted that not all measure definitions lend themselves to an eCQM data capture (see our discussion in the OQR Program above on Excessive Radiation eCQM). To help REHs and all hospitals with successful eCQM reporting, CMS should be thoughtful of implementation timeframes taking into account voluntary versus mandatory reporting, software development, and organizational readiness to operationalize workflows and tracking. Ideally, we suggest at least three years post introduction of a new measure, with at least one mandatory reporting year in quality program (no incentive-based outcome) prior to moving to any incentivized quality program.

We will also refer CMS to our formal comment letter to the CY2022 IPPS proposed rule and the request of information on Fast Healthcare Interoperable Resources (FHIR). In that letter, we highlighted the operational challenges of trying to chase ever-changing technology standards. We stated:

> With health care systems historically being the first to implement electronic health records (EHRs) and FHIR, our 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 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. UnityPoint Health uses a combination of DSTU 2, STU 3 and R4 FHIR Versions to meet our requirements for sending data. Since 2017, four main 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 hospitals are at v4.1.0 yet because vendors and providers are not required to meet ONC CURES Edition CEHRT.

While UnityPoint Health appreciates the attempt to align health care interoperability resources, integrated health systems have competing information technology builds and priorities across care settings, which is true on a smaller scale for individual providers and smaller hospitals. When UnityPoint Health rolled out an EHR through Meaningful Use requirements in the hospital inpatient setting, it was a multiyear process. Overall, UnityPoint Health 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 social determinates of health (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.

For the most part, these concerns remain and are applicable to REHs.

**COMMUNITY MENTAL HEALTH CENTERS CONDITIONS OF PARTICIPATION (CoPs)**

*CMS proposes to modify CoPs to reflect the statutory addition of the new Medicare benefit category for intensive outpatient services (IOP) and revise the personnel qualifications of mental health counselors and add personnel qualifications for marriage and family therapists.*

**Comment:** *UnityPoint Health supports these changes.* In addition, it is unclear at this point how the inclusion of IOP services might impact the ability of Community Mental Health Centers to meet the threshold requirement of providing at least 40% of its services to individuals who are not eligible for Medicare Part B. We request that CMS (1) monitor this issue using claims data as it is difficult to craft a solution without understanding the problem to be solved and (2) seek input from stakeholders on an ongoing basis and in a variety of forums, including future OPPS proposed rules. We do not believe that Congress would intend for Community Mental Health Centers to be penalized for implementing a program it established and authorized Community Mental Health Center participation.

**HOSPITAL REQUIREMENTS TO MAKE PUBLIC STANDARD CHARGES**

*CMS proposes to revise current hospital price transparency requirements. Proposals include use of a CMS template to display required standard charges; encoding standard charge information in a CSV or JSON format; affirmation of truth, accuracy and completeness of machine-readable file information; additional requirements for hospital websites; certification by a hospital official of accuracy and completeness; and acknowledgement of receipt of an enforcement warning notice.*

**Comment:** *When choosing health care providers, consumers consider a number of factors in their value equation, including location, experience, services, quality, outcomes, and cost. UnityPoint Health is committed to meaningful price transparency for patients.* Our approach to price transparency focuses on providing each patient or prospective patient personalized information for them to understand their benefit plans and their out-of-pocket responsibility, enabling them to be educated consumers.

As CMS proposes to further refine the public release of hospital standard charge information, *UnityPoint Health supports the formal comments submitted by the American Hospital Association.*

**REQUEST FOR INFORMATION – ESSENTIAL MEDICINES**

*CMS requests comment on a separate inpatient Medicare payment for hospitals establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. The payment is anticipated as budget neutral and could be adopted as soon as cost reporting periods beginning on or after January 1, 2024.*
Comment: UnityPoint Health supports incentivizing the creation of private sector reserves of essential medicines not adequately provided in the Strategic National Stockpile, and we appreciate that CMS has included this request for information. As a member of Civica Rx, we generally support the suggestions offered in their comment letter. At a high level, CMS should consider the following:

1. Incentivize a 6-month, rather than 3-month, inventory to create effective resiliency.
2. In general, prefer a buffer inventory that sits upstream of individual hospitals, to improve efficiency in allocation and inventory management.
3. Allow companies to provide data on the cost of buffer stock using accepted financial calculations.
4. To reduce reliance on companies likely to have quality failures, exclude drugs from manufacturers with a recent history of FDA warning letters.

UnityPoint Health does have a concern that this inventory payment is proposed as budget neutral, as it is unclear where funding would be shifted from to support this effort. With the current financial environment and thin hospital operating margins, this funding source is important for hospitals to understand prior to implementation. We encourage CMS to continue to work with the stakeholders, including the American Society of Health-System Pharmacists, in crafting a solution to assure access to essential medicines.

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

Sincerely,

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

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2 Civica Inc. (Civica RX) response letter submitted on August 30, 2023 – tracking # llp-c9bi-vx2z