

September 24, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-1695-P – Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; published at Federal Register, Vol. 83, No. 147, July 31, 2018.

Submitted electronically via www.regulations.gov

Dear Ms. Verma,

UnityPoint Health (“UPH”) appreciates this opportunity to provide feedback on the proposed rule. UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 38 hospitals in metropolitan and rural communities and 15 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits. In addition, UPH is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Health Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program as well as providers from the Pioneer ACO Model.

UPH appreciates the time and effort of CMS in developing and proposing this rule and respectfully offers the following comments.

SITE NEUTRALITY: PAYMENT FOR CERTAIN ITEMS AND SERVICES FURNISHED BY CERTAIN OFF-CAMPUS DEPARTMENTS OF A PROVIDER

Section 603 of the Bipartisan Budget Act of 2015 changed the reimbursement structure for off-campus provider-based departments (PBDs). In general, existing (excepted) off-campus PBDs are eligible for reimbursement under the Outpatient Prospective Payment System (OPPS), while new off-campus PBDs must seek reimbursement under a separate fee schedule. In this proposed rule, excepted off-campus PBDs

will be reimbursed under Physician Fee Schedule rates for a clinic visit service (HCPCS code G0463) as well as for items and services provided under new service clinical families. In addition, CMS is proposing to reduce reimbursement for 340B drugs by non-excepted off-campus PBDs and to initiate a new code modifier to track off-campus emergency department services.

- ***Comment:*** First, UPH has expressed concerns with the methodology that CMS is using to set the Physician Fee Schedule rates.¹ For CY 2019, CMS is proposing to continue the use of a single scaling factor “until we identify a workable alternative mechanism that would improve payment accuracy.” We are disappointed that CMS continues to use this imprecise methodology and is now expanding its use to other services prior to developing a workable alternative. **Until CMS develops a more accurate cost methodology, we would request that CMS refrain from further expansion efforts.**

Second, the concept of site neutrality is an attempt to “fix” inequities in the Fee-For-Service payment structure. The proposed reimbursement change to HCPCS code G0463 (clinic visit service) alone is projected to have a net impact of -\$1.2 million taking into account \$1.8 million in savings estimated from our participation in the Next Generation ACO model. While the net impact would have been in excess of \$3 million if we were not participation in a Medicare ACO, we question whether CMS should penalize site of service delivery decisions for organizations engaged in two-sided risk models. Because the overall site neutral approach is embedded in Fee-For-Service reimbursement, we believe this approach is flawed in that it exacerbates inequities across sites of service and undermines initiatives that promote value-based care. Further, while the intent of site neutral policies is to allow healthcare decisions to focus on delivery instead of payment, we do not believe that this can be effectively accomplished under Fee-For-Service parameters. We are concerned that the proposed CMS code-by-code approach based on revenue that identified HCPCS code G0463 will perpetuate any perceived “gaming” and will hamper access by Midwest providers to serve patients. The CMS approach is based on the assumption that this payment structure will curb excess use; however, access to care in the Midwest and in rural areas is primarily driven by geography and efficiencies and not cost. Instead of employing resources to examine individual procedures by code and revenue amount, **we would recommend that CMS encourage value-based programs and allow providers through shared decision-making with their patients to determine appropriate and convenient delivery options.** Aside from resources required for the code-by-code approach, we believe that there are unintended consequences to “resetting the table” in this fashion. Namely, this approach fails to recognize that independent (free-standing) and for-profit entities will cherry pick certain lower-acuity patients to increase their operating margins and erode already fragile PBD operating margins for Midwest providers. Without developing a holistic payment approach that takes into consider all payments, fee schedules will continue to drive healthcare builds and infrastructure. **We wholeheartedly urge CMS to focus on population health objectives and the path to value within this and all Medicare payment regulations and to promote regulatory and payment flexibility for providers who engage in financial risk.**

¹ UnityPoint Health comment letters for CY 2018 and CY 2019 Physician Fee Schedules; See “PFS_2018_UPC_9-11-17” at Regulations.gov tracking number 1k1-8ym0-6v25 and “PFS_2019_UPH_9-19-18” at Regulations.gov tracking number 1k2-95ck-wei9

Third, as CMS continues to revisit provider-based regulations, we want to state our **support for the retention of the 250-yard test for both on-campus PBDs and remote locations**. Any narrowing of this distance requirement would cause significant hardship to our organization and the patients we serve.

CHANGES TO THE INPATIENT ONLY LIST

In regards to the Inpatient Only list, CMS is proposing to remove (1) CPT code 31241 (nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery) and (2) CPT code 01402 (anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty) and to add HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel).

- ***Comment:*** We would reiterate our concerns from last year regarding removal of total knee arthroplasty (TKA) from the IPO list.² We believe that our concerns are still outstanding. That said, we urge CMS to continue to review TKA in terms of patient acuity and outcomes in both inpatient and outpatient settings. Although not included within this year's proposal, we would continue to have similar concerns for the removal of partial and total hip arthroplasty from the IPO list.

As an early adopter of value-based arrangements, including ACO contracts, we understand and support transitioning care to lower acuity settings as dictated by each patient's status and population health principles. **From a policy perspective, this again raises issues related to inequities within the Fee-for-Service structure.** Currently, lesser costs from "healthier" patients balance greater costs from more complex patients. As procedures are removed from the IPO list, "healthier" patients are transitioned to outpatient settings leaving more complex, costly patients within inpatient settings. These policies perpetuate a for-profit mentality, will encourage more infrastructure builds to cater to younger, healthier and less costly patients, will divert resources from inpatient settings, and lead to great healthcare costs. In the Midwest where access is determined by geography, this approach significantly impacts the sustainability of inpatient services, particularly in the nonprofit arena, and ultimately undermines access to care. While our preference would be for CMS to encourage value-based arrangements instead of further Fee-For-Service arrangements, we urge 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. At the very least, we would recommend that CMS consider inpatient rate updates that more closely follow the consumer price index.

UPDATES TO THE AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM

CMS is proposing to revise the ASC covered procedures list for procedures to be designated as office-based as well as procedures to be added. Specifically, the additions to the list are 12 CPT codes related to cardiac catheterization.

- ***Comment:*** Again, we believe that the Fee-For-Service reimbursement structure has created unnecessary complexity within the service delivery environment. We believe that CMS should

² UnityPoint Health comment letter ("2018OPPS_UPH_9-11-17") dated September 11, 2017, accessed at <https://www.regulations.gov/document?D=CMS-2017-0091-3211>

encourage value-based programs and allow providers through shared decision-making with their patients to determine appropriate and convenient delivery options. We also urge CMS to monitor these procedures and sites of service for quality/safety, patient acuity and total cost of care.

340B DRUG PRICING PROGRAM

In last year's OPPS final rule, CMS reduced the payment for non-pass-through, separately payable drugs purchased by 340B-participating hospitals through the 340B Drug Pricing Program. The resulting payment rate is the average sales price (ASP) minus 22.5 percent instead of ASP+6 percent – a total reduction of nearly 30%.

- **Comment:** We support the preservation of access to low-cost medications for vulnerable patients. In last year's comments, UPH opposed this reduction and its impact on our ability to provide outreach and needed services in our communities.³ This policy impacted 12 of our nonprofit hospitals across Illinois, Iowa and Wisconsin that are eligible for the 340B Drug Pricing Program. Prior to the reduction in 2017, UPH received \$49.9 million in total savings from the 340B Drug Pricing Program through its 33 locations and 141 contract pharmacy sites. **UPH would like to be on record in opposition to any efforts to redirect resources from or place moratoriums on safety-net providers, but in support of initiatives to strengthen manufacturer and covered-entity transparency.** Along those lines, we support the American Hospital Association's principles for communicating the values of the 340B Program and the disclosure of Hospital's 340B estimated savings⁴ and encourage CMS to work with stakeholders in developing future regulations.

In addition, the following are some recent examples from our affiliates of community impact from the 340B Program. The purpose is to demonstrate the diversity of community needs and the desire of 340B covered entities to continue to have flexibility to employ savings to serve these diverse and local needs.

- **Public Emergency Response:** In the spring of 2018, at least 150 people were poisoned in Illinois – more than 83 people in the Peoria area – and four people died. The culprit was tainted synthetic cannabinoid, known as K2 or Spice, that was laced with a long-acting coumarin derivative. Many victims were hospitalized for internal bleeding as well as blood coming from the ears, eyes and mouth associated with brodifacoum. Treatment involves managing and building up the blood clotting function with high-dose vitamin K, at costs exceeding \$50,000 for a month's supply. Once stabilized, uninsured patients were faced with continued hospitalization to maintain the pricey drug regime. The 340B Program enabled UnityPoint Health – Methodist Hospital in Peoria to discharge 47 impacted patients to home with supplies of high-dose vitamin K for \$17 per week, instead of \$13,000 per week. In a period of two months, more than \$1.7 million worth of supplies were provided.
- **Improved Access:** Fort Dodge, Iowa, a community of roughly 24,000 residents, is served by UnityPoint Health – Trinity Regional Medical Center, a Sole Community Hospital and Rural

³ Id.

⁴ AHA, "340B Hospital Commitment to Good Stewardship Principles" accessed at https://www.aha.org/system/files/2018-09/Final-Stewardship-Principles_Sept-2018_0_1.pdf

Referral Center. There are no 24-hour pharmacies in Fort Dodge and weekend pharmacy hours are limited. The 340B Program has funded an InstyMeds dispenser, which is an automated system much like a bank ATM, that dispenses prescription medications directly to patients 24 hours per day. Located in the Emergency Department, more than 5,600 prescriptions have been dispensed via InstyMeds over the past two years. Of these prescriptions, more than 800 or 14% were provided to patients at no cost through the Compassion Care Rx program. The 340B program has not only enabled timely community-wide access to prescriptions in Fort Dodge, but an average of one prescription per day has been delivered to vulnerable individuals under the Compassion Care Rx program.

- Chronic Care Outreach: UnityPoint Clinic physicians noticed that high drug costs for patients with chronic conditions often resulted in patients stopping their medications. Ongoing drug regimens are particularly important for managing diabetes, congestive heart failure and pulmonary conditions. Despite understanding the health benefits of taking medications, individuals who are uninsured, lack drug coverage or reach the Medicare "donut hole" are more likely to stop filling their prescriptions. UnityPoint Health – Methodist Hospital in Peoria has established special hospital clinics for patients with large ongoing out-of-pocket medication costs. They have worked with a 340B contract pharmacy to provide virtual insurance that enables them to receive discounted pricing. For diabetic patients, cost savings can be hundreds of dollars per prescription. For example, Levemir is provided for \$16.50 rather than \$500. More importantly, patients are remaining on their prescribed medications. Clinic have been piloted with diabetic patients and pulmonary patients.

OPPS PAYMENTS AND AMBULATORY PAYMENT CLASSIFICATION (APC) GRO POLICIES

CMS is proposing an increase of 1.25 percent to the outpatient department (OPD) fee schedule as well as the continuance of the 7.1 percent increase for certain sole community hospitals (SCHs).

- **Comment**: We are pleased that CMS is continuing the current payment rate for SCHs. Within our integrated health system, we have three SCHs located in Iowa (Fort Dodge, Marshalltown and Muscatine) which provide vital access to healthcare for their communities. **We support a reimbursement structure for rural facilities that recognizes payment for access as a component.** While CMS has attempted to address this concern through heightened Fee-For-Service rates in various fee schedules, the price of access for essential hospitals and safety net facilities will require continued vigilance as CMS encourages providers to transition to value-based arrangements.

HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM AND AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM

CMS is proposing to update the measure removal policies consistent with recommendations in other fee schedules and based upon work from the Meaningful Measures initiative. For the OQR, CMS is proposing to remove 10 measures; and for the ASCQR, 8 measures are proposed for removal.

- **Comment**: **We are extremely supportive** of the Meaningful Measures initiative and its goals align with prior UnityPoint Health comment letters on the need to simplify and streamline quality measures. As for the addition of Factor 8 for measure removal (costs associated with a measure outweigh the

benefit of its continued use in the program), we concur. In terms of the measures slated for removal, we have reviewed and support these efforts to provide regulatory relief.

ADDITIONAL HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM POLICIES

CMS is proposing to modify the HCAHPS Survey measure by removing the Communication about Pain questions effective with January 2022 discharges for the FY 2024 payment determinations.

- **Comment: We support removal of this measure.**

We are pleased to provide comments to the proposed regulations and their impact on our patients and integrated healthcare system. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,



Sabra Rosener, JD
VP, Government & External Affairs
UnityPoint Health