UnityPoint Health

Government & External Affairs
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October 5, 2020

Administrator Seema Verma
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1736–P
P.O. Box 8013
Baltimore, MD 21244–1850

RE: CMS–1736–P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals, published in Vol. 85, No. 156 Federal Register 48772-49082 on Wednesday, August 12, 2020.

Submitted electronically via www.regulations.gov

Dear Administrator Verma:

UnityPoint Health appreciates the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services proposed rule. With more than 400 physician clinics, 40 hospitals, 16 home health locations, 7 Community Mental Health Centers and 4 accredited colleges, UPH is one of the nation's most integrated health care systems. Our more than 32,000 employees provide care throughout Iowa, western Illinois and southern Wisconsin. UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 7.9 million patient visits annually.

UnityPoint Health (UPH) respectfully offers the following comments.

OPPS PAYMENTS UPDATES

CMS is proposing an increase of 2.6 percent to the hospital outpatient department (HOPD) fee schedule as well as the continuance of the 7.1 percent increase for certain sole community hospitals (SCHs).

Comment: While **UnityPoint Health generally supports the increase to the OPPS base rate**, we have concerns related to other proposals within this rule that erode payment reimbursement to this vital care setting. Those comments and our recommendations are detailed in the other sections of this letter.

We are pleased that CMS is continuing the current payment rate for SCHs. Within our integrated health care system, we have three SCHs located in Iowa (Fort Dodge, Marshalltown and Muscatine) which

provide vital access to health care 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.

PRICE TRANSPARENCY

In 2019, CMS finalized rules related to price transparency of hospital standard charges in the CY 2020 Hospital Outpatient Prospective Payment Final Rule. No further changes are proposed in this rule.

Comment: UPH is committed to meaningful price transparency for patients. **We reiterate our request from last year's comment letter to urge CMS to reconsider this rule altogether or, at minimum, delay the unrealistic timeframe for implementation** given the current COVID pandemic and the heavy infrastructure lift needed to comply with these requirements. While we do not agree with the rule's overly prescriptive approach to price transparency, our primary concern is that the rule has missed the mark in its effort to make price transparency meaningful for consumers and would even suggest that it creates more consumer confusion. As an alternative, we encourage that CMS institute a pause and take steps to facilitate the development and voluntary adoption of patient cost-estimator tools and resources by convening stakeholders to identify best practices, recommending standards for common features of cost-estimator tools, and developing solutions to common technical barriers.

SITE NEUTRALITY

Section 603 of the Bipartisan Budget Act of 2015 changed the reimbursement structure for off-campus provider-based departments. CMS is proposing to continue the 40 percent PFS-equivalent rate for CY 2021. The payment reduction continues to target rates for a clinic visit service (HCPCS code G0463).

Comment: **UPH is opposed to this payment reduction for clinic visit services and supports restoring the former reimbursement methodology**. The impact is that CMS is financially penalizing hospital-based clinics (1) who are providing services not otherwise available to vulnerable populations (low-income and underserved) and patients with heightened acuity or medical complexity and (2) whose infrastructure costs by necessity reflect a more comprehensive licensing, accreditation and regulatory environment.

As this issue is subject to ongoing litigation, we are pleased that CMS has chosen to pause any further expansion of payment reductions in this rule. On September 17, 2019, the U.S. District Court for the District of Columbia found "*the 'method' developed by CMS to cut costs is impermissible and violates its obligations under the statute. While the intention of CMS is clear, it would acquire unilateral authority to pick and choose what to pay for HOPD services, which clearly was not Congress' intention*."[1] The US Court of Appeals for the District of Columbia Circuit reversed this on July 17, 2020, and currently there is a pending petition for rehearing filed on August 31, 2020. We support the arguments raised by the American Hospital Association and the decision rendered by the District Court.

[1] American Hospital Association, et. al., v. Azar, Civil Action No. 18-2841 (RMC), accessible at https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2841-31

340B DRUG PRICING PROGRAM

CMS is proposing to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs. Rural SCHs, Critical Access Hospitals (CAHs)*, PPS-exempt cancer hospitals and children's hospitals would be exempted from this payment reduction. Alternatively, CMS is proposing to continue the current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.*

Comment: **We support the preservation of access to low-cost medications for vulnerable patients**. Congress enacted the 340B Drug Pricing Program to provide resources to hospitals serving high volumes of low-income and rural patients to enable those hospitals to provide more comprehensive services and treat more patients.[2] As a large nonprofit, integrated health care system in the Midwest, the UPH network of Disproportionate Share Hospitals (DSH), SCHs, CAHs 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. ***Of our senior affiliates, we have 12 hospitals that participate as covered entities under the 340B Drug Pricing Program***. 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.

Proposed CY 2021 Payment Reductions: For CY 2018, CMS instituted a nearly 30 percent reduction in reimbursement for certain 340B hospitals, and this rule proposes to deepen those cuts and further erode the program's core principle of suppporing direct service and outreach to vulnerable populations. **We respectfully urge CMS to reverse the payment cuts already in place and not finalize its proposal to deepen the cuts.**

- Transfer of Program Benefits from Safety-Net Institutions. The 340B Drug Pricing Program enables access to care for services provided by DSH or rural hospitals. CMS's proposal would harm our ability to treat low-income patients without reducing costs for hospital patients, Medicare beneficiaries, or the Medicare program. CMS proposes to implement the payment reduction in a budget neutral manner, ensuring that any reduction in spending for 340B drugs would be offset by increased spending and co-payments for other services. **Although we generally oppose a policy which diverts 340B Drug Pricing Program resources to subsidize non-340B providers, the timing of cuts to safety-net hospitals during the COVID pandemic is illogical and perverse**. During this public health crisis, we believe this signals a lack of recognition by CMS for the important role played by hospitals who disproportionately serve vulnerable and rural populations.

- Accurate 340B Discount Estimates. We are concerned with the accuracy of CMS's 340B discount calculation. **ASP minus 34.7 percent is not a precise estimate, and its miscalculation could have grave consequences resulting in reduced patient access to care**. While we concur that penny-priced drugs should be excluded from the discount calculation, we request that drugs with inflationary penalties should likewise be excluded from this calculation. Excluding drugs with

[2] Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106, Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b; see also H Rpt. No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session.

inflationary penalties will reduce the potential for losses that are unevenly distributed across drugs and across hospitals. Additionally, the discount must take into account the substantial compliance costs incurred by our hospitals as a result of 340B participation, such as the cost of implementing software and hiring additional staff to ensure 340B compliance. Furthermore, the estimate does not account for our facilities which are subject to the GPO Prohibition and must purchase some products at the Wholesale Acquisition Cost (WAC). Our billing system capabilities do not allow us to parse out all instances where the JG modifier should not be applied. In these instances, our safety-net hospitals are forced to purchase the drugs at a premium (i.e. the full WAC price) yet still receive nearly 35 percent less reimbursement than non-safety-net hospitals. The failure to factor in these operational costs unfairly inflates the discount.

- Inclusion of Add-On Payment. **Like non-340B hospitals, 340B hospitals should also receive an add-on payment of 6 percent of a drug's ASP**. A given drug will have similar handling, storage, and other pharmacy-related overhead costs regardless of whether the drug was purchased under the 340B Drug Pricing Program or by a non-340B entity. Since drug overhead and handling costs are also incurred for drugs acquired under the 340B Drug Pricing Program, these costs need to be added to the significant costs unique to participation in the 340B Drug Pricing Program.

Unilateral Action by Drug Manufacturers to Establish Conditions of Participation. Recently, major drug manufacturers have taken actions to limit the distribution of certain 340B drugs to our hospitals. Specifically, drug manufacturers are engaging in strategies to interfere with 340B discounts for drugs distributed through contract pharmacy arrangements and/or demanding of 340B hospitals superfluous claims data requirements. **These actions apply to all 340B hospitals, including SCHs and CAHs, and undermine 340B hospitals' ability to serve vulnerable communities**, particularly in rural areas, where contract pharmacies a vital to providing access to more affordable medications.

What is troubling is that many of the impacted drugs targeted in these drug manufacturer actions are medications that our patients consistently struggle to afford. ***In one of our most rural regions, we estimate these changes at roughly a $1 million negative impact with 82 percent from insulin and other drugs for diabetes, 11 percent from inhalers for asthma and/or COPD, and 5 percent from high-priced anticoagulants and other medications for heart disease***. This is a community that cannot support a 24-7 pharmacy and contracted pharmacies provide vital access throughout the region.

The 340B Drug Pricing Program statute is clear that manufacturers participating in the Medicaid program must enter into agreements with the Department of Health and Human Services (HHS) that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[3] There is no statutory provision that allows these manufacturers to deny 340B pricing to eligible hospitals for any drug. In addition, 340B programmatic guidance states unequivocally that, "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not

[3] 42 U.S.C. 256b(a)(1)

to exceed the statutory 340B discount price."[4] **HHS has the authority to administer the 340B program and to prevent external parties, including drug manufacturers, from inserting additional conditions of participation within the 340B Drug Pricing Program. We request immediate enforcement action by HRSA/HHS/CMS.**

INPATIENT ONLY (IPO) LIST CHANGES

CMS is proposing to eliminate the IPO list over the course of three calendar years beginning with the removal of approximately 300 musculoskeletal-related services in CY 2021. Overall, more than 1,700 services are implicated. CMS is also soliciting comments on whether three years is an appropriate timeframe for transitioning to eliminate the IPO list; other services that are candidates for removal from the IPO list for CY 2021; and the sequence in which to remove additional clinical families and/or specific services from the IPO list in future rulemaking.

Comment: **UPH opposes the proposal to eliminate the IPO list over a three-year period.** 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. Over the course of recent years, CMS has significantly eroded the IPO list without allowing time for evaluation and analysis of quality and beneficiary safety as these procedures have been transitioned. 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 addition, we recommend that any pilot or trial to elect an outpatient procedure be authorized only for providers participating in an Advanced Alternative Payment Model. This would encourage providers to transition to risk-based service delivery models and also provide a platform to develop best practices in terms of workflows, beneficiary eligibility, and quality outcomes. While CMS acknowledges that an outpatient setting would be applicable for "appropriately selected patients," we remain concerned that CMS offers no minimum exclusionary circumstances based on evidence-based safety criteria.

More generally, we encourage CMS to place these site of care issues within a larger policy context. As an early adopter of value-based arrangements, including ACO contracts, UPH understands and supports 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 perpetuated 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 and encourage more infrastructure builds to cater to younger, healthier and less costly patients, divert resources from existing inpatient settings, and lead to greater health care costs overall.** 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. Case in point are SCHs, in which IPO list erosion will directly impact their financial sustainability. 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

[4] https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

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.

LEVEL OF SUPERVISION FOR OUTPATIENT THERAPEUTIC SERVICES

CMS is proposing to change the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service. Additionally, the direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services would include virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician.

Comment: **We enthusiastically support this change in level of supervision for hospitals and CAHs**. Given workforce shortage designations in our service areas, we appreciate this flexibility as it will enable our providers to practice at the top of licensure and increase physician bandwidth. We appreciate that this proposal enables the supervising physician/practitioner to have discretion related to the use of telehealth in this area generally and as dictated by patient needs.

PRIOR AUTHORIZATION PROCESS AND REQUIREMENTS FOR CERTAIN HOPD SERVICES

CMS is proposing the addition of two categories of services to the prior authorization process beginning for dates of service on or after July 1, 2021: (1) Cervical fusion with disc removal and (2) implanted spinal neurostimulators.

Comment: **Generally, we oppose instituting a prior authorization process resulting in accompanying administrative burdens for both providers and CMS as well as delay in providing patient care**. We do not believe that section 1833(1)(t)(2)(F) of the Act[5] grants authority for CMS to implement this process. CMS is asserting unilateral authority to pick and choose procedures for which payment is conditioned upon additional medical necessity documentation. This process is not aimed at "*controlling unnecessary increases in the volume of covered OPD services*" but rather targeting procedures that are not covered HOPD services. We also believe this over-bearing proposal is premature, as other regulatory avenues including local coverage decisions and audits exist. If CMS believes that there is fraud and abuse in this area (i.e. "*utilizing codes because of financial motivations, as opposed to medical necessity reasons*"), we encourage CMS to use its enforcement authority rather than a broad stroke, upfront approach as proposed here. When CMS identifies "bad apples", CMS should use targeted enforcement instead of punishing all providers with further restrictions, particularly when proposed solutions put in place restrictions that delay patient care.

SPECIMEN COLLECTION FOR COVID-19 CLINICAL DIAGNOSTIC TESTS

CMS is requesting comment on whether HCPCS code C9803 should continue to be payable under the OPPS to support COVID–19 testing beyond the conclusion of the COVID–19 Public Health Emergency (PHE).

Comment: During the PHE, CMS established HCPCS code C9803 (Hospital outpatient clinic visit specimen

[5] This section states "the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services".

collection for severe acute respiratory syndrome coronavirus 2, any specimen source), which is conditionally packaged. **We support the continuation of this code to maintain this payment stream**. The COVID-19 virus will not cease to exist once the PHE terminates, and specimen collection will be ongoing.

HOSPITAL QUALITY STAR RATINGS

Among the revisions, CMS is proposing to update and simplify how the ratings are calculated, reduce the total number of measure groups, and stratify the Readmission measure group based on the proportion of dual-eligible patients. Changes are intended to simplify the methodology and reduce provider burden, improve the predictability of the star ratings, and increase the comparability between hospital star ratings.

Comment: UPH supports accountability and transparency in quality programs, and we believe that the health care industry should emphasize value from all providers, regardless of practice setting. For HOPDs and ASCs, like other health care settings, quality should be tied to reimbursement. We are encouraged that CMS continues to refine this star rating system and believe that some of the proposed changes make program outcomes easier to understand, more predictable to forecast, and better aligned to similarly sized organizations. **We support**:

- Merger of three existing domains to the new **Timely and Effective Care domain**;
- **Voluntary participation by CAHs**;
- **Removal of the Latent Variable model** to the simplified average measure score plan; and
- Moving to a **star rating peer groups concept**.

When implementing the peer groups, we request a descriptor of this comparison group be part of the public reporting response—explaining that hospitals are being compared to other hospitals reporting the same volume of data.

Although we agree that a star rating or other comparison is beneficial, there are still outstanding questions with the rating methodology as proposed that leave UPH hesitant to fully support linking this rating system to reimbursement without further refinement and testing.

- Update to the Reporting Thresholds. This is the third leg of the combined methodology proposal. To be eligible for a star rating, a hospital must report at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group. Approximately 30 percent of specialty, 90 percent of teaching, 60 percent of safety-net, and 40 percent of CAHs are estimated to be unable to meet these reporting requirements. Given that reporting participation is estimated to be inconsistent among and within hospital types, we question its value as a comparison tool.

- Peer Grouping and Reliance on CAH Participation. We find peer groupings attractive when performing comparisons; however, all hospitals are not eligible to participate, which will skew peer groupings. For instance, many CAHs are unable to participate in relevant quality measures because of the low volume of their services. This makes it difficult at best for CAHs to voluntarily submit quality measures included in CMS hospital programs and publicly report their quality measure data on one of CMS' public websites. As noted by CMS, the "proposal to peer group

hospitals by the number of measure groups . . . is dependent on CAH participation in the Overall Star Rating since CAHs make up approximately half of the hospitals within the three measure peer group and excluding CAHs from the Overall Star Rating would not provide a sufficient amount of hospitals to make peer group comparisons." This appears to be a fatal flaw in the peer grouping methodology; however, we do not agree that CMS has set forth a runway in which mandatory participation by CAHs is envisioned or under which they can be successful included.

- Alignment of Star Rating Methodology Across Settings. CMS is offering a highly complex rating methodology. The fact that it took 12 tables in the narrative (Tables 64 – 75) just to describe various components and combinations of the proposal speaks volumes. With the level of complexity and detailed analysis, we are struck by the lack of discussion on how these efforts coordinate with star ratings for Part C and Part D plans, with star ratings in other care settings, such as nursing homes and home health, and to quality measures in the Quality Payment Program for Part B. We encourage CMS to reflect on population health objectives across sites of care and providers to align quality objectives and payment reimbursement and reform initiatives. Although well-intentioned, we believe CMS is missing a huge opportunity to streamline quality measurement and rating systems.

AMBULATORY PAYMENT CLASSIFICATION (APC) UPDATES

CMS is proposing to continue the update for ASC payment using the hospital market basket update instead of CPI-U. The proposed rate increase is 2.6 percent.

Comment: We support the proposed rate update.

ASC COVERED PROCEDURES LIST (CPL) CHANGES

CMS is proposing to add eleven procedures to the ASC CPL, including total hip arthroplasty (CPT 27130). Additionally, the proposal offers two alternatives for adding procedures to the ASC CPL: (1) Establish a nomination process beginning in CY 2021 and CMS would review nominated procedures and add to the ASC CPL through annual rulemaking; or (2) revise the criteria under 42 CFR 416.166 by keeping the general standards and eliminating five of the general exclusions. The second alternative would result in the addition of approximately 270 surgery or surgery-like codes to the CPL. Finally, CMS solicits comment on whether the conditions for coverage for ASCs should be revised if the second alternative is adopted.

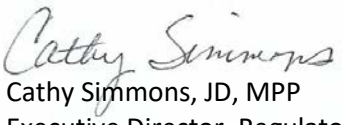
Comment: **UPH opposes the addition of total hip arthroplasty (THA) to the CPL list**. THA was only removed from the IPO list in 2019 and we do not believe there has been sufficient time or study to indicate that the HOPD setting change has been successful and then that it warrants further site of service shifts to an ASC. As stated above under our IPO commentary, we would suggest that CMS take a more measured approach and gather outcome data for THA through a pilot or trial to elect an ASC setting for providers participating in an Advanced Alternative Payment Model. Without study, we are concerned that any cost savings attributed to a lesser acuity facility will come at the risk of complications and adverse health outcomes as well as overbuilding specialized health care facilities with associated costs and diversion of the health care workforce.

To hasten the process of adding procedures to the CPL list, CMS is proposing two alternatives. **We fundamentally disagree that this ASC CPL list process should be hastened and support the current**

method for adding or removing procedures. As an integrated health care system, UPH ownership interests include hospitals, HOPDs, ASCs and physician offices. There are different licensing and regulatory requirements per health care setting for a reason. Payment policy should reflect licensure, staffing, quality and safety considerations and must be matched to patient acuity, co-morbidities and the potential for complications as well as the complexity of the procedure and the associated expertise and infrastructure needs. We are concerned that proposed alternatives will not encourage broad stakeholder input or demand careful study prior to implementation. At their core, these decisions involve patient safety and quality outcomes and should likewise consider "right-sizing" health care service delivery through appropriate health care investments and workforce allocations. There are consequences to increasing procedures in ASCs - revenue is diverted from the existing health care footprint and scarce health care professional workforce is diluted. We do not believe that CMS has made its case to abandon the current review process for either of the two alternatives proposed.

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

Sincerely,



Cathy Simmons, JD, MPP
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