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September 27, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1717–P
P.O. Box 8013
Baltimore, MD 21244–1850

RE: CMS–1717–P – Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals; published at Vol. 84, No. 154 Federal Register 39398-39644 on August 9, 2019.

Submitted electronically via www.regulations.gov

Dear Administrator 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 32,000 employees and our relationships with more than 310 physician clinics, 39 hospitals in metropolitan and rural communities and 19 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.

OPPS PAYMENTS AND AMBULATORY PAYMENT CLASSIFICATION (APC) UPDATES

CMS is proposing an increase of 2.7 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: 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 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.

PRICE TRANSPARENCY: HOSPITALS TO MAKE PUBLIC A LIST OF STANDARD CHARGES

CMS is proposing: (1) A definition of ''hospital''; (2) different reporting requirements that would apply to certain hospitals; (3) definitions for two types of ''standard charges'' and a request for public comment on other types of standard charges that hospitals should be required to make public; (4) a definition of hospital ''items and services''; (5) requirements for making public a machine-readable file that contains a hospital's gross charges and payer-specific negotiated charges for all items and services provided by the hospital; (6) requirements for making public payer-specific negotiated charges for select hospital-provided items and services that are ''shoppable''; (7) monitoring for hospital noncompliance; (8) actions that would address hospital noncompliance; and (9) appeals of civil monetary penalties. CMS estimates the total annual burden for hospitals to review and post their standard charges to be 12 hours per hospital.

Comment: When choosing healthcare providers, consumers consider a number of factors in their value equation, including location, experience, services, quality, outcomes and cost. **UPH is committed to meaningful price transparency for patients**. Our price transparency focus is 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. This is the information patients want and need. In terms of price, UPH provides personalized education and anticipated personal liability information. Our approach respects that each patient is different, that consumers information technology IQ is not equal in ability to navigate websites and understand large volumes of data, and that individual counseling adds value, especially for uninsured or underinsured consumers who can be connected with financial counselors. Our price transparency resources include:

- Websites – In accordance with the FY2019 IPPS final rule, our websites have available to the public both easily accessible complete chargemaster information and a listing of average charge by Inpatient Diagnosis Related Group (DRG). These lists are in a machine-readable format. To assist with consumer viewing, a PDF format is also available for the complete charge master and average DRG charge lists.
- Toll-free number – Available to the public, consumers may call and receive individual pricing/out-of-pocket information. This toll-free number is listed on all of our hospital websites.

- Online form – Available to the public, consumers may use this online form to request individual pricing/out-of-pocket information in addition to the toll-free phone number. Requested information is provided within 2 business days.
- Financial clearance department – This service is triggered for procedures scheduled in advance as well as for high-dollar imaging cases. This department proactively contacts patients in advance of their scheduled services to validate their demographic/insurance information, review their insurance benefit and provide their estimated patient liability. If the patient is uninsured or underinsured, this department can connect them with our patient financial coordinators to assist in identifying payer sources or in completing a Financial Assistance application.

As we enhance our price transparency tools, future opportunities will explore coupling price information with current quality and patient satisfaction information for specific services in a fashion and format that makes sense and is easy to understand.

We do not agree with the overly prescriptive approach to price transparency within the proposed rule. As an alternative, we encourage CMS to 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. We believe this proposed 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. This proposal raises legal concerns, anti-competition issues, policy questions as well as operational challenges and even impossibilities. In addition, CMS greatly underestimates implementation time and effort. Our detailed concerns are:

- Legality: We believe the proposed disclosure of payer-specific negotiated charges violates federal statutes. CMS lacks the legal authority to require hospitals to make public payer-specific negotiated charges. **Section 2718(e) of the Public Health Service Act (PHSA) does not provide CMS with authority to establish these requirements.** CMS's proposal is contrary to the plain language of the statute, as negotiated charges are not "standard charges." By definition, a "standard charge" is not privately negotiated and does not contemplate different charges for different payers. "Standard charges" has long been understood to be a technical term that means a hospital's usual or customary chargemaster charge.

  CMS's proposed definition also violates the Administrative Procedure Act (APA) because it is unreasonable. In general usage, "standard" means "usual, common or customary."[1] Payer-specific negotiated charges are not usual, common or customary. They vary year by year, payer by payer and even health plan by health plan. Indeed, CMS has defined "charges" to mean "the regular rates established by the provider for services rendered to both [Medicare] beneficiaries and to other paying patients. Charges should be . . . uniformly applied to all patients . . . ."[2] And CMS's rationale for seeking to require that payer-specific negotiated charges be made public undercuts the notion that those charges are standard: CMS wants payer-specific charges to be public precisely because those charges are not standard.[3]

[1] *See, e.g.,* https://www.dictionary.com/browse/standard.
[2] Provider Reimbursement Manual, No 15-1, ch. 22, § 2202.4. (Emphasis added.)
[3] *See, e.g.,* 84 Fed. Reg. 39,175, 39,577 (Aug. 9, 2019).

CMS's proposal also is much more extensive than necessary to serve the proffered interest. **CMS has failed to demonstrate that the proposed regulation is narrowly tailored or that its interests "cannot be protected adequately by more limited regulation of . . . commercial expression."**[4] Because our hospitals rely heavily on the confidentiality of health plan-negotiated charges to permit them to negotiate arm's-length charges with other health plans, disclosure of prices negotiated with individual health plans would unduly burden our hospitals' ability to enter into competitive contracts; it goes well beyond the level of regulation necessary to promote the stated government interest. The charges negotiated between hospitals and health plans are confidential trade secrets.[5] As such, requiring their public disclosure would infringe upon intellectual property rights recognized by Congress and individual states.[6] This public disclosure of trade secrets protected under both federal and state law would result in extreme harm to hospitals and health plans alike.

- Market Competition: We believe that disclosure of payer-specific negotiated charges would harm consumers and competition. Apart from its legal infirmities, **the proposed disclosure threatens competition and the movement toward value-based care**. The Federal Trade Commission (FTC) has warned numerous times against the disclosure of competitively sensitive information, such as payer-negotiated prices. Such disclosure can "facilitate collusion, raise prices and harm…patients…."[7] That warning extends explicitly to contract terms with health plans.[8] The FTC has urged that transparency be limited to "predicted out-of-pocket expenses, co-pays, and quality and performance comparisons of plans or providers."[9] In addition, at least one commercial health insurer warned that disclosure of payer-specific negotiated charges would "impair the movement to value-based care" and allow "[d]ominant health plans to seek and use that information to deter and punish hospitals that lower rates or enter into value-based arrangements with the dominant plan's competitors."[10]

- Policy Purpose: This proposal references a speech from Administrator Verma that stated transparency in health care pricing is "critical to enabling patients to become active consumers so that they can lead the drive towards value."[11] **We question whether this proposal most appropriately and directly accomplishes this objective of educating consumers**. First, we believe the underlying CMS assumption ("gross charges found in the chargemaster as well as negotiated charges are both informative and necessary for consumers to understand their potential out-of-pocket cost obligations"[12]) is flawed. Gross charges are not reflective of out-of-pocket costs and are more confusing than helpful to patients.

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[4] *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 570 (1980).
[5] *See West Penn Allegheny Health Sys., Inc. v. UPMC*, 2013 WL 121441532 (W.D. Pa. Sept. 16, 2013) ("[i]nformation regarding pricing and rates constitutes trade secret information").
[6] 18 U.S.C. § 1836.
[7] FTC Letter to the Hon. Nellie Pou, April 17, 2001.
[8] FTC Letter to Hons Joe Hoppe and Melissa Hortman, June 29, 2015.
[9] Id.
[10] UnitedHealth Group Comments on Re: RIN 0955-AAOI, 21st Century Cures Act, Proposed Rule, June 3, 2019.
[11] Bresnick J. Verma: Price Transparency Rule a ''First Step'' for Consumerism. January 11, 2019. Available at: https://healthpayerintelligence.com/news/verma-price-transparency-rule-a-first-step-forconsumerism.
[12] Page 39578, CY 2020 OPPS Proposed Rule

Second, we do not believe that healthcare providers are the best source of pricing information for many consumers. Out-of-pocket costs are most readily available from a consumer's insurer or health plan and may be obtained by contacting the health plan directly. As opposed to a healthcare provider, the third-party health plan will have access to the consumer's contract rates and specific benefits, such as deductibles, co-pays or co-insurances. The health plan also has the ability to give the consumer the full out-of-pocket costs that would include the hospital, physician and any other normal services for the episode of care as well as the ability to compare across all providers. Health plans currently provide cost/liability information in a pre-authorization process as well as in an explanation of benefits document.

- Operational Challenges: Aside from our overall objections, the scope of, and outstanding questions within, this proposal makes a January 1, 2020 go live date virtually impossible.
    - *Hospitals:* As proposed, any licensed hospital is included with the exception of federally-owned or -operated hospitals. **We request that CMS also exempt non-enrolled Medicare institutions and hospitals not reimbursed under a prospective payment system.** In particular, **we encourage critical access hospitals to be excluded** as their payment structure and service volume are not conducive to the proposed disclosure of shoppable services.

      CMS is also seeking comment on hospital exemptions for those going above and beyond these proposed requirements. Although there could potentially be merits to such an exemption, CMS has not provided sufficient details to enable appropriate comment. We are unclear what constitutes patient-friendly price transparency tools that calculate individualized out-of-pocket cost estimates. Other areas of uncertainty include whether CMS is suggesting a grandfather status, what benefits this would entail or how it would be implemented.
    - *Standard Charge for Items and Services*: While CMS has expanded the definitions of standard charges as well as items and services, these definitions do not correspond to the information readily accessible or even available to hospitals. As previously noted, standard charges include both gross charges and payer-specific negotiated charges. Services and items are single items and services as well as service packages and include facility fees (supplies, procedures, room and board, use of the facility and other items), professional fees (services of employed physicians and non-physician practitioners) and any other items or services for which a hospital has established a charge, such as drugs.

      For consumers to comparison shop, we agree that professional fees are a vital component and that ideally this information would be included in a comprehensive price comparison. **We disagree that hospitals are the appropriate source for complete professional fee information.** As proposed, CMS requires hospitals to report costs for employed physician and non-physician practitioners only. This requirement creates more pricing confusion than simply excluding professional fees. Provider employment arrangements vary by hospital and will prevent true price comparisons from being made, unless that pricing information is obtained from the health plan or each individual provider. In the case of UPH, our hospitals employ physicians, the health system has an ambulatory enterprise which employs physicians, and our hospitals have various arrangements, including value-based arrangements, either directly or indirectly (via our ACO) with independent physicians. In

addition, UPH has nine regions covering multiple states with differing employment relationships. While we believe this rule would cover providers directly employed by hospitals, we are uncertain how other relationships would be handled. Within our integrated health system, this varied provider relationship landscape leads to varied provider costs and difficulties comparing standard charges across our regions. For instance, UPH hospitals vary on whether we employ ED providers and consequently charges for ED services would greatly vary depending upon whether professional fees are included. We believe this difficulty will be more pronounced when consumers attempt to comparison shop using disparate hospital gross charges or payer-specific negotiated charges.

We are similarly concerned with the likely variation that will result in prices associated with service packages that fall outside a standardized definition with a single payment per claim (e.g. MS DRG). Service package is defined as the "aggregation of individual items and services into a single service with a single charge." For service packages with custom definitions or multiple payments per claim, this is problematic because hospitals often cannot get to that level of rate detail – gross charge rates are not set – and there simply is no price for some bundled drugs and supplies. When definitions are not standardized or consistently used across hospitals, price transparency will not aid consumers in comparison shopping.

Overall, standard charges are not the best information to determine consumer out-of-pocket costs. Hospitals have ready access to chargemasters containing gross charges. Therefore, **to reduce administrative burden related to price transparency, disclosed information from hospitals should rely on readily available per unit service pricing (e.g., CDM, HCPCS) or standardized service package pricing (e.g., MS DRG).** Should CMS desire to provide more meaningful price points, we would suggest that gross charge comparisons be replaced with average charges by encounter. CMS should work with stakeholders to develop standardized language to explain how this information could be used to further educate consumers in making healthcare decisions. Again, we do not support the disclosure of payer-specific negotiated charges; **however, if CMS finalizes such disclosure, we would recommend that this list be limited to standardized service packages, excluding professionals fees, and costs listed as an average across all payers, not payer-specific.**

- *Disclosing Standard Charges*: CMS is requiring machine-readable formats for gross charges and payer-specific negotiated charges to be displayed on each hospital's website. This format is being significantly revised. **We are concerned that these changes are not directly assisting consumers, but are being made at the behest of for-profit EHR and third-party data vendors to enhance price transparency tools**.[13]

  CMS is proposing that description codes be changed to user-friendly descriptions, which will take significant time and effort. For example, one of our hospitals has 6250 lines in its

[13] Page 39582, CY 2020 OPPS Proposed Rule – "data could be of most use to health care consumers indirectly; that is, such data could be used by the public in price transparency tools or integrated into EHRs for purposes of clinical decision-making and referrals."

chargemaster, each of which will need to be reviewed and edited accordingly. If CMS finalizes payer-specific negotiated charges for display, not only will this entail more than 700 health plans/contract combinations, but several of our larger payers do not use APC methodology (i.e. CPT codes). This includes the largest private payer in Iowa and all managed care organizations (MCOs) in both Illinois and Wisconsin, which translates to extra time and effort in producing crosswalks and inherent difficulties in producing equivalent service package comparisons.

We do not agree that the standardized data elements should include revenue code, as applicable. This code does not promote consumer understanding and differs depending upon site of service and underlying CPT code. In addition, some procedures have the same charge, but the revenue code differs. **We would recommend that CMS eliminate revenue code as a standardized data element.**

- *Consumer-Friendly Display of Payer-Specific Charges*: CMS is requiring the posting of 300 "shoppable services" furnished by hospitals. Shoppable services are defined as typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient. Along with negotiated charges for specific services, charges for associated ancillary services must be provided. CMS mandates disclosure of 70 shoppable services listed in Table 37 with the remaining 230 services to be selected by each hospital.

  UPH does not support the disclosure of payer-specific negotiated charges. As proposed, we are concerned that the shoppable list reflects line/procedural level items which do not match the claims-based payment system, that gross charges are not established for all shoppable list items, and that ancillary services are often highly variable. First we would suggest that CMS limit the number of shoppable services to 100 or less. As we have started the identification process, we struggled to list 300 shoppable services, even for our largest hospitals. As a result, we backfilled services with extra laboratory procedures to reach the 300 total. By reducing the number of reportable services, this would decrease administrative burden and also allow CMS to monitor this requirement and its impact on consumer decision making prior to ramping up efforts. Second, as with the disclosure of standard charges, there will be extra time and effort associated with inserting a plain-language description. We would request that CMS produce a guidance to suggest best practices in this area. Third, instead of payer-specific negotiated charges, we would suggest inserting the average gross charge. As stated previously, health plans are the best source for this information. Fourth, we believe listing all associated ancillary items and services is unnecessary and unduly burdensome and, in some instances, pricing is unavailable. Instead we would recommend displaying an average claim charge to include both the primary items as well as all ancillary items. Fifth, we do not support the display of any primary code used for accounting of billing. These codes are not meaningful to the consumer.

- Time and Effort: **CMS has significantly underestimated the proposal's administrative burden – 12 hours per hospital**. Our system has already exceeded these hours in just identifying applicable shoppable services. With a health system that includes 14 PPS hospitals, we are anticipating this will take at least 250 hours per hospital given the expansive definition of items and services and

the inclusion of all facilities. Most of this work would fall to our Revenue Integrity team, and we estimate it will take 7 FTEs approximately 9 weeks to manually collect and populate fields for our more than 700 payer contracts/plans. These are current FTEs, so workload will need to be reprioritized with other year-end tasks. The remainder of the hours will come from our Pharmacy team to determine and populate National Drug Code (NDC) information, our IT team in conjunction with our Marketing and Communications team to revise the website and lists/reports and Legal / Compliance team for general review and oversight.

Aside from our concerns above, this rule has a major timing flaw. Most payer negotiated rates will be outdated on the day they are required to be posted – January 1 – and cause further consumer confusion and frustration. Most larger commercial payers utilize Medicare APC information, which have annual updates that usually become effective on January 1, based on the Inpatient Prospective Payment System and OPPS final rules. As a result, there are numerous annual changes – new CPT codes, retired CPT codes, changes to what is separately payable, changes to what bundles or service packages contain and more. For instance, in this OPPS rule, CMS is proposing to remove THA from the IPO list. If we publish based on information prior to January 1, shoppable service lists would not include THA in the outpatient setting. **We would recommend that CMS delay until April 1 the posting or publication requirement for this year as well as future years**.

Given the challenges identified as well as the significant work effort required, we urge CMS to reconsider implementing this rule altogether or, at minimum, delay the unrealistic timeframe of January 1, 2020 for making these charges public.

PRICE TRANSPARENCY QUALITY MEASURES – *REQUEST FOR INFORMATION*

CMS is seeking stakeholder input on facilitating the development of price transparency tools and communication of health care services charges and improving incentives and assessing the ability of health care providers and suppliers to communicate and share charge information with patients.

Comment:

- What existing quality of health care information would be most beneficial to patients, and how can health care providers and suppliers best enable patients to use quality of health care information in conjunction with information on charges in their decision making before or at the time a service is sought?

  We believe that it is important to advance greater awareness and use of quality information paired with appropriate pricing information. Our focus should be on engaging consumers in their care. To do that we need to be transparent about what consumers can expect from their providers. The better picture we paint, the better consumers can predict an outcome. This is aided when we have standardized quality outcome measures and technology in place that enables easy access to the information. In addition, consumers need to be able to understand the data, and payers and providers both have a role to provide knowledgeable experts to provide context for the data. Among the important take-aways for consumers are (1) lower costs do not automatically equate to lower quality; (2) understand what the data / numbers mean (i.e. whether a high percentage is desirable or undesirable); and (3) other patient experience data, such as safety and patient satisfaction, may be available to complement price and quality information and can be factored into the healthcare decision-making process.

Quality information is available from a multitude of sources, including providers, payers, third-party quality organizations, and consumer advocacy groups. In some instances, quality information is included within hospital association pricing websites and provided by insurers when out-of-pocket estimates are requested. Medicare has several "Compare" tools to assist consumers with comparing quality by sites of service – hospitals, physicians, home health, nursing homes, dialysis facilities, long-term care hospitals (LTCH), inpatient rehabilitation facilities, and hospice. At UPH, our website links consumers to CMS measure results for Heart Failure; Heart Attack; Pneumonia; 30-Day Readmission and Mortality; Surgical Care; Healthcare Associated Infections; Preventive Care; Emergency Department Care; and Use of Medical Imaging. Results for these measures are consistently provided for each UPH hospital regardless of our achievement/scores, so that consumers have an easy method to compare UPH care to the care of other providers.

- How Medicare providers and suppliers engage in shared decision making for future care, including discussions of both charges and quality of referral services?

  We would encourage CMS to continue to pilot through Advanced APMS the use of steerage to high-value resources. While hospitals and discharge planners are currently prohibited from recommending particular PAC providers, we would encourage CMS to allow exceptions or flexibilities, such as enabling hospitals to engage in post-acute care steerage as under the Chronic Care for Joint Replacement ("CJR") model.

PRICE TRANSPARENCY: COST REPORTING, HOSPITAL CHARGEMASTERS AND RELATED MEDICARE PAYMENT ISSUES – *REQUEST FOR INFORMATION*

CMS is soliciting comments on:

- *Continued value of the chargemaster charges in setting hospital payment and to other stakeholders, as well as the costs associated with maintaining the chargemaster for purposes of Medicare cost reporting and payment;*
- *Whether it would be possible to modernize or streamline the Medicare cost reporting process, including replacing it or modifying its content, methodology or approach;*
- *Whether and how replacement or modification of the chargemaster might affect the submission of data used by CMS to calculate other payments, as well as alternative sources to calculate these payments; and*
- *Why the chargemaster might be updated more frequently than on an annual basis and how this could affect costs for patients.*

Comment: **There is continued value for hospitals to maintain chargemasters**. While chargemasters are not particularly useful for consumers to determine out-of-pocket expenses, they are important internal documents that ensure alignment between CPT coding and revenue coding. Hospital finance staff use the chargemaster to track productivity, utilization and costs. In addition, the chargemaster may be referenced in public and private payer contracts, so any substantive changes could impact contractual terms with multiple health plans.

We do not see the need to require update frequency more than once every 12 months. Since the chargemaster does not directly relate to out-of-pocket costs, more frequent updates should not increase costs to patients, unless frequency was significantly increased to require additional FTEs.

SITE NEUTRALITY: OPPS PAYMENT FOR HOSPITAL OUTPATIENT VISITS AND CRITICAL CARE SERVICES

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 an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate. In this rule, the proposed PFS-equivalent rate for CY 2020 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate) for CY 2020. The payment reduction targets 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 CY 2020 proposed rule completes the two-year phase-in of a method to reduce unnecessary utilization in outpatient services by addressing payments for clinic visits furnished in the off-campus setting. Specifically, Medicare payment rates for E/M services furnished in excepted off-campus hospital provider-based departments were targeted for further reductions. By continuing payment cuts for hospital outpatient clinic visits, CMS has not only undermined clear congressional intent, but has threatened to impede access to care, especially in rural and other vulnerable communities. 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 OPD services, which clearly was not Congress' intention*."[14] Given this ruling, CMS needs to reconsider its approach to site neutrality and abandon the methodology overturned by the District Court. By continuing this approach despite an adverse court ruling, not only is CMS perpetuating an unlawful exercise of authority, but CMS is financially penalizing hospital-based clinics who are providing services not otherwise available to vulnerable populations (low-income and underserved) and patients with heightened acuity or medical complexity and whose infrastructure costs by necessity reflect a more comprehensive licensing, accreditation and regulatory environment.

340B DRUG PRICING PROGRAM

For CY 2020, Department of Health and Human Services (HHS) is proposing to continue to pay an adjusted amount within the CY 2018 OPPS final rule, in which HHS 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%. HHS is seeking comment on the appropriate OPPS payment rate for 340B-acquired drugs both for CY 2020 and for purposes of determining a remedy for CYs 2018 and 2019 as well as the structure of such remedy for CYs 2018 and 2019. In the event of an adverse decision on appeal, HHS intends to propose a specific remedy for CYs 2018 and 2019 in the CY 2021 OPPS/ASC proposed rule.

Comment: We support the preservation of access to low-cost medications for vulnerable patients, and the 340B Drug Pricing Program enables UPH to provide such outreach and needed services in our communities. The nearly 30% reduction in reimbursement for certain 340B hospitals that a district court

[14] 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

judge ruled were unlawful impacted 12 of our nonprofit hospitals across Illinois, Iowa and Wisconsin. We appreciate the opportunity to offer potential remedies for the CY 2018 and CY 2019 payments and for use in CY 2020 payments in the event CMS receives an adverse ruling by the U.S. Court of Appeals.

Remedy: **Refund payments should be made to each affected 340B hospital and calculated using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018 and 2019 OPPS final rules; and others not adversely impacted by the reductions should be held harmless**. This remedy would not disrupt the Medicare program and is consistent with those for past violations of law.

- *Proper Remedy Is Straightforward and Easily Administered*. This remedy is easy to implement, will not be disruptive, does not require new rulemaking, and is comparable to those the courts, and HHS have adopted to correct other unlawful Medicare payment reductions. Specifically, HHS can recalculate the payments due to 340B hospitals based on the statutory rate of ASP plus 6% provided by the 2017 OPPS final rule. Hospitals that have already received partial payment should receive a supplemental payment that equals the difference between the amount they received and the amount they are entitled to, including ASP plus 6% plus interest. Claims that have not yet been paid should be paid in the full amount, including ASP plus 6%.

  While claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case. These calculations should be on a hospital-by-hospital basis. Once the total amount that each hospital was paid is calculated, that amount can be multiplied by a single factor — which will be uniform across hospitals — to determine how much should have been paid and thus how much the reimbursement was reduced. Each hospital can be compensated according to the amount that its reimbursements were reduced plus interest.
- *Ample Precedent for Full Retroactive Adjustments that Are Not Budget Neutral*. There is ample authority for HHS to remedy the underpayments caused by its unlawful rule, including: Cape Cod Hospital v. Sebelius, (D.C. Cir. 2011) (HHS corrected errors for the future and past claims for which hospitals had been underpaid), H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar, (D.D.C. 2018) (HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that received a statutorily mandated adjustment a year later than the law required), and Shands Jacksonville Medical Center v. Burwell, (D.D.C. 2015) (HHS compensated hospitals for three years of across-the-board cuts with a one-time, prospective increase of 0.6%).

  The remedy need not be budget neutral. The authority HHS cites is not applicable because such expenditures would be required by a court decision in service of fixing a prior unlawful underpayment. Moreover, HHS does not consistently apply budget neutrality to fix its missteps and in other relevant instances. For example, HHS allows for retroactive correction of the wage index without any budget-neutrality adjustment when it makes an error and it is not something a hospital could have known or corrected. In addition, budget neutrality does not apply to changes in enrollment or utilization for drugs when the ASP increases.
- *No Basis for Paying Hospitals Less than the Statutory ASP Plus 6%*. The OPPS mandates HHS reimburse hospitals for covered outpatient drugs at ASP plus 6%. This was the methodology used from 2013 to 2017. HHS has now requested comment on adjusting the payment for 2018, 2019 and 2020 from ASP plus 6% to ASP plus 3%. Although HHS has some authority to deviate from this

law, HHS is attempting to use a policy rationale that is inconsistent with the law itself and, therefore, it would be unlawful to reduce ASP to 3%.

- *New Patients Co-Pays Are Not Required*. Medicare reimburses hospitals 80% for covered outpatient services and the remaining 20% is collected from the patients or their insurance. Because HHS deviated from the lawful payment rate for 2018 and 2019 with a 30% reduction, in theory hospitals could collect from patients or their insurance companies the difference between 20% of the lawful payment rate and the 20% copay that was actually collected. HHS has requested comment on the "most appropriate treatment of Medicare beneficiary cost-sharing responsibilities."

  Although HHS has raised the specter that a remedy would require patient co-pays to be adjusted retroactively, we do not believe that there is any law that would require hospitals to collect payments altered by HHS's illegal act. Neither the False Claims nor anti-kickback statutes would apply since patients would not have been induced to seek services. Patients who reasonably believe that they have fully paid for hospital care provided months ago, or in some cases years ago, should not have to make these payments if hospitals are willing to forego them. We urge HHS to state this clearly in the final rule.

Transparency**:** UPH continues to be in support of initiatives to strengthen manufacturer and covered-entity transparency. We believe that this issue is appropriately being addressed on a voluntary basis. 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 savings[15] and encourage CMS to work with stakeholders should future regulations be considered.

INPATIENT ONLY (IPO) LIST AND ASC COVERED PROCEDURES LIST (CPL) CHANGES

In regard to the IPO, CMS is proposing to remove CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft) (Table 24). CMS is also seeking public comment on the removal of 2 arthrodesis procedures and 4 laminectomy procedures from the IPO (Table 23). CMS is proposing to establish a one-year moratorium from IPO removal for QIO referrals to RACs and RAC "patient status" reviews. For the CPL, CMS is proposing eight additions – a total knee arthroplasty procedure, a mosaicplasty procedure, as well as six coronary intervention procedures (Table 32). CMS is soliciting comments on whether certain other surgical procedures related to the cardiovascular system should be added to the CPL (Table 33).

Comment: In terms of the IPO list, **UPH supports the retention of partial hip arthroplasty (PHA) on the IPO list and opposes the removal of total hip arthroplasty (THA)**. Foremost, we do not believe THA meets the removal criteria. Specifically, CMS has not established that most hospital outpatient departments could perform this procedure, nor that it is substantially related to other codes already removed from the IPO list. Until CMS can reference an ample evidence basis from the Medicare population to support a change in setting, we would encourage this procedure to remain IPO. In addition, we would recommend that any pilot or trial to elect an outpatient procedure only be permitted 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

[15] 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

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.

We would 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, 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.

In terms of the ASC CPL, UPH opposes the addition of total knee arthroplasty (TKA) to the list. TKA was only removed from the IPO list in 2018 and we do not believe there has been sufficient time or study to indicate that the outpatient hospital department 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 TKA 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 healthcare facilities with associated costs and diversion of the healthcare workforce.

The proposed addition, and future consideration, of percutaneous coronary interventions (PCI) to the ASC CPL also raises concerns. Generally we urge caution in this arena as only low-risk PCI procedures could be acceptable in the ASC setting. With that in mind, Table 32 procedures (Stent, angioplasty) would likely be safe for the low-risk patients; however, this proposal brings issues of staff competency and experience, patient safety and health outcomes to the forefront. **We recommend that CMS delay the additions of coronary intervention procedures (PCI) to the ASC CPL until infrastructure builds and staff competency are further evaluated.** We do not believe that staff who participate in low-risk procedures (in an ASC setting) will have the expertise to deal with complications if they occur. Cath lab staff must be exposed to all types of coronary interventions (elective, urgent, emergent, high risk) to remain skilled and competent to be properly ready to deal with a complication from PCI that will eventually occur even with low-risk patients. Furthermore, CMS is seeking feedback on potential procedures listed in Table 33 for ASC CPL inclusion. **UPH is opposed to including Table 33 procedures**

in the ASC CPL. Table 33 references atherectomy procedures, interventions through preexisting coronary bypass(s) grafts and attempted interventions through a chronic total coronary occlusion. By definition, these procedures are considered high-risk and thus not appropriate in an ASC setting.

LEVEL OF SUPERVISION FOR OUTPATIENT THERAPY SERVICES

CMS is proposing to revise the level of supervision of outpatient therapy services from direct supervision to indirect supervision.

Comment: **We enthusiastically support this critical change in level of supervision,** which is needed and long overdue. Given workforce shortage designations in our service areas, we appreciate the flexibility provided by this proposed change as it will enable our providers to concentrate time and effort on patients over administrative requirements.

PRIOR AUTHORIZATION PROCESS AND REQUIREMENTS FOR CERTAIN HOPD SERVICES

CMS is proposing to implement a prior authorization requirement for Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty and Vein Ablation as a "method for controlling unnecessary increases in volume." The implementation date for this change is July 1, 2020.

Comment: **Generally, we oppose instituting this additional process with accompanying administrative burdens for both providers and CMS**. First, we do not believe that section 1833(1)(t)(2)(F) of the Act[16] 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 OPD services. Second, we believe it is inappropriate to characterize the majority of these procedures as "merely cosmetic." Through delay and additional administrative burden, the proposed process penalizes those procedures that do in fact have therapeutic indications. Third, we believe this 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, we would suggest that CMS use its enforcement authority rather than a broad stroke, upfront approach as proposed here. Fourth, we are concerned that CMS has limited the scope of this prior authorization to hospital outpatient departments and not to ASCs. We believe this oversight could have unintended consequences and have little impact on overall procedure volume. Should this be adopted in final rule, we would encourage CMS to correct this oversight.

CLINICAL LABORATORY FEE SCHEDULE (CLFS)

The Laboratory Date of Service (DOS) exception sets forth 5 criteria, which if all are met, unbundles the test from the hospital outpatient encounter and subjects it to directs billing to Medicare under the CLFS. If the exception is met, the date of service is defined as the date the test was performed, instead of the date of specimen collection. CMS is seeking stakeholder input on three potential revisions to this exception – (1) Require the ordering physician to determine and document whether the results of the advanced diagnostic laboratory test (ADLT) or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter; (2) Remove molecular pathology tests from this exception altogether, so that it applies only to ADLTs; and (3) Exclude blood banks and blood centers from this exception.

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

Comment: We appreciate that CMS is seeking stakeholder input. Of these potential revisions, **we are most supportive of and prefer item #2 – complete removal of molecular pathology tests altogether from this exception** – and encourage its adoption. In effect, only ADLTs would remain, which would greatly reduce the workflow impact anticipated from its application to molecular pathology tests. Although we believe item #1 would also be helpful, if molecular pathology tests are included, we would expect providers would find this difficult to operationalize and to fully comply with.

HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

For the Hospital OQR, CMS is proposing to remove the External Beam Radiotherapy (EBRT) for Bone Metastases (OP-33) measure and seeking comment on future measures under consideration ASC-1: Patient Fall, ASC-2: Patient Burn, ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant, and ASC-4: All-Cause Hospital Transfers/Admissions. For the OQR, CMS is proposing to adopt one claims-based measure beginning with the CY 2024 payment determination, ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357). To further develop a comprehensive set of quality measures for informed decision-making and quality improvement in HOPDs, CMS is seeking input on the addition of outcome measures or the elimination of process measures.

Comment: UPH has been a proponent of streaming quality programs and meaningful measurement. As such, **we support the removal of OP-33**. As for the four future measures under consideration from the ASC setting, we generally have concerns with placing "never events" within this program or any quality incentive program. As such, these measures theoretically should be "topped out" or the distinctions among providers will be based on a very small or rare (although serious) occurrence. These measures track fundamental safety issues and, while we agree that the events with these four measures should be monitored and timely addressed, we do not see a value add in including them within this program. This would seem at odds with Factor 1 for quality measure removal. Additionally, CMS has noted that data collection has been suspended in the ASCQR Program, which raise concerns about readiness; and we would note that measures tailored for ACSs would need to be revised to the HOPD environment. For these reasons, **we do not support these four future measures for inclusion in the Hospital OQR Program**.

AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM

For ASCQR, CMS is proposing to adopt ASC–19: Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) for the CY 2024 payment determination and subsequent years. CMS is also requesting comment about changing the data submission method for ASC–1: Patient Burn, ASC– 2: Patient Fall, ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and ASC–4: All-Cause Hospital Transfer/Admission to a CMS online data submission tool. The QualityNet website is the current CMS online data submission tool.

Comment: Although CMS is seeking information about the method of data submission for measures ASC-1, ASC-2, ASC-3 and ASC-4, **we would reiterate our overall concern with including "never events" within quality programs** such as the ASCQR Program.

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,

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