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Sept. 27, 2019

The Honorable Seema Verma
Administrator
Center for Medicare and Medicaid Services
7500 Security BLVD
Baltimore, MD

Submitted electronically

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

Dear Administrator Verma:

On behalf of the New Jersey Hospital Association (NJHA) and its over 400 hospital, health system, PACE and post-acute members, thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Calendar Year 2020 Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems proposed rule.

NJHA and its members support many of the aims included in the proposed rule. We strive to provide transparent and timely information on price and quality of services to patients so that they can make informed health care decisions. However, we have significant concerns that the steps suggested in the proposed rule do not accomplish the goals of providing consumers with the best information to make an informed decision.

REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF STANDARD CHARGES

We are deeply committed to ensuring patients have the information they need to make informed health care decisions, including timely, accurate estimates of their out-of-pocket costs. The agency's approach would confuse – not help – patients in understanding their potential out-of-pocket cost obligations, would severely disrupt contract negotiations between providers and health plans, and exceeds the Administration's legal authority. **We urge CMS to abandon this proposal**

and instead convene providers, health plans, patients and other stakeholders on approaches to meet patient needs.

In particular, 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.

The Proposed Disclosure of Payer-Specific Negotiated Charges is Unlawful

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." 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. And the agency'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.

CMS's proposal would violate the First Amendment as well, by compelling the public disclosure of individual charges privately negotiated between hospitals and health plans. Government regulation of non-misleading commercial speech is unlawful unless it "directly advances" a "substantial" governmental interest, and is no "more extensive than is necessary to serve that interest."

CMS's stated interest in putting consumers "at the center of their health care" is unlikely to be served by the mandated disclosures. The agency's own research makes clear that when it comes to price, patients are interested in their *own* out-of-pocket costs—not their health plan's costs. CMS' repeated admissions that the proposed disclosures are merely a "first step" or a "step towards" the rule's stated goals make clear that the proposed rule does not "directly" and "materially" serve the stated interest.

CMS's proposal also is much more extensive than necessary to serve the proffered interest. Because 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 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. As such, requiring their public disclosure would infringe upon intellectual property rights recognized by Congress and individual states.

Mandating the public disclosure of trade secrets protected under both federal and state law would result in extreme harm to hospitals and health plans alike. The agency 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."

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…." That warning extends explicitly to contract terms with health plans. 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."

CMS Vastly Underestimated the Proposal's Operational Challenges
In addition to our legal and public policy concerns, we have significant operational concerns with this proposal. This proposal, if finalized, would pose excessive burden on hospitals and health systems – far exceeding CMS's estimate of 12 hours.

In summary, CMS's proposed approach would not give patients the information they need to make informed health decisions, yet would introduce significant additional burden and resource requirements into the health care system. For all of this effort, we anticipate that patients will not use this information; instead they will continue to contact hospitals and health systems directly for more accurate out-of-pocket cost estimates.

340B DRUG PRICING PROGRAM REMEDIES

In the proposed rule, CMS issued a request for comment on potential remedies for the nearly 30% reduction in reimbursement for certain 340B hospitals that a district court judge ruled were unlawful. Specifically, the agency seeks potential remedies for the calendar year (CY) 2018 and 2019 payments and for use in CY 2020 payments in the event the agency receives an adverse ruling by the U.S. Court of Appeals.

We believe the remedy should be as follows: **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 hospital outpatient prospective payment system (OPPS) 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. Our detailed comments follow.

The Proper Remedy Is Straightforward and Easily Administered
There is a straightforward remedy that is easy to implement, will not be disruptive, does not require new rulemaking, and is comparable to those the courts and agency have adopted to correct other unlawful Medicare payment reductions. Specifically, the agency can recalculate the payments due

to 340B hospitals based on the statutory rate of average sales price (ASP) plus 6% provided by the 2017 OPPS 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 the 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.

There Is Ample Precedent for Full Retroactive Adjustments that Are Not Budget Neutral.
There is ample authority for the Department of Health and Human Services (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 the agency cites is not applicable because such expenditures would be required by a court decision in service of fixing a prior unlawful underpayment. Moreover, the agency 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 made the error and it was 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 average sales price increases.

There Is No Basis for Paying Hospitals Less than the Statutory ASP Plus 6 percent
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 the agency has some authority to deviate from this law, the agency 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 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 the agency 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 the agency'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, 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.

SITE-NEUTRAL PAYMENT POLICIES

CMS introduced the site-neutral payment policy in CY 2017 for nonexcepted off-campus HOPDs, those off-campus PBDs that were not billing under the OPPS prior to November 2, 2015. Payment to those off-campus PBDs that were billing prior to November 2, 2015 were grandfathered into OPPS. Under the policy, CMS pays the nonexcepted off-campus PBDs at 40 percent of the full OPPS rate. In last year's CY 2019 OPPS final rule, CMS finalized the expansion of that policy to off-campus PBDs specifically excepted from that reduction to address what it deems "an unnecessary shift of services from the physician office to the HOPD," and implemented the policy in a non-budget neutral manner. CMS claimed that growth in outpatient services is caused by the difference in payment between sites of care.

In the CY 2019 OPPS final rule, CMS finalized its proposal to pay a physician fee schedule-equivalent rate for an outpatient clinic visit, HCPCS code G0463. CMS finalized its change to this code, the most frequently billed service with the "PO" modifier, which is used to identify services in excepted off-campus PBDs, paying for G0463 at 40 percent of the full OPPS rate. In a deviation from the proposed rule, however, the Agency elected to phase in the payment reduction over two years – 50 percent in CY 2019 and the remaining 50 percent in CY 2020. We strongly opposed the reduction in payments. Reducing reimbursement for items and services received in excepted off-campus PBDs is detrimental to the important care provided by teaching hospitals to vulnerable Medicare beneficiaries.

A coalition of hospital associations and hospitals filed suit in January 2019 to challenge the new clinic visit payment policy. The parties alleged that hospitals with excepted off-campus PBDs faced imminent injury as a result of CMS's unlawful decision to reduce clinic visit payment rates and to do so in a non-budget neutral manner.

In the CY 2020 OPPS proposed rule, CMS refers readers to the CY 2019 OPPS final rule for "a detailed discussion of the background, legislative provisions, and the changes in payment policies we developed to address increases in the volume of covered OPD services." The agency then explains that, through the CY 2020 OPPS rule, it is completing the phase-in of the reduction in payment.

We continue to believe that the non-budget neutral payment cut for clinic visits furnished by excepted off-campus PBDs in 2019 is unlawful and is causing undue harm to hospitals. Among other things, Congress has established a clear structure for CMS to make annual changes to

payments for covered hospital outpatient services under Medicare. Changes to payments that target only specific items or services must be budget neutral. In addition, by subjecting excepted and nonexcepted PBDs to the exact same payment system and payment rate, the Agency has inappropriately abolished the statutory distinction between those two entities.

The court recently found that CMS exceeded its statutory authority when it cut the payment rate for clinic services at excepted off-campus provider-based clinics.

We therefore urge CMS to:

1. **Immediately restore the higher payment rates for clinic visits furnished by excepted off-campus PBDs that existed before CMS adopted the unlawful payment cuts;**
2. **Promptly repay hospitals the difference between the amounts they would have received under those higher rates and the amounts they were paid under the unlawful payment rates; and**
3. **Abandon its proposed second phase of the payment cut in 2020.**

AMBULATORY SURGICAL CENTER (ASC) LIST CHANGES

While Medicare's overall costs may be lower in the ASC for some procedures, beneficiaries are not protected from cost-sharing liabilities in the ASC as they are in the HOPD. Currently, a beneficiary's cost-sharing liability is limited to the Part A deductible for a service performed in the HOPD; there is no such protection in the ASC. For beneficiaries who choose to have a total knee arthroplasty (TKA) in an ASC, for example, their cost sharing would be higher than if that same procedure was performed in an HOPD. In HOPDs the OPPS beneficiary coinsurance for the TKA would be capped at $1,364 for a single procedure in 2019. In contrast, in ASCs, beneficiaries would be subject to 20 percent of the "Addendum AA" amount or $1,727.99 for that procedure, as well as additional coinsurance for separately paid ancillary services integral to the surgical procedure. As CMS seeks to add more procedures to the ASC list, CMS should carefully consider these issues so beneficiaries are protected from additional liability and the potential to be referred for procedures in an ASC when a hospital outpatient or inpatient stay could be more appropriate for their clinical circumstances.

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

CMS proposes to remove one measure from the Hospital OQR Program beginning in CY 2022 – OP-33: External Beam Radiotherapy for Bone Metastases. We recognize the importance of quality measurement to ensure that hospitals and physicians are providing high quality care. However, reporting and transmitting quality measures requires intensive staff training, labor, and resources – and ultimately limits the time clinicians spend with their patients. **We support removing this measure from reporting.**

We support the agency's Meaningful Measures framework and the proposals to remove measures across the hospital quality programs to align programs and better address quality priorities. We urge CMS to continually review measures and consider the removal of additional measures from its programs.

CMS is seeking feedback on the potential to take measures from Ambulatory Surgical Center (ASC) Quality Reporting Program (ASCQR) for future inclusion in the OQR. Specifically, CMS is considering the following measures: 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/Admissions. **We agree that patients should be able to compare the quality of care for the same services between ASCs and hospital outpatient departments (HOPDs)**. However, as CMS notes, these measures have been suspended from the ASCQR due to issues with data submission methods and the measures have not been specified for the HOPD setting. We support the agency's plan to work with the measure developer to improve the data submission methods and to ensure the measures are appropriately re-specified for the hospital setting.

PRIOR AUTHORIZATION REQUIREMENTS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

CMS has identified five general categories of services that it believes have experienced unexpectedly greater volume increases between CY 2007 and CY 2017. The categories include: blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. The services within the select categories have clinically valid, medically necessary, therapeutic uses for which Medicare and other payers provide reimbursement. In an effort to control what it describes as "unnecessary increases in the volume of OPD services", CMS proposes to introduce stringent prior authorization requirements for these identified service categories.

Prior authorization is a utilization management tool that payers often use to manage utilization of certain services. However, prior authorization often causes delays in patients' ability to receive timely, medically necessary care and imposes additional administrative burden on providers by requiring providers to manually navigate time-consuming requirements. The clinical and administrative impact resulting from prior authorization requirements prompted the American Medical Association (AMA) to create twelve guiding principles related to the appropriateness and execution of any prior authorization process, some of which are noted below as they relate to CMS's proposal.

We urge CMS to not finalize its proposal to introduce new prior authorization requirements for the five specified service categories. Before finalizing this proposal, CMS should undertake a more careful analysis to determine whether the increase in these services are truly "unnecessary." CMS also should evaluate the process and clinical workflow factors contributing to the burden associated with prior authorization to see how they can be reduced.

Increased Utilization for Specified Services Does Not Mean Services Were Not Medically Necessary

CMS justifies the use of prior authorization as a method to control increased utilization volume for these services, which it claims exceeds what would be expected based on the average rate-of-increase in Medicare beneficiaries. CMS also specifies that it is "unaware of other factors that might contribute to clinically valid increases in volume."

We believe that these increases in volume for select services are caused by factors that indicate they are for medically necessary care. For example, the increased use of botulinum toxin (BOTOX) injections accounts for the most significant increase in utilization of the service categories. However, the U.S. Food & Drug Administration (FDA) approved BOTOX for new clinical indications between CY 2007 and CY 2017, the period CMS used for its analysis. Notably, in 2010 the FDA approved BOTOX-A injections for the treatment of chronic migraine. According to the American Migraine Foundation, each Botox-A treatment for migraines involves 31 injections approximately every 12 weeks to dull symptoms. Providers submit claims for each injection site, which may account for a substantial increase in claims for medically necessary use of BOTOX during the period specified in CMS's analysis. Independent analysis of claims conducted by Watson Policy Analysis revealed that chronic migraine was the most common diagnosis code associated with the use of BOTOX between 2014 and 2017, suggesting that the steep increase was likely a result of increased clinically necessary treatments due to new FDA indications, with the lag reflecting clinical acceptance. Given that the approved indications for use expanded significantly during the time period in question, we suggest CMS reevaluate whether BOTOX truly experienced "unnecessary increases" in volume or whether these increases reflect medically necessary procedures.

Prior Authorization May Negatively Impact Beneficiary Well-Being and Would Place Undue Burden on Providers

In its proposal, CMS would require providers to submit a prior authorization request in order to receive "provisional affirmation" from CMS or the Medicare Administrative Contractor prior to performing a given procedure and submitting the claim for payment. The appropriate reviewer would grant provisional affirmation if the request "includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules." CMS specifies that a claim submitted without provisional affirmation would be denied.

CMS notes that requests for provisional affirmation would receive a decision within 10 business days, or, for expedited requests, two business days. Because a service cannot be provided until the claim receives provisional affirmation, Medicare beneficiaries that suffer from ailments treated by the services offered in these five categories could potentially experience significant delays in care, despite clinician judgement that such care is medically necessary.

We urge CMS to not finalize the prior authorization requirements for the specified categories of services. Finalizing the requirements could potentially delay medically necessary care for beneficiaries and would introduce added complexity and administrative burden for providers. Ultimately, providers strive to deliver quality health care in an efficient manner. However, the operational complexities required of providers in order to obtain prior authorizations hinder efficient care. CMS has not adequately demonstrated that the increase in these services are truly medically unnecessary.

ORGAN PROCUREMENT ORGANIZATIONS AND TRANSPLANT CENTER REGULATIONS

CMS has proposed revisions to the definition of "expected donation rate." These revisions would harmonize the CMS definition with the Scientific Registry of Transplant Recipients (SRTR) definition to expressly state the expected donation rate per 100 eligible deaths is the rate expected for an organ procurement organization (OPO) based on the national experience for OPOs serving similar eligible donor populations and donation service areas (DSAs) with adjustments to reflect demographic distributions.

Nationally, there are approximately 113,000 candidates awaiting a lifesaving organ transplant. Despite a record-breaking year of performing 36,529 transplants in 2018, the need to increase the number of organs recovered and utilized for transplantation remains critical. The recommendations to reform OPO metrics with dual accountability from transplant centers is meant to increase the donor pool, while simultaneously increasing the number of organs accepted and transplanted into patients awaiting a lifesaving organ transplant. This dual accountability for the yield metric supports the OPO's initiatives to expand the pool of donor organs with the understanding that the transplant center will expand their organ acceptance practices to increase yield and lower the organ discard rate.

The transplant community understands the importance of the lifesaving work performed by OPOs and we must continue to commit to collaborating with OPOs to increase organ yield. This encourages the transplant community to examine their organ acceptance practices and determine if there is an opportunity to utilize more organs. Even though the transplant community is committed to transplanting more organs, every transplant center is also mindful of their one-year patient and graft survival outcomes and the ongoing monitoring of these survival statistics by CMS and the Organ Procurement and Transplantation Network (OPTN). This oversight of outcomes can sometimes influence a center's decision to utilize more organs as there may be a real concern about potential noncompliance with patient and graft survival standards. Only time and assessment of the data will determine if the increase in organ yield will have a positive or negative impact on patient and graft survival outcomes on the transplant community.

The second intent of this proposal is to implement defined standardized metrics across all OPOs that will factor in rate adjustments for the distributions of age, sex, race and cause of death among eligible deaths. The revised donation metric will help the community at large understand OPO performance and the impact of geography and other characteristics on the donation rate. The newly defined donation metric for OPOs will be based on the national experience for OPOs serving similar eligible donor populations and DSAs.

We support the proposal's ultimate goal to increase the donation rate, maximize the recovery of organs and increase the number of patients transplanted off the national waitlist by utilizing more organs. This new proposal is mutually beneficial for OPOs and the transplant community.

We thank you for the opportunity to provide these comments on this proposed rule and look forward to working with you in the future to find solutions to benefit hospitals, providers and patients. Should you have any questions, please do not hesitate to contact Jonathan Chebra, Senior Director of Federal Affairs, at jchebra@njha.com or 609-275-4100.