September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS–1717–P, 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 Ms. Verma:

On behalf of our 26 acute care hospitals, the New Hampshire Hospital Association (NHHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2020.

NHHA is supportive of CMS’s efforts to standardize supervision requirements for outpatient therapeutic services in hospitals and Critical Access Hospitals (CAHs), but we have concerns with certain proposals that CMS has established within this rule. Specifically, NHHA strongly opposes the price transparency proposals and the 340B proposals. There are more proposals detailed below that negatively impact beneficiary access and dramatically increase regulatory burden which we cannot support as well.

**Price Transparency Provisions**

The Centers for Medicare & Medicaid Services (CMS) proposes to require that hospitals publicly post on the internet a machine-readable file containing both gross charges and “payer-specific negotiated charges” for all items and services. It also proposes to require hospitals to display, in an easy-to-understand format, negotiated charges and certain other information for 300 “shoppable” items and services.

Our member hospitals 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 key stakeholders (such as providers, health plans, and patients) to identify best practices, recommend standards for common features of cost-estimator tools, and develop solutions to common technical barriers.

We believe 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.”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 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.3

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.”4

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 it clear that when it comes to price, patients are interested in their own out-of-pocket costs—not their health plan’s costs. CMS’s 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.5

---

1 See, e.g., https://www.dictionary.com/browse/standard.
2 Provider Reimbursement Manual, No 15-1, ch. 22, § 2202.4. (Emphasis added.)
4 Central Hudson Gas & Electric Corp. v. Public Service Comm’n of New York, 447 U.S. 557, 566 (1980). The agency has failed to identify a sufficient predicate to justify the application of Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626 (1985) to the facts presented here. But the regulation fails under either test. Even under Zauderer, a disclosure requirement cannot be “unjustified or unduly burdensome.” Id. at 651.
5 See id. at 39,574, 39,585, 39611.
CMS’s proposal also is much more extensive than necessary to serve the stated 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.”

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.”

**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. We have heard from numerous members that this requirement is a virtual impossibility that couldn’t be accomplished in any timeframe to the degree that CMS requires. Hospitals in New Hampshire already go to great lengths to ensure consumers get meaningful price transparency information that will actually inform them of estimated out-of-pocket costs.

**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 this effort, we anticipate that patients will

---

11 Id.
not use this information; instead they will continue to contact hospitals and health systems directly for more accurate out-of-pocket cost estimates. NHHA strongly urges CMS to not finalize this proposal.

Payment for 340B Drugs

CMS seeks 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 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 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.

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 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.

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%.

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 this to be clearly stated in the final rule.**

**Proposed Reduction in Payment for Hospital Outpatient Clinic Visits in Excepted Off-Campus Provider-Based Departments (PBDs)**

CMS proposes to complete the phase-in of payment reductions for the hospital outpatient clinic visit in excepted off-campus provider-based departments (PBDs) to the “physician fee schedule equivalent” rate of 40% of the OPPS rate. CMS was recently found by the courts to have exceeded statutory authority when it cut the payment rate for clinic services at excepted off-campus PBDs.

CMS’s identification of the “unnecessary” shift of services from physician offices to PBDs completely ignores substantial factors outside of a hospital’s control. These factors result in increased OPPS expenditures and volume, such as the impact of other Medicare policies that increase the volume of services in PBDs (for example, the “two-midnight” policy) and the excessive increase of drug prices. Furthermore, CMS fails to recognize the fact that physicians refer beneficiaries to a hospital outpatient department (HOPD) for services they are incapable of providing in their offices. These services are essential to the community that could otherwise not be provided.

According to the American Hospital Association (AHA), the significant cuts in payment proposed in the clinic visit policy would be excessive and endanger the critical role that HOPDs play in their communities in providing convenient access to care for the most vulnerable beneficiaries, including the most medically complex patients.
Specific policies that promote the utilization of outpatient services are a significant factor in increasing OPPS volume. Such policies include:

- Hospital Readmissions Reduction Program
- Two-Midnight Policy
- Packaging of Clinical Laboratory Services into the OPPS
- Changes to the Inpatient Only List

NHHA urges CMS to:

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

Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

This proposal is contrary to law and the agency stating the increase is “unnecessary” is arbitrary. As the federal court recently said when addressing CMS’s clinic visit policy, “Congress did not intend CMS to use an untethered ‘method’ to directly alter expenditures independent of other processes. To the contrary, Congress directed that any ‘methods’ developed under paragraph (t)(2)(F) be implemented through other provisions of the statute.” That conclusion applies to the proposed prior authorization requirement because the proposal is contrary to the OPPS statute. CMS has not established that the increase in volume for these services is “unnecessary.”

There are medically necessary indications for each of the procedures that would be subject to the prior authorization process in this proposal. Two such examples are with blepharoplasty and botulinum toxin injections. Blepharoplasty corrects disfigurements/deformities of the eyelids. Sometimes when people age, the eyelid droops and can obscure a person’s vision enough to impact quality of life. Botulinum toxin injections are approved by the Food and Drug Administration (FDA) to treat chronic migraines and adults with upper limb spasticity. We strongly agree with the details AHA has provided on the medically necessary use of all these procedures.

CMS should consider other existing processes to verify medical necessity due to the fact that burden associated with prior authorizations are drastically increasing for hospitals. Imposing a burdensome and costly prior authorization process in the OPPS would be premature and unnecessary. Medicare could use Local or National Coverage Determinations or the Target, Probe, and Educate program to ensure only medically necessary services are paid for under Medicare. These should be used first and foremost to reduce the need for prior authorizations.

NHHA is opposed to the CMS proposal to implement a prior authorization process for five categories of outpatient department services and we urge the agency to withdraw this proposal.
Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs

NHHA strongly supports CMS’s proposal to reduce the minimum required level of supervision from direct supervision for hospital outpatient therapeutic services provided by all hospitals and CAHs to general supervision. The proposal creates standardization in supervision, and we applaud this effort.

Area Wage Index

CMS has proposed to adopt the IPPS final rule wage index as the wage index for the OPPS. In the IPPS, CMS increases the wage index value for hospitals below the 25th percentile by half the difference between the between the otherwise applicable wage index value for the hospital and the 25th percentile wage index value for all hospitals. CMS does this in a budget neutral manner and would do so in the OPPS by adjusting the conversion factor.

NHHA appreciates the need to address area wage index disparities, but any changes to the wage index should not be budget neutral. Improving the wage index for some hospitals while cutting payments to other hospitals is very troubling. Medicare already pays less than the cost of care and CMS has the ability to provide relief to low-wage areas without penalizing higher-wage areas.

Request for Information (RFI) on Quality Transparency Relating to Price Transparency

CMS included an RFI seeking feedback on how quality performance information could be combined with price transparency information. NHHA agrees with the AHA’s concerns that all quality-related initiatives need to be done within the agency’s quality strategy. If CMS created quality measures that were too focused on their price transparency agenda it could actually hurt the progress that has been made under their “Meaningful Measures” initiative.

Thank you for the opportunity to provide input on this proposed rule. In addition to above, NHHA fully supports the detailed comments submitted by the AHA regarding the OPPS proposed rule for CY 2020. If you have any questions, please feel free to contact me or Nick Carano, Director, Financial Policy and Reimbursement at (603) 415-4253 or ncarano@nhha.org.

Sincerely,

Steve Ahnen
President