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Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Baltimore, MD 21244-1850

September 27, 2019

*RE: 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 (the Proposed Rule.)*

Dear Administrator Verma:

Thank you for the opportunity to submit comments in response to the *Outpatient Prospective Payment System Rule (CMS-1717-P)* (the Proposed Rule.) We applaud CMS's efforts in the Promoting Interoperability Program to focus on patients' need for critical data, including clinical information and real price and payment information and encourage CMS to continue implement policies to ensure that patients have the information they need to make important decisions about their health care.

In support of this vision, we encourage CMS to do the following:

- Use all available authorities to require patient access to Real Price Information<sup>1</sup> in advance of receiving care.
- Finalize its proposal to include payer-specific negotiated charges, defined as "the charge that the hospital has negotiated with a third party payer for an item or service,"<sup>2</sup>

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<sup>1</sup> **Real Price Information** is the amount paid to providers for healthcare by the patient as well as any other payers, either by an agreed upon cash price by the patient or contract negotiated rates paid by patients as well as any other payers. It includes discounts and other itemized financial incentives and payments transacted by middlemen or other actors in the healthcare supply chain. Real Price Information shall be real-time, dynamically updated, and in machine-readable format, to reflect the true, real price. When it pertains to a specific patient, it shall include the total and the net negotiated amounts paid including itemized payments paid to providers, regardless of the combination of payers, and the patient's complete out-of-pocket cost information, based on the benefit plan (including deductibles and co-payments).

<sup>2</sup> Please note that some components of our definition of Real Price Information may not be included, such as "discounts and other itemized financial incentives and payments transacted by middlemen or other actors in the healthcare supply chain." It also would not necessarily include "itemized payments paid to providers, regardless of the combination of payers, and the patient's complete out-of-pocket cost information." However, making the payer-specific negotiated charge available would make it much easier for a third-party application to calculate out-of-pocket cost.

specifically publication of payer-specific negotiated charges across all plans (i.e., patients and employers should be able to see all negotiated rates across all plans).

- Require hospitals to provide easily searchable access to Real Price Information in real-time, through an open API in machine-readable format. This information should be automatically available to the public, not to a specific patient only by his or her request. An open API requirement is consistent with the ONC and CMS proposed rules on interoperability and patient access, and is a better, clearer approach than creating a new and potentially problematic or vague requirement.
- Require hospitals to provide price information in paper form if the patient specifically requests this format. There should be a paper copy of the most common and shoppable services and/or the services the patient is most likely to receive, for all payers (including contracted plans, non-contracted plans, and self-payers), made available immediately, not within 72 hours as proposed.
- Include all services provided by any practitioner who is practicing within the walls of a hospital in the final rule. The Proposed Rule only applies to services furnished by practitioners who are employed by the hospital. This approach leaves out services by practitioners who are independent contractors or otherwise providing services in the hospital but are not employees, such as emergency physicians or anesthesiologists and other specialties that are often outsourced by hospitals. Including prices for all physicians and services within a hospital will eliminate surprise billing and price gouging. Negotiated price disclosure for contracted services by hospitals should also include the network status with the contracted payer of each provider involved in delivering care for that service.
- Require disclosure of cash price. To both insured and uninsured individuals, cash prices are equally as important as the negotiated rates across plans and prices directly contracted with employers.
  - Many consumers have Health Savings Accounts (HSAs), Health Reimbursement Arrangements (HRAs), high deductible health plans, and high co-pays, and the cash price may be better than the negotiated rate.
  - Patients should have negotiating leverage should they be price gouged, surprise billed, or balance billed or billed facility fees without prior knowledge to engagement with the hospital.
  - Cash prices can often be as low as 40% of the negotiated rate, according to actual, nationwide claims data.<sup>3</sup>
  - Employers and consumers may shop and choose to pay cash— especially those incentivized by innovative, self-insured employers who steer their employees to the best quality providers offering low cost alternatives. Today, those employers are saving 30-50% by contracting with price transparent primary care doctors,

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<sup>3</sup> <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/>

telemedicine, and surgical centers, as well as direct contracting with hospitals. Examples of these employers are listed in Exhibit B.

- Focus on disclosure of payer-specific negotiated charges. We support publication of the Medicare prices, but only as **references** in addition to the standard charges CMS has proposed. Median or average prices are not real prices and are not useful to patients or employers.
  - For example, claims data in Boston showed the negotiated price of a normal, uncomplicated childbirth to be \$42,000 at one hospital and \$7,000 at another nearby, for the same plan.
  - Use of an average price would actually increase prices, since the outlying, egregious price would distort the average and normalize the price-gouging hospitals and providers.
  - Ultimately, the most useful price to patients is the actual, negotiated price, compared to the lowest price, not an average.
- Adopt a strong enforcement approach that ensures that stakeholders pay attention to and comply with these rules; they are critical for patients to make informed health care decisions. Specifically, we recommend that CMS:
  - Require entities to attest that they have met the requirements for price transparency, in order to implicate the False Claims Act and associated civil monetary penalties.
  - Increase the potential penalties for non compliance. Hospitals that do not want to make this data available would not see a maximum annual fine of \$109,500 (\$300 per day) as a deterrent to non-compliance, and CMS would ultimately spend more money to enforce than it would collect.
  - Hold providers who do not provide Real Price Information accountable for Information Blocking at a penalty of \$1 million per instance. As Health Information includes past, present, and future payment information,<sup>4</sup> withholding real prices from patients should be considered Information Blocking. Hospitals and providers should be accountable for the same penalties as technology and EHR vendors for Information Blocking practices.
- Ensure patients have access to their real-time, comprehensive Electronic Health Information (EHI). Comprehensive EHI should be consistent with the broad HIPAA definition of “health information” which is defined to include information about their

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<sup>4</sup> “Health Information” means “any information, including genetic information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the **past, present, or future payment for the provision of health care to an individual.**” 45 CFR § 160.103 (emphasis added).

past, present, or future physical or mental health, the provision of care, and past present and future payment information and would include Real Price Information.

- Ensure that comprehensive Electronic Health Information, inclusive of Real Price Information be available in real-time, immediately upon its availability to the provider, rather than every few days or even one business day. There is no reason why providers should delay a patient’s access to their own information. Real Price Information should be readily accessible to patients online in advance of seeking services, so they can shop for the best quality care at the lowest possible price.
- Ensure patients have persistent, real-time access to comprehensive Electronic Health Information, in easily searchable, machine-readable format, via open APIs as a condition of receiving CMS funds for any purpose, unless prohibited by law.

## Detailed Comments

### I. Authority

CMS cites Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) as its primary authority for issuing this price transparency proposed rule. Section 2718 of the PHSA, “Bringing Down the Cost of Health Care Coverage,” requires each hospital operating within the United States for each year to establish and make public a list of the hospital’s standard charges for items and services provided by the hospital. This rulemaking is intended to “further implement section 2718(e) of the PHS Act.”

**We believe that CMS’s authority is valid under the cited statutes; however, CMS should also rely on its authority under the Medicare and Medicaid programs to enact its proposals.**

#### *a. Conditions of Participation (CoPs)*

**CMS has the legal authority to, and should require, health care providers to disclose Real Price Information to consumers through Conditions of Participation (CoPs) in order to further the health and safety of patients.** CMS has broad authority to implement CoPs for quality and safety of beneficiaries. The Social Security Act lists the requirements that a hospital must meet to be eligible for Medicare participation, and specifies that a hospital must also meet such other requirements as HHS finds necessary in the interest of the health and safety of the hospital’s patients. Under this authority, HHS has established regulations at 42 CFR Part 482 that describe detailed requirements that a hospital must meet to participate in the Medicare program.

**CMS already uses CoPs to require patient access to information; CMS should modernize this requirement to include Real Price Information.** CMS published the first patients’ rights CoP in 1999 as an interim final rule with comment.<sup>5</sup> In 2006, CMS finalized rules for CoPs focused on protecting and promoting patients’ rights. One of those CoPs is already focused on disclosure of information to the patient:

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<sup>5</sup> 64 FR 36070.

“The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.”<sup>6</sup>

In proposing this CoP, CMS explained that patient access to information is necessary to support patient care: “...we firmly believe that a patient cannot take an active, meaningful role in his or her health care decisions if he or she is not allowed to know what is happening to his or her own body or mind... The patient’s right to be informed of his treatment, his health status, and his prognosis is just that—his inherent right, to be exercised by the individual... We believe that this right is best supported by giving the patient access to his or her own record in all but the most extreme cases.”

Access to Real Price Information is equally important to enable a patient to take an “active, meaningful role in his or her health care decisions” and therefore, goes to the quality of the care. Knowing costs in advance of care can also improve the quality of care by ensuring that the patient considers options for treatment based on whether they can engage in the follow up required to lead to outcomes. For example, if a patient can’t afford medication, he or she may split pills or take less than is recommended to spread out the cost. Ensuring that the patient knows the price upfront allows the patient and the doctor to discuss the most effective treatment that will be sustainable to the patient.

Given this precedent from over a decade ago, CMS clearly has the authority to modernize this requirement to require providers and plans participating in the Medicare and Medicaid programs to electronically disclose “health information” as defined under HIPAA, including Real Price Information, in a timely, easily accessible, machine readable format.

*b. Medicare Advantage Regulations*

**CMS has the authority to and should modify existing requirements on Medicare Advantage (MA) organizations to electronically disclose certain information to the patient.** The Social Security Act gives CMS the authority to publish regulations on disclosure of information to Medicare Advantage plan enrollees.<sup>7</sup> Under existing regulations, MA organizations must disclose certain information to each enrollee in the plan, at certain time periods, such as the time of enrollment.<sup>8</sup> This information currently includes benefits offered under a plan, applicable conditions and limitations, premiums and cost-sharing (e.g. copayments, deductibles, and co-insurance) and any other conditions associated with receipt or use of benefits. CMS should modernize these requirements to reflect real-time, machine-readable, electronic access to Real Price Information that health plans have through an open API.

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<sup>6</sup> 42 CFR 482.13 (d)(2).

<sup>7</sup> 42 U.S.C. 1395w-22.

<sup>8</sup> 42 CFR § 422.111.

## II. Proposed Definitions

### *a. Hospitals, Items and Services*

We recommend that CMS adopt the proposed definitions for “Hospitals” and “Items and Services.” These definitions would require the intended providers to provide price information for all of the items and services that are rendered to patients.

However, we suggest that CMS revisit its approach regarding practitioners that are not employed by the hospitals. CMS should include services furnished by physicians and non-physician practitioners who are employed by the hospital. Although these practitioners may be practicing independently, establishing their own charges for services, and receiving the payment for their services, the hospitals are granting them access to its facilities. **CMS should ensure that the practices that have allowed providers to surprise patients with bills from out-of-network providers are not permitted. Patients must have confidence that the price information posted by hospitals includes all potential items and services, as well as network status, from all potential providers at that facility.**

### *b. Standard and Gross Charges; Other Charges*

**CMS should finalize its proposal to include “payer-specific negotiated charges” in their standard and gross charges files.** Finalizing this proposal will provide patients with the transparency and critical information they need to make informed decisions about their health care. Furthermore, employers will be able to assess the value that their employees are receiving from their health benefit plans and will be better situated to assess their employee health care costs and the effectiveness of the payers with which they contract.

CMS also notes a number of other types of charges that hospitals could potentially provide. We strongly urge CMS to focus on disclosure of payer-specific negotiated charges rather than these other charges. We do believe that additional price data elements, such as Medicare allowable amount could potentially provide value to patients, **only if they are in addition to the standard charges CMS has proposed.**

Average rates are not useful for patients, as they reflect outliers, and can be gamed and have a distortive effect on the healthy market convergence around a competitive price in the face of fully disclosed real price information, similar to the vast range of prices for a Boston childbirth as mentioned earlier. Patients deserve to know their actual bottom line, not be forced to interpret an estimate or average.

We support CMS’s proposal that patients get access to discounted cash prices and any processes for qualifying for those prices. Ultimately, the price patients need and want is the real price they will pay and how it compares to the lowest price. Averages or medians allow entities that have exorbitant prices to obscure the extent of their price inflation behind the distortive reference, rescuing them from having to compete honestly and explain their prices to patients.

## III. Public Disclosure Requirements

We support CMS’s proposed requirements for hospitals to make public their standard charges in two ways: (1) a comprehensive machine-readable file that makes public all standard charge

information for all hospital items and services and (2) a consumer-friendly display of common “shoppable” services derived from the machine-readable file. Further, we believe that CMS’s proposed location, accessibility, and technical requirements would allow patients to easily access price information.

**However, we suggest that CMS require hospitals to keep this information updated in real-time.** CMS’s proposal only requires the information be updated once annually; this requirement can mislead patients and result in unintended and unforeseen costs for the patient. It could also lead to calendar-related gaming by hospitals to avoid disclosure of rate hikes or true prices. For instance, under the CMS proposal, a hospital could lower prices on December 31<sup>st</sup>, post the new lower price on January 1<sup>st</sup>, and then raise them again on January 2<sup>nd</sup>. In this way, the true price being charged by the hospital during a two year period is obscured by a misleading annual report on a single day at the beginning of the year.

CMS seeks comment on technologies or standards that could facilitate public access to real-time updates to make this information readily available to consumers via applications. Specifically, CMS asks for comments on adopting a requirement that standard charges be made available through an open API. **We encourage CMS to make the standard charge data available via an open API, as it has done in the other proposed rules. CMS should not adopt a new, and potentially inconsistent, definition of “machine-readable.”**

#### IV. Monitoring, Enforcement, and Addressing Noncompliance

**We recommend a strong enforcement approach to hospitals that fail to comply with these new requirements.** While we believe that CMS’s proposal to rely mainly on complaints made to CMS by individuals or entities regarding a hospital’s noncompliance, as well as direct audits of hospital’s websites is an appropriate process to identify hospitals that are noncompliant with the rule, we encourage CMS to develop robust auditing procedures rather than relying solely on patients to know how to and take steps to report violations. CMS initiated activity is necessary to ensure that patients have access to the critical data they need to make informed health care decisions. Alternatively, or in addition, we encourage CMS to post prominently on key web sites, such as Medicare.gov and Healthcare.gov, methods for patients to report when they are billed at rates that are inconsistent with publicly posted prices for their payer, including a hotline or email address. This strategy could feed into and supplement CMS enforcement efforts, as well as deter noncompliance by hospitals.

Furthermore, we suggest that CMS include requirements in the Final Rule that would require hospitals to attest that they have are in compliance with the rule. Hospitals would be at risk of implicating the False Claims Act and associated civil monetary penalties. In addition, we propose that CMS increase the potential penalties for noncompliance. The proposed maximum cost of \$109,500, or \$300 per day, would be an insufficient deterrent for hospitals to comply with the rule – CMS would have to spend more money to enforce the rule than what they would collect. We recommend that penalties be consistent with information blocking penalties, which can be up to \$1 million per violation, given that failure to disclose price information would be a violation of information blocking. Electronic health information should be consistent with the broad HIPAA definition of “health information” which is defined to include information about

their past, present, or future physical or mental health, the provision of care, and past present and future payment information and would include Real Price Information.

#### V. Additional Comments – Quality Transparency

Finally, while we applaud the price transparency in the CMS proposal, we urge you to take an equally robust approach to quality transparency, pursuant to Section 4 of President Trump’s June 24, 2019 Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First.

Transparency measures should be meaningful, focused on health outcomes and not merely clinical inputs or process metrics, prioritize clinician-anonymously reported culture of safety, volume thresholds, appropriateness, and especially patient-reported outcomes. These measures should be developed in coordination with patients, physicians with knowledge of relevant specialties, and nursing and other clinical care providers relevant to the care being measured. Results for each provider and facility should be standardized and publicly available in real time or regular time periods using open APIs.

Metrics should be reported for individual physicians by name, as well as departments and facilities. Value to the patient is a subjective combination of price and quality and patients can only evaluate the value of healthcare if they have access to transparent price and quality information.

#### VI. Conclusion

We appreciate the opportunity to submit comments on the Proposed Rule and thank CMS for its commitment to requiring hospitals to provide the critical clinical and price data that patients need to make informed health decisions. We believe that the inclusion of comprehensive Electronic Health Information inclusive of Real Price Information in requirements for hospitals will lead to reduced costs and improved patient outcomes. **It is critical that patients be able to easily access their real-time and readily searchable comprehensive Electronic Health Information as soon as the data is available in the electronic health record or billing record.**

Sincerely,



Cynthia A. Fisher  
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Founder, Former CEO, ViaCord, Inc.