CMS Issues New Final Rule on Pricing Transparency

November 2019

On November 15, CMS issued the Price Transparency Requirements for Hospitals to Make Standards Charges Public Final Rule ("Final Rule"), as directed by President Donald Trump's Executive Order on Improving Price and Quality Transparency in American Healthcare and as originally authorized by Section 2718(e) of the Public Health Service Act ("PHS Act"). The Final Rule is effective January 1, 2021.

CMS indicated that greater health care pricing transparency is not only something that consumers want, but cited numerous studies showing a direct connection between transparency in hospital standard charge information leading to more affordable health care and lower health care coverage costs. Hospitals have historically disagreed and, notably, three days after the release of the Final Rule, a number of hospital associations issued a statement indicating that they will collaborate in filing a lawsuit charging that the Final Rule exceeds the federal government's authority to regulate the industry.

The Final Rule focused primarily on new requirements for hospitals to disclose how much hospital services cost, including negotiated rates with payers and minimum and maximum negotiated charges that apply to inpatient and outpatient services. CMS also outlined its expectations for how to make these price transparency websites for certain services "shoppable," such as making them digitally searchable and requiring plain language descriptions of services. Finally, CMS promulgated standards for monitoring and enforcement of the price transparency rules, which can rise to the level of civil monetary penalties.

Definition of Hospital/Scope of Applicability

The Final Rule applies to all "hospitals" operating within the United States and defers to State and local laws to define which institutions qualify as "hospitals." As such, the definition includes (i) any institutions licensed as a "hospital" by a State or local agency, plus (ii) any institutions that are approved by a State or local agency as meeting the standards for licensing as a "hospital" under State or local law, irrespective of the institution's ability to be categorized as a "hospital" under Medicare or actual Medicare-enrollment.

CMS did not provide an exhaustive list of qualifying institutions, but clarifies that critical access hospitals (CAHs), inpatient psychiatric facilities (IPFs), sole community hospitals (SCHs), inpatient rehabilitation facilities (IRFs), and any other institutions meeting state or local licensing standards for hospitals are "hospitals" subject to this Final Rule. To the extent any hospital has other locations operating under the same license or hospital approval (e.g., an off-campus hospital outpatient department), such locations are subject to the Final Rule and, if they operate under a separate chargemaster, the hospital must separately publish the charges for each location.

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However, federally owned or operated hospitals that do not treat the public (outside of emergencies) and have non-negotiable rates are excluded from the Final Rule. Further, physician offices, ambulatory surgical centers (ASCs), and non-hospital sites-of-care from which consumers may seek health care items and services are also excluded. However, any hospital locations that have different sets of charges than other location(s) operating under the same license/approval are subject to and must independently comply with the Final Rule Geographically, the definition of "hospital" is broad as well. All institutions qualifying as "hospitals" in any of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands must comply with the Final Rule.

Definition of "Items & Services" Provided by Hospitals

Section 2718(e) of the PHS Act requires hospitals to make public a list of standard charges for "items and services" provided by the hospital, including for DRGs established by Section 1886(d)(4) of the SSA. CMS interprets "items and services" provided by the hospital to include all items and services that could be provided by a hospital to a patient in connection with an inpatient admission or outpatient department visit, including (a) all individual items and services, and (b) all "service packages" for which the hospital has established a standard charge.

First, CMS defines "individual items and services" for which standard charges must be reported to include: (i) each item or service appearing on the hospital's chargemaster (e.g. charges for supplies, procedures, room and board, and facility fees (charges for use of facilities and other items)); and (ii) services performed by hospital-employed physician and non-physician practitioners (but not services by independent practitioners, such as contracted anesthesiologists who separately bill for their services). Notably, CMS did not confirm whether employees of hospital-associated entities would be captured nor did it otherwise codify a definition of "employment" to clarify which employment models or contracting relationships trigger a duty to disclose professional service fees.

Second, CMS defines the "service packages" for which standard charges must be reported as "any aggregation of individual items and services [provided by a hospital] into a single service with a single charge." This includes all DRGs established under section 1886(d)(4) of the Social Security Act plus all other service packages for which a hospital has set a standard charge—such as the rates negotiated with third party payers for certain bundles of services (e.g. outpatient service packages, episodic care rates, ancillary services attributed to a primary service, service packages grouped by CPT codes, HCPC codes, or APC codes, etc.) CMS recognized that the payer-specific charges that hospitals have negotiated with payers for such service packages would not appear on the hospital's chargemaster but noted such rates could be pulled from rate tables and rate sheets included in the hospital's payer contracts for (allegedly) easy reporting to comply with the Final Rule.

Definition of "Standard Charges"

While several states have already imposed price transparency requirements, such as all payer claims databases or requiring providers to post certain charges online, the definition of "standard charges" in this Final Rule imposes far more exacting and all-encompassing transparency demands than most state transparency laws.

In crafting the definition of "standard charge," CMS attempted to capture all of the different rates that hospitals may charge to patients, regardless of their insurance status. To accomplish this, CMS defined "standard charge" as "the regular rate established by the hospital for the items and services provided to a specific group of paying patients," including all of the following categories of charges:

1. Gross charges: The charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts;

2. Payer-specific negotiated charges: The charge that the hospital has negotiated with a third party payer for an item or service;

3. Discounted cash price: The charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service;

4. De-identified minimum negotiated charge: The lowest charge that a hospital has negotiated with all third party payers for an item or service; and

5. De-identified maximum negotiated charge: The highest charge that a hospital has negotiated with all third party payers for an item or service.

The inclusion of gross charges and discounted cash price captures the charges applicable to self-pay patients, while the remaining categories capture rates applicable to insured patients. CMS believes that providing gross charges will increase transparency overall and provide useful data to patients and consumer advocates, and providing the de-identified minimum and maximum negotiated charges will provide a useful benchmark for consumers in understanding the range of hospital charges.

Despite significant pushback on the requirement to disclose negotiated rates, CMS believes that this requirement in particular will be instrumental in lowering health care costs. CMS dismissed concerns that requiring hospitals to disclose negotiated charges would violate free speech protections or antitrust law or that releasing these rates could drive prices up or discourage patients from seeking care. CMS did acknowledge the administrative burden associated with disclosing payer-specific negotiated charges and postponed implementation of this requirement until 2021.

Requirements for Public Disclosure of All Hospital Standard Charges for All Items and Services in a Comprehensive Machine Readable File

CMS reiterated its commitment to requiring transparency in the disclosure of hospital charge data and negotiated rate data under the authority of section 2718(e) of the PHS Act. The Final Rule does not require hospitals to report data in a standardized format; however, it did provide an example of compliant format in text of the Final Rule.

The Agency largely finalized the proposed data elements with few exceptions. Beginning in 2021, hospitals are required to publicly report:

- A description of each item or services (including individual items and services and service packages);
- The gross charge that applies to each item or service for both the hospital inpatient and hospital outpatient settings, as applicable;
- The corresponding payer-specific negotiated charge applicable to each item and service with each payer-specific negotiated charge clearly associated with the payer, the payer-specific negotiated charges are required for both the hospital inpatient and hospital outpatient setting, as applicable;
- The minimum and maximum de-identified negotiated charge that applies to each item or service for both the hospital inpatient and hospital outpatient setting, as applicable;
- The discounted cash price that applies to each item or service for both the hospital inpatient and hospital outpatient setting, as applicable; and
- Any code used by the hospital for accounting or billing (including common codes such as CPT, HCPCS, DRG, NDC, or other common payer identifiers).

CMS is requiring hospitals to make their standard charge information available via a machine-readable format but did not require the use of a specific file type. Hospitals may not use PDF formats, but are permitted to use file types, including but not limited to, .XML, .JSON and .CSV. The standard file must be displayed on a publicly-available website and accessible to the public without charge and without establishing a user name and password or submitting personally identifiable information. Hospitals must update their standardized files and the information for all items and services at least once per year.

Requirements for Displaying Shoppable Services in a Consumer-Friendly Manner

In addition to the disclosure of pricing information on its standard charges for all hospital items and services, CMS is also finalizing its proposal to require hospitals to publish separately the standard charges for a subset of "shoppable" services.

CMS defines a "shoppable service" as "a service that can be scheduled by a health care consumer in advance." They noted that in addition to the primary shoppable service, each hospital should be able to query its billing system by CPT code to determine what other services from other departments (laboratory, radiology, etc.) are typically billed with the primary service and offered as a package. CMS is requiring that the hospital have a list of at least 300 selected shoppable services for which it must offer pricing, including a list of as many of 70 CMS-specified services as possible. While the hospitals retain flexibility on how best to display the standard charges (so long as the website is easily accessible to the public), this list must be updated annually. The shoppable services listed by the hospital must also provide a specific set of information to be most useful to the patient as a consumer. These data elements include:

- A plain-language description of each shoppable service
- An indicator when one or more of the CMS-specific shoppable services are not offered by the hospital
- The payer-specific negotiated charge that applies to each shoppable service
- The discounted cash price that applies to each shoppable service
- The de-identified minimum negotiated charge that applies to each shoppable service
- The de-identified maximum negotiated charge that applies to each shoppable service
- The location at which the shoppable service is provided (inpatient, outpatient, etc.)
- Any primary code used by the hospital for purposes of accounting or billing for the shoppable service

CMS also gave fairly detailed guidance on the format of display of consumer-friendly information. While paper copies are not required to be provided, the shoppable service webpage must be displayed prominently, be able to be digitally searched, and must clearly identify the hospital location within which the standard charge is associated. The shoppable services must be free of charge, accessible without having to register, accessible without having to submit patient information, and searchable by service description, billing code, and payer.

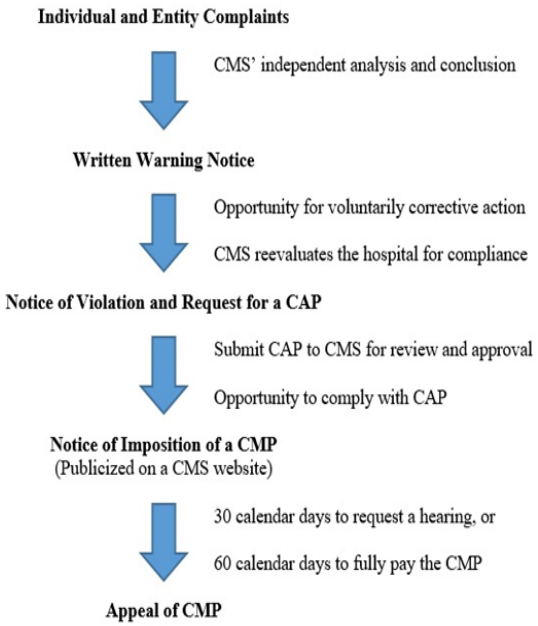
Monitoring and Enforcement

The Final Rule sets forth three different methods for monitoring a hospital's compliance with the new price transparency requirements. CMS will:

1. Evaluate complaints made by individuals and entities to CMS;
2. Review individuals' or entities' analysis of noncompliance; and
3. Audit hospital websites.

Complaints by individuals and entities are made simply by emailing CMS at PriceTransparencyHospitalCharges@cms.hhs.gov. However, CMS clarified that such complaints do not directly trigger enforcement actions, but instead merely causes CMS to conduct its own independent analysis and conclusion.

If CMS concludes, after conducting its independent analysis, that a hospital is noncompliant with one or more of the price transparency requirements, CMS will provide a written warning notice to the hospital specifying the violation(s).



This written warning notice provides the hospital an opportunity to take voluntary corrective action without incurring any penalties. The Final Rule is unclear as to how long a hospital has to comply before CMS reevaluates the hospital. Presumably, written warning notices will provide greater detail regarding the timeframe for voluntarily corrective action.

If CMS determines that the hospital remains noncompliant after reevaluating it, and the noncompliance is a material violation (i.e. failure to make its prices public, or failure to use the form and manner required), CMS will then issue a notice of violation and require the hospital to submit a Corrective Action Plan (CAP). The notice of violation will detail specifics regarding the form and manner, and the deadline to submit a CAP. Once a CAP is submitted and approved, CMS may monitor and evaluate the hospital's compliance with the CAP.

In the event a hospital (i) fails to respond to CMS' request to submit a CAP, (ii) fails to submit a CAP in the form, manner, or by the deadline specified in the notice of violation, or (iii) fails to comply with the approved CAP, CMS may impose Civil Monetary Penalties (CMPs) on the hospital. A written notice of imposition of a CMP will be issued to the hospital, and such notice will be publicized on a CMS website for consumers to see. A hospital must pay the CMP in full within 60 days after the notice of imposition of a CMP. Furthermore, CMS may impose additional CMPs for continuing violations that the hospital fails to correct. The Final Rule forth a right to a hearing before an Administrative Law Judge (ALJ) that will be discussed in the next section on Appeals.

The maximum total daily CMP amount a single hospital is subject to is $300, even if the hospital is in violation of multiple discrete requirements. This CMP amount will be adjusted annually using a multiplier determined by the Office of Management and Budget. Commenters have expressed concerns that the CMP amount is trivial for larger hospitals and does not pose a real financial burden; a large hospital could decide that $300 per day ($109,500 per year) is worth paying to not disclose pricing information. On the other hand, the CMP amount may be overly burdensome and potentially detrimental for smaller hospitals with low margins. In response, CMS stated that it believes the CMP amount is reasonable because failure to make pricing information public has less severe consequences than noncompliance that poses harm to patients. Additionally, CMS believes that $300 per day ($109,500 per year) is higher than their estimated cost for a hospital to comply with the regulations. Moreover, CMS believes it is important to consistently apply monitoring and enforcement across all entities that meet the definition of "hospital" regardless of hospital size, revenue, or location.

CMS's enforcement regime may seem fairly lenient as there are multiple opportunities for a hospital to correct its noncompliance prior to the imposition of any penalties. However, missing deadlines and failing to respond are grounds for imposing CMPs, thus, it is important to ensure hospitals have teams that knows how to recognize and timely respond to these notices from CMS.

While not directly addressed, it is likely that an unpaid CMP will be treated as an uncollected debt by CMS, and the associated risks of enrollment revocation or termination could apply. Furthermore, it is likely that CMS will consider the imposition of CMPs as a triggering event requiring disclosure pursuant to 45 C.F.R. § 424.519.

Appeals

Once CMS has imposed a CMP, the hospital has 30 days from the notice of imposition of a CMP to request a hearing before an ALJ. If a hospital does not request a hearing within 30 days, CMS may impose additional penalties for continuing violations without the right to appeal; however, a hospital may still request a hearing if it shows good cause for failing to timely exercise its right to a hearing. Therefore, it is essential that hospitals maintain its appeal rights, otherwise it could waive the right to appeal continuing violations.

In deciding whether the amount of the CMP is reasonable, it is important to know that the ALJ may only consider evidence relating to (i) the hospital's postings of its standard charges, (ii) material the hospital timely previously submitted to CMS (including with respect to CAPs), and (iii) material CMS used to monitor and assess the hospital's compliance. No additional evidence may be considered at this stage, thus, it is important to submit all supporting documentation and meaningfully respond during the previous stages of enforcement and corrective action plans prior to requesting an ALJ hearing.

If a hearing is requested, CMS will update its online public posting of the hospital's notice of imposition of a CMP to indicate that the CMP is under review. If the CMP is upheld in part after a final and binding decision, CMS will modify the notice on its website to conform to the decision. If the CMP is overturned in full by a final and binding decision, CMS will remove the posting from its website altogether. However, if the CMP is upheld in whole by a final and binding decision, CMS will maintain the posted notice on its website.

Conclusion

For the last several years the federal government, as well as almost every state government, has struggled with the issue of how to achieve price transparency to health care consumers. State laws have focused on providing patients with upfront estimated costs, itemized bills, and lists of estimated prices for their most common procedures (usually 25-30).

These laws have been promulgated as a direct result of voter interest and advocacy, and have received bipartisan support in most states. This Final Rule is much broader than existing state laws in certain ways, requiring hospitals to post several pricing measures for *all* items and services furnished by the hospital and to create a distinct consumer-friendly site for so-called "shoppable" services. But it does not address one primary concern of many state laws, which is the "surprise billing" by out-of-network physicians providing services within an otherwise in-network hospital.

The Final Rule has already received negative reviews from affected health care industry stakeholders, including both hospitals and health insurance trade groups. In a joint statement from the American Hospital Association, Association of American Medical Colleges, Children's Hospital Association and Federation of American Hospitals, the hospital coalition made clear its intent to file a legal challenge and reiterated the concern that "instead of helping patients know their out-of-pocket costs, this rule will introduce widespread confusion, accelerate anticompetitive behavior among health insurers, and stymie innovations in value-based care delivery." A further concern, particularly for large national hospital chains with hospitals in a number of states, is that hospitals will struggle to manage compliance with both this Final Rule and individual state laws, to the extent they conflict or overlap.