## Price Transparency Rules

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*Building on an executive order issued by US President Donald Trump in June, the administration released a pair of broad and inclusive rules aimed at advancing price transparency in healthcare on November 15, 2019. Key themes emerging from the hundreds of pages of price transparency rules impacting hospitals, health plans, and third-party payers include major changes in how health plans, consumers, and providers will interact over the coming years. Whether these changes will lead to price transparency and downward pressure on healthcare pricing or to further confusion is unknown, and it will be left to the courts to determine whether the price transparency rules have gone too far under other legal constructs.*

Price Transparency Requirements for Hospitals to Make Standard Charges Public (the Final Rule) adopts a new Part 180 to 42 CFR that requires hospitals to make "standard charge" information available online, to post this data for a limited set of "shoppable services" in a "consumer-friendly" manner and form, and to disclose contract rates with health plans. Published by the Centers for Medicare & Medicaid Services (CMS) as a supplement to the calendar year 2020 proposed outpatient prospective payment system (OPPS) rule, the Final Rule will take effect January 1, 2021—delayed an additional year from the originally proposed date because of the recognized burden on the industry.

The proposed Price Transparency in Coverage rule (the Proposed Rule) would implement Section 2715A of the Public Health Service (PHS) Act and Section 1311(e)(3) of the Affordable Care Act (ACA), which require that group health plans and health insurance issuers make information on claims payment policies, rating practices, and cost sharing available to the public and also disclose negotiated rates with providers and out-of-network estimates for consumers. Published by the US Departments of Treasury, Labor, and Health and Human Services (Departments), the Proposed Rule would require health plans (including self-insured plans) and insurance issuers to provide online access to personalized cost-sharing information for plan participants, and to disclose their in-network provider negotiated rates and out-of-network allowed amounts for covered items and services to the public.

### FINAL RULE: PRICE TRANSPARENCY REQUIREMENTS FOR HOSPITALS TO MAKE STANDARD CHARGES PUBLIC

For the last year, hospitals have been required to post on the internet a list of their standard charges under CMS rules. In frequently asked questions published in connection with last year's final inpatient prospective payment system (IPPS) rule mandating such posting, CMS described the requirement as applying to "standard charges as reflected in its chargemaster." The Final Rule offers a substantial widening of this obligation for hospitals, defying a number of comments that warned of concerns by the industry.

## Definitions and Requirements

*Standard Charges*

The Final Rule codifies the proposed definition of a "standard charge" as the regular rate established by a hospital for an item or service provided to a specific group of paying patients, including all of the following charges:

- *Gross charge:* The charge for an individual item or service reflected on the hospital's chargemaster, absent any discounts.
- *Payer-specific negotiated charge:* The charge that a hospital has negotiated with a third-payer for an item or service. CMS defines a third-party payer as an entity that is by statute, contract, or agreement legally responsible for payment of a claim for a healthcare item or service.

CMS expanded the definition of standard charges to include the following, which did not appear in the OPPS proposed rule:

- *De-identified maximum negotiated charge:* The highest charge that a hospital has negotiated with all third-party payers for an item or service.
- *De-identified minimum negotiated charge:* The lowest charge that a hospital has negotiated with all third-party payers for an item or service.
- *Discounted cash price:* The charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service.

The historic understanding of the term "charges" in the Medicare program has traditionally been gross charges before contractual allowances (i.e., "as reflected in the chargemaster"). CMS casts its definition of "standard charges" in a much wider light under the PHS Act, incorporating into the definition the rates a hospital has negotiated with third-party payers.

*Hospital*

"[T]o ensure that section 2718(e) of the PHS Act applies to each hospital operating within the United States," the Final Rule adopts the proposed definition of "hospital" as follows:

> [A]n institution in any State in which State or applicable local law provides for the licensing of hospitals that is licensed as a hospital pursuant to such law, or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing.

Continuing its emphasis on the breadth of the PHS Act pricing transparency rules beyond traditional understandings of Medicare terminology, the term "hospital" includes any institution that satisfies this definition, regardless of whether the institution participates in the Medicare program. Sole community hospitals, critical access hospitals, or hospitals that treat special populations (e.g., children's hospitals, state psychiatric hospitals, long-term care hospitals, inpatient rehabilitation facilities) will likewise fall under the definition.

The standard charge disclosure requirements do not apply to exempt federally owned or operated hospitals (e.g., Indian Health Service facilities, Veterans Affairs facilities, and military treatment facilities) because these facilities do not provide services to the general public and the established payment rates for services are not subject to negotiation, according to CMS. Similarly, ambulatory surgery centers or "other non-hospital sites-of-care from which consumers may seek health care items and services" are also exempt.

*Hospital Items and Services*

Hospital "items and services" are defined as all items and services provided by a hospital in connection with an inpatient admission or outpatient department visit for which the hospital has established a charge. Examples of "items and services" provided by the Final Rule include supplies and procedures, room and board, facility fees, professional charges, and any other items or services for which the hospital has established a charge. In addition, CMS requires the reporting of "service packages," which are defined as the aggregation of individual items and services into a single charge. CMS suggests that the PHS Act's requirement to include information relating to diagnosis-related groups incorporates a requirement to bundle certain common services, although many commenters argued that the uniqueness of payer packaging may create confusion and burdens in implementation.

## Public Disclosure Requirements

Beginning January 1, 2021, at each hospital location, hospitals will be required to make a list of their standard charges for all items and services available online in a single, machine-readable digital file. This information must be free of charge; available to view without registering or establishing an account; searchable by service description, billing code, and payer; and displayed in a prominent manner that also identifies the hospital's location associated with the standard charges.

Hospitals are required to post a "consumer-friendly" searchable list of payer-specific negotiated charges, de-identified minimum and maximum negotiated charges, and discounted cash prices for at least 300 "shoppable services" (which the Final Rule defines as a service that can be scheduled by a healthcare consumer in advance), including 70 CMS-selected shoppable services and 230 additional hospital-selected shoppable services. Hospitals must include charges for services in conjunction with the primary service that is identified by a common billing code (e.g., Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), Diagnosis-Related Group (DRG)).

CMS categorizes the 70 CMS-selected shoppable services, found in Table 3 of the Final Rule, as evaluation and management (E&M) services, laboratory and pathology services, radiology services, and medicine and surgery services. As for the 230 hospital-selected shoppable services, hospitals may select these services based on the utilization or billing rate of the services in the last year. If a hospital does not provide one or more of the 70 CMS-specified shoppable services, the hospital must select additional shoppable services such that the total number of shoppable services is at least 300. In response to comments, CMS added a requirement to the Final Rule that if a hospital does not provide 300 shoppable services, it must list as many shoppable services as it provides.

The Final Rule provides that standard charges for shoppable services be displayed along with charges for "ancillary items and services" the hospital customarily provides as part of, or in addition to, the primary shoppable service. Such items may include laboratory, radiology, drug, delivery room, and operating room (including postanesthesia and postoperative recovery rooms) fees; therapy services; hospital fees; room and board charges; charges for employed professional services; and other special items and services for which charges are customarily made in addition to a routine service charge. Hospitals that do not employ the professionals responsible for the ancillary services are not required to report those professional charges. CMS urges that "for the sake of consumer-friendly presentation, we strongly encourage and recommend that the hospital indicate all ancillary services the customer may expect . . . and indicate that they may be billed separately by other entities." The disparity in hospital-physician organizational structures may create confusion and unrealistic variability in the pricing information available to consumers, which in turn may work counter to the agency's overall aim for transparency.

Standard charge information must be updated at least annually with the date of the last update clearly indicated. While some commenters sought more routine updates (i.e., as rates change), CMS felt limited by the "each year" language of the PHS Act, and given the volume of data required to be reported by hospitals, it chose not to increase the burden it was imposing. Nevertheless, depending on the consistency in timing for the effective dates of contracted rates across all of its payers, hospitals may be burdened by real market pressures for more frequent updates to avoid consumer confusion (and potential complaints).

In a modification from the OPPS proposed rule, the Final Rule specifies that a hospital will be deemed by CMS as meeting the requirements of the public disclosure rule if it maintains "an Internet-based price estimator tool" that provides estimates "for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services."

## Monitoring and Enforcement

CMS may impose a civil monetary penalty (CMP) after giving warning notice to a noncompliant hospital, or subsequent to a request for a corrective action plan. If the hospital fails to respond to the agency's request for a corrective action plan, or fails to comply with the plan's requirements, CMS may impose a CMP on the hospital not in excess of $300 per day, and publicize these penalties on its website. The Final Rule establishes an appeals process for hospitals to request a hearing before an administrative law judge should it be subject to the new enforcement rules.

Given the volume of data and potential for confusion from a variety of complexities surrounding pricing issues, a public complaint process for the initiation of investigations could prove to be burdensome as consumers and hospitals alike work their way through the requirements. Though the CMP amounts are modest in the Final Rule, those who recall the implementation of HIPAA (and the enforcement kickers in HITECH) will look for a similar "ramping up" of enforcement over time.

## PROPOSED RULE: TRANSPARENCY IN COVERAGE

### Applicability

The Proposed Rule attempts to ensure the intent for price transparency is as comprehensive on the health plan side as it is on the provider side. Consequently, the Proposed Rule applies to group health plans and health insurance issuers of individual and group market health insurance coverage, including self-insured group health plans, with a handful of exceptions. Plans grandfathered under the ACA, plans providing excepted benefits, account-based plans, and short-term/limited-duration plans are exempt from the Proposed Rule.

The upshot of the Proposed Rule is that plans and issuers would be required to ensure that all the information required under the regulations is available on an internet website and, if requested, through noninternet means. Negotiated in-network and out-of-network rates would be required to be disclosed through two machine-readable files posted on an internet site ensuring the public has access to health insurance coverage information that can be used to understand healthcare pricing and improve healthcare competition on pricing.

The Proposed Rule is promulgated pursuant to certain legislative mandates under the ACA focused on reducing surprises in relation to consumer out-of-pocket costs for healthcare services. The hope is to create a competitive dynamic that will narrow price differences in markets.

### Disclosure of Cost-Sharing Information

Upon the request of an enrollee or beneficiary, a plan or issuer would be required to disclose price and benefit information specific to a particular healthcare service or item prior to its delivery. The Departments' purpose is to provide the information in a form similar to the explanation of benefits (EOB) template currently in use by plans to outline participants' services after delivery thereof.

The disclosure would have to include the following seven elements outlined in the Proposed Rule:

- *Estimated Cost-Sharing Liability:* A participant's cost-sharing amount for covered items or services under the terms of the plan, including elements such as deductibles, coinsurance, and copayments. This would exclude premiums, balance billing amounts, and noncovered items or services.
- *Accumulated Amounts:* The amount of financial responsibility that a participant has incurred at the time the participant requests cost-sharing information. Similar to cost sharing liability, any expense that counts toward the deductible or out-of-pocket limit—like copayments or coinsurance—would fall in this category, while premiums, out-of-pocket expenses for out-of-network services, and costs of noncovered services would not. Plans that require cumulative limitations on specified services must include the amount a participant has already accrued toward the limit on the service.
- *Negotiated Rate:* The amount a plan has contractually agreed to pay an in-network provider for a covered item or service translated into dollars. Participants would be

permitted to request the billing codes of specific items or services, including prescription drugs, to ascertain the estimated cost of an item obtained directly through a provider.

- *Out-of-Network Allowed Amount:* For noncovered services, plans would be required to include each unique out-of-network allowed amount in connection with a covered service by a particular out-of-network provider. Furthermore, plans must disclose the aggregate of the actual amount the plan paid to the out-of-network provider and the participant's share of the cost separately.
- *Items and Services Content List:* If a participant requests information on bundled services or items, the plan would be required to disclose a list of each covered item and service included in the bundled arrangement and the participant's share of the cost for the bundle as a whole. The plan would not be required to provide the participant's cost-sharing liability for each separate element of the bundle.
- *Notice of Prerequisites to Coverage:* Whenever applicable, plans would be required to inform participants of any prerequisite (defined to include concurrent review, prior authorization, step-therapy, or fail-first protocols) specific to the item or service for which the participant requests cost-sharing information.
- *Disclosure Notice:* Plans must provide a notice alerting participants to any balance billing and noting that any estimate may differ from actual charges and does not represent a guarantee of coverage, and provide any additional disclaimers or information that plans deem appropriate. Plans may not include any language that could be construed as disclaiming a plan's responsibility to provide an accurate cost-sharing estimate to participants.

**Required Methods of Disclosure**

The Proposed Rule would require that plans make cost-sharing information generally available to their participants both online and in paper form at no cost to their beneficiaries. Online, plans must provide a self-service tool that enables participants to search for cost information for particular services or items provided by individual providers whether in or out of network. Plans must ensure that participants have access to accurate, real-time information based on information participants enter into the tool (i.e., billing code or zip code). Participants must be able to sort results by location and cost. For participants without internet access, plans must provide the same information in paper form. Hard copies must be mailed to a participant within two days of receipt of the participant's request for information.

**Special Rules to Avoid Duplication**

In the group health context, the Departments have included guidelines to streamline plans' provision of the necessary information without unnecessary overlap. To the extent that a plan consists of group health coverage, the plan would satisfy the disclosure requirements if the issuer offering coverage were contractually required to provide the information pursuant to a written agreement between the plan and the issuer. If the issuer failed to meet the disclosure requirements of this Proposed Rule, then the issuer would be solely liable.

**Medical Loss Ratio**

With regard to the medical loss ratio (MLR), the Proposed Rule would amend 45 CFR Section 158.221 to allow health insurance issuers that share with consumers the savings that result

from consumers shopping for lower-cost, higher-value services to take credit for such "shared savings" payment in the MLR calculations.

## KEY TAKEAWAYS: BOTH RULES

### Antitrust Considerations

Publishing prices is not inherently unlawful under federal or state antitrust laws. However, it is unlawful for competitors to agree on their prices or coordinate aspects of their service offerings. In addition, communications with competitors about prices, particularly future price movements, could be problematic under the antitrust laws even without an explicit agreement. While pricing-related antitrust risk has always been present in the healthcare sector, it is likely to become more acute when the new rules go into effect. Healthcare providers and insurers should consider proactively designing or refreshing their antitrust policies and compliance programs to spot and minimize the potential risks posed by the new rules. While no policy or compliance program can eliminate antitrust risk, effective antitrust compliance programs can help flag problematic conduct early, and, under a new Department of Justice policy, may be considered in the event of an antitrust violation.

### *Texas v. United States*

It is important to note that both rules derive their authority from the besieged ACA. With *Texas v. United States* under review in the US Court of Appeals for the Fifth Circuit, it is unclear how a determination that would overturn the ACA would affect these and the many other ACA-implemented rules. And while a Supreme Court writ would surely be sought, the resulting impact on all these rules while the status of the ACA plays out promises to create significant additional uncertainty. These days, federal health policy—such as price transparency—is more likely to be made in the judicial branch, as more and more rules are being challenged in the courts.

### *Other Considerations*

The rules have little impact for participants requiring costly emergency care or consumers without coverage who use emergency rooms as their sole source of medical care.

Across the industry as a whole, plans and providers alike will have to undertake additional costs to update their current programs, technology, and web pages to comply with the newly imposed requirements, as well as take on or train personnel to maintain that programming and technology.

## KEY TAKEAWAYS: FINAL RULE

Whether or not healthcare consumers will ultimately gain from the Final Rule, they are certainly the intended beneficiaries of its dramatic expansion in hospital charge reporting requirements. The fundamental change to the definition of "standard charges" to include all third-party negotiated rates and cash discount rates will generate volumes of additional data for patients to absorb. But differences in hospital specialties, unique service packages with payers, hospital-physician employment structures, and the unique nature of hospital uncompensated care costs

all lurk within the pricing transparency model established by the Final Rule. These elements, among others highlighted by commenters, may only trade the current pricing confusion for a new type of confusion. In an era of patient-centered care, the consumer need for more usable healthcare pricing information is undeniable—whether the Final Rule furnishes that "usable" solution remains to be seen.

Additionally, the American Hospital Association has already sued CMS to seek to have the rule reversed, adding even more uncertainty. If the case is successful, then CMS will likely need to ask Congress for new authority, meaning that any meaningful attempt at price transparency could still be years away.

**KEY TAKEAWAYS: PROPOSED RULE**

The Departments' often-repeated objective for enhanced cost transparency is to provide consumers the information necessary to navigate the healthcare market with greater ease and make educated decisions about their healthcare needs. This way, the Departments' posit, competition within the healthcare market will increase and downward pricing pressure will be applied to costs associated with US healthcare. Beyond this driving force, the Departments focus significant portions of the preamble on discussing two secondary benefits created by enhanced transparency: (1) previously inaccessible cost information provided to uninsured participants and (2) medical software development opportunity.

Once cost-sharing information becomes more widely available, the Departments hypothesize that uninsured participants will have access to more affordable healthcare. Uninsured participants will be able to review historic out-of-network costs for various healthcare services and find better bargains. The Departments acknowledge that the complexity of our healthcare system makes it difficult for the average consumer to understand the full picture of medical billing. Moreover, without plans being obligated to supply to uninsured consumers the seven content requirements that insured participants receive, uninsured consumers are left with quite a bit of guesswork to do in finding more affordable options.

As far as medical software developers are concerned, the Proposed Rule signals a huge opportunity for growth and profit. The Departments note opportunities for software developers to create and market mobile applications to consumers that would help organize and analyze the cost-liability information that plans would be required to release, as well as to create new programs or revamp existing technology for plans to assist in transparency compliance. But with this boon to the medical technology industry comes increased privacy risk. The rules do not excuse plans from complying with any existing data privacy laws (e.g., HIPAA), and with an influx of new market actors comes the dangerous possibility of data breaches.