



CMS's Hospital Price Transparency Final Rule and Related Legal Challenge

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Addressing the rising cost of health care, including reducing the prices consumers pay for health care services and products, has been an area of interest for Congress and the Trump Administration. One approach is promoting price transparency, which proponents argue could lower costs by enabling healthcare consumers to comparison shop, prompting providers of healthcare services and products to offer more competitive pricing. The Administration has announced price transparency proposals both in the context of prescription drugs and health care provider services. Earlier in 2019, for instance, the Centers for Medicare and Medicaid Services (CMS) issued a final rule that would have required direct-to-consumer television advertisements for certain prescription drugs to disclose the drugs' list prices. Several pharmaceutical manufacturers sued to challenge the rule, and the U.S. District Court for the District of Columbia agreed, in a decision that the U.S. Department of Health and Human Services (HHS) has appealed to the D.C. Circuit, that this disclosure requirement exceeded the Secretary's statutory authority under the Social Security Act.

More recently, CMS, on November 15, 2019, issued a final rule (effective January 1, 2021) that requires each hospital operating in the United States to post to the public online a yearly list of five types of "standard charges" for every item and service it provides, discussed below. Like the drug price disclosure rule, this hospital price transparency rule has sparked debate and drawn a legal challenge by entities— here, several hospitals and hospital associations—affected by the rule. Given the legal challenge, this sidebar provides an overview of the CMS hospital price transparency final rule, the bases of the legal challenge against it, and how the legal challenge may be relevant to other legislative healthcare price transparency proposals that Members of Congress may continue to consider.

CMS Hospital Price Transparency Final Rule

CMS issued the hospital price transparency final rule to implement Section 2718(e) of the Public Health Service Act (PHSA). Enacted as part of the Patient Protection and Affordable Care Act (ACA), Section 2718(e) requires each hospital operating in the United States to establish, update, and make public annually, "in accordance with guidelines developed by the Secretary," a list of the hospital's "standard charges" for "items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act." When CMS initially implemented this

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https://crsreports.congress.gov LSB10392 provision in 2014, it took a less prescriptive approach and allowed hospitals to fulfill their obligations under this requirement by making public a list of their standard charges "either in the form of the hospitals' chargemaster itself or in another form of their choice." A chargemaster is a file a hospital typically maintains that lists (often by code) all items and services the hospital may charge for and the list prices for those items and services. Alternatively, CMS also allowed hospitals to comply with the requirement by publicizing their policies for requesting a viewing of such a list. In 2018, CMS updated its guidelines on Section 2718(e) to remove the latter option, requiring hospitals to post online and annually update a list of their current standard charges "either in the form of their chargemaster itself or in another form of their choice."

In its November 15, 2019 final rule implementing Section 2718(e), CMS expanded the scope of required public disclosures to five types of "standard charges" based on what CMS found to be "standard for different identifiable groups of people":

- (1) gross charges: charges reflected on a hospital's chargemaster, absent any discounts;
- (2) **payer-specific negotiated charges:** charges that a hospital has negotiated with a third party payer (e.g., a commercial health insurer) for the items and services;
- (3) discounted cash price: price a hospital would charge those who pay cash for an item or service;
- (4) **de-identified minimum negotiated charges:** the lowest charge that the hospital has negotiated with all third party payers for an item or service; and
- (5) **de-identified maximum negotiated charges:** the highest charge that a hospital has negotiated with all third party payers for an item or service.

Each hospital would need to disclose online these standard charges two ways: by (1) posting a list containing these five standard charges for all items and services the hospital provides; and (2) providing a consumer-friendly display of all standard charges except gross charges for certain 300 common "shoppable" services. (A "shoppable" service is generally a routine, non-urgent service that a healthcare consumer can schedule in advance).

Legal Challenge Against the Final Rule

Shortly after CMS issued the final rule, a number of hospitals and hospital associations sued to challenge the rule as unlawful on two principal grounds.

CMS's Interpretation of "Standard Charges." The first ground for challenging the new rule centers on the plain meaning of Section 2718(e) and its use of the phrase "standard charges." When reviewing an agency's interpretation of a statute it is charged with administering, courts generally apply the two-step analysis the Supreme Court articulated in *Chevron U.S.A., v. NRDC*. Under step one, courts analyze the statute's language to determine whether the law clearly speaks to the question at issue. If so, "that is the end of the matter" and courts must enforce the "unambiguously expressed intent of Congress." If, however, the statute leaves a gap or is ambiguous, courts then "typically interpret it as granting the agency leeway to enact rules that are reasonable" in nature. Under this step two analysis, courts will generally uphold a reasonable agency interpretation even if it is not "the reading the court would have reached."

With respect to the new transparency rule, plaintiffs argue that *Chevron* analysis should stop at step one because Section 2718(e)'s requirement to disclose "standard charges" unambiguously precludes disclosing insurer-specific negotiated rates and discounted cash prices and is restricted to hospitals' chargemaster charges. This interpretation, according to plaintiffs, is supported by the plain meaning of "standard," which means "usual, common, or customary"—a definition that necessarily excludes insurer-specific rates that are individually and privately negotiated, as well as individualized cash discounts that a

hospital may or may not voluntarily offer at set rates to self-pay patients. Plaintiffs also assert that "standard charges" are commonly understood to mean "a hospital's usual or customary chargemaster charges," citing in support several court cases.

In response to similar arguments that arose when CMS initially proposed the rule, CMS maintains the term "standard charges" is ambiguous. The agency observed that term is not defined under the PHSA, nor is the agency "aware of any historical usage of the term by the industry." Certain stakeholder comments addressing the earlier CMS rule on Section 2718(e) expressed concerns that "the definition of standard charges is unclear," as hospitals use various overlapping terms on price that can have different or interchangeable meanings. In CMS's view, Section 2718(e)'s reference to disclosure of "standard charges" for "diagnosis related groups"-a type of billing code used to represent service packages-also suggests that the statute contemplates disclosure beyond what is in the chargemaster. A chargemaster, according to CMS, typically contains only list prices for individual items and services and not for service packages. Given this ambiguity, CMS believes that the statute provides discretion to define "standard charges," and its effort to define five standard charges based on "different identifiable groups of paying patients"—including insured and self-pay patients—is reasonable. The payer-specific negotiated charges, in CMS's view, are a necessary "starting point"-when combined with the patients' specific plan information—for insured patients to understand their out-of-pocket cost obligations. On the other hand, discounted cash prices-which CMS asserts many hospitals have developed and standardized-would provide helpful cost information to self-pay patients. If the court agrees that the statutory meaning of "standard charges" is ambiguous—a critical threshold question—it is more likely that the court would accept CMS's argument concerning the final rule's reasonableness under Chevron step two.

The First Amendment. Along with challenging CMS's interpretation of Section 2718(e), plaintiffs also argue that the final rule unconstitutionally compels speech in violation of the First Amendment's Free Speech Clause. Because the Clause generally protects not only the right to speak, but also the right *not* to speak, commercial disclosure requirements may implicate the Clause. In analyzing the constitutionality of such a requirement, a threshold question for the court is the applicable standard of review.

Historically, the Supreme Court has accorded commercial speech less protection under the First Amendment than other speech and has generally applied less rigorous standards of review to commercial disclosure requirements. Current law still applies a relatively lenient "reasonableness" review to certain commercial disclosure requirements under *Zauderer v. Office of Disciplinary Counsel*. Specifically, *Zauderer* review applies if the requirement compels speech that is "factual and uncontroversial" and related to the goods or services the speaker provides. Under this standard, the government generally need only show that the requirement is reasonably related to a legitimate and significant government interest and is not "unjustified or unduly burdensome." If *Zauderer* review does not apply—for instance, because the required disclosure is not "factual and uncontroversial"—higher levels of scrutiny would apply. Under higher levels of scrutiny, the government must show an increasingly closer fit between the interest it is pursuing and the means by which it is using to achieve that interest.

In the context of a First Amendment analysis, the standard applied can often determine the case outcome. While lower courts have approved several commercial disclosure requirements under *Zauderer* review, for instance, government actions rarely survive the highest level of scrutiny. At the same time, however, the application of *Zauderer* implicates a number of unsettled legal questions. These questions include (1) whether *Zauderer*, a case involving certain required disclosures in attorney advertisements, applies to commercial disclosure requirements outside of consumer advertising, (2) when a required disclosure is "factual and uncontroversial" for purposes of *Zauderer*, and (3) when such a requirement is "unduly burdensome" under *Zauderer*. In addition to these questions, there are also unsettled questions relating to the government's evidentiary burden under each standard of review.

In the case of the new final rule, the parties will likely dispute the applicable standard of review and how it should be applied. It is difficult to predict how a court will analyze these issues given that the final rule

implicates many of these unsettled questions. Plaintiffs believe a standard higher than Zauderer review applies because the final rule does not regulate disclosures in consumer advertising. Plaintiffs further argue that the required disclosure of negotiated rates would not provide consumers with information about their own out-of-pocket costs, which depend on the design of their specific health plans and the applicable deductibles, co-payments, and co-insurance. Similarly, plaintiffs assert that discounted cash prices may not accurately reflect the actual costs to self-pay patients, given that hospitals may not offer such "one size fits all" discounts and may offer case-specific discounts that would not be reflected in the disclosed rate. Embedded within these arguments appear to be the view that the required disclosures are also outside the scope of Zauderer because they would be confusing or misleading to consumers and thus not "factual and uncontroversial" for purposes of Zauderer. The required disclosure of negotiated rates is also insufficiently tailored to survive higher scrutiny, plaintiffs argue, given that it would wipe away the current legal protection—including trade secret protection—that allegedly applies to the highly confidential negotiated-rates data. Such compelled disclosure would, according to plaintiffs, dampen rather than promote price competition by removing the negotiating parties' incentives to offer discounts. The overall disclosure requirements under the final rule, plaintiffs also argue, are also not narrowly tailored because they would impose enormous burdens on the hospitals, requiring the compilation of "hundreds to thousands of columns" for "tens of thousands" of items, services, and packages.

In contrast, CMS has stated that it believes *Zauderer* review applies to the final rule, noting that several lower courts have applied this standard to commercial disclosure requirements outside the advertising context. In CMS's view, *Zauderer* supplies the appropriate framework for review because the final rule requires the disclosure of factual commercial information—i.e., rates actually negotiated or offered by hospitals. At the same time, CMS has also expressed its views that the final rule would pass constitutional muster under even a higher level of scrutiny. In the agency's view, the required disclosures would advance the government's substantial interests "in providing consumers with factual price information to facilitate more informed health care decisions" and in "lowering health costs." CMS believes the rule is tailored to achieve these interests because each type of "standard charges" is targeted to a specific group of healthcare consumers. For instance, the government argues that the negotiated rates are relevant to insured consumers because insurers often use those rates to determine the consumers' out-of-pocket costs. The rule, in CMS's view, is also sufficiently tailored and not unduly burdensome because it does not prohibit hospitals from conveying other information they believe would be helpful to consumers.

Implications for Legislative Transparency Proposals

The legal challenge against the hospital price transparency final rule (as well as the drug price transparency rule) illustrates how transparency measures that take place in the highly regulated healthcare industry often may raise not only important policy questions, but also several complex legal issues relating to the relevant statutory framework(s) and the Constitution. While statutory ambiguities may be addressed through legislative actions, the constitutional issues define the outer bounds of such measures. As some Members of Congress continue to consider legislative proposals to enhance healthcare price transparency as a way to lower healthcare costs, these legal challenges may be cases to watch, as they may provide opportunities for the courts to clarify the relevant parameters for legislation.

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