



Drug Price Disclosure to Consumers: Current Legal Authority and Considerations for Congress

Updated July 9, 2019

Update: On July 8, 2019, the U.S. District Court for the District of Columbia [held](#) that the Department of Health and Human Services (HHS) exceeded its statutory authority in promulgating its new rule on drug list price disclosures. As the court explained, “[n]either the [Social Security] Act’s text, structure, nor context evince an intent by Congress to empower HHS to issue a rule that compels drug manufacturers to disclose list prices. The Rule is therefore invalid.” The court ultimately vacated the rule. Because the court concluded that the agency lacked the statutory authority to issue the rule, the court did not evaluate whether the rule violated the First Amendment. HHS has not yet signaled whether it will appeal the decision.

The original post from July 5, 2019 is below.

Drug price transparency measures are a key feature of recent efforts to reduce the escalating prices of many prescription medications. Some Members of Congress and the Trump Administration are currently exploring various initiatives intended to demystify drug prices, make patients more savvy consumers of pharmaceuticals, and, in turn, reduce the costs of these products. Notably, as part of these initiatives, the Centers for Medicare and Medicaid Services (CMS) recently issued a [final rule](#) requiring certain prescription drug and biological product television advertisements to convey specified pricing information. This rule has [sparked debate](#), as well as a [legal challenge](#) involving two distinct, but related legal issues: (1) whether the disclosure requirement would run afoul of the First Amendment of the Constitution, and (2) whether CMS possesses the statutory authority to promulgate this rule under its general authority to administer the Medicare and Medicaid programs. This Sidebar surveys the latter issue (see this [earlier](#) Legal Sidebar on the first question). In so doing, the Sidebar addresses the Executive Branch’s current legal authority to promote drug price transparency to consumers and explores legislative proposals concerning drug price transparency currently before the 116th Congress.

CMS Drug Pricing Transparency Regulation

Effective July 9, 2019, the [new CMS rule](#) will require direct-to-consumer (DTC) television advertisements for covered pharmaceutical products to include a textual statement indicating the current

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wholesale acquisition cost (WAC, also referred to as the list price), for a typical 30-day regimen or a course of treatment, whichever is more appropriate. In general, the WAC is the manufacturer's published or listed price for a pharmaceutical product to wholesalers or direct purchasers, absent any discounts, rebates, or other reductions in price that drug purchasers may receive. Some commentators compare the WAC to a sticker price on a car, as pharmaceutical manufacturers, much like car manufacturers, commonly negotiate price concessions with entities along the distribution chain, such as wholesalers, pharmacies, health insurers, and pharmacy benefit managers (PBMs). Additionally, a consumer's health insurance (offered through the private insurance market or a government-sponsored health care program such as Medicare) may subsidize a portion of a drug's cost, with the consumer paying only set cost-sharing. For these reasons, the WAC may not reflect the actual price that parties in the pharmaceutical supply chain (including consumers) pay for a medication.

Pursuant to the final rule, the requisite pharmaceutical pricing statement that must be included in DTC advertisements is as follows:

“The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.”

Subject to an exception for certain low-cost medications, the final rule applies to products for which payment is available, directly or indirectly, under Medicare or Medicaid. CMS estimates that about 25 pharmaceutical companies will run approximately 300 distinct television advertisements each quarter that are subject to the disclosure requirements of the final rule.

CMS depends on its authority under Medicare and Medicaid provisions of the Social Security Act (SSA) to promulgate the drug price disclosure rule. As background, Title XVIII of the SSA establishes the Medicare program, which provides health coverage to persons age 65 and older, as well as certain other qualified beneficiaries. Medicaid, created under Title XIX of the SSA, is a cooperative effort by the federal government and the states to provide medical assistance for low-income and certain medically needy individuals. The Secretary of Health and Human Services (HHS) has charged CMS with administration and enforcement of these health care programs. In general, drug coverage is available under Medicare and Medicaid, but there is variation in the structure of available drug benefits and out-of-pocket costs for eligible beneficiaries. While these health care programs have certain mechanisms in place to let beneficiaries know about available covered medications and the amount they will need to pay for their prescriptions (e.g., the Medicare Plan Finder), Congress has not explicitly permitted CMS to compel disclosure of pharmaceutical list prices to the public.

In requiring list price disclosure in television advertisements, CMS relies on two statutory provisions: sections 1102(a) and 1871(a) of the SSA. Section 1102(a) permits the Secretary to “make and publish such rules and regulations non inconsistent with this Act . . . as may be necessary to the efficient administration of the functions” with which the Secretary is charged under Medicare and Medicaid. Section 1871(a) directs the Secretary to “prescribe such regulations as may be necessary to carry out the administration of [Medicare]”

Authority for CMS to Promulgate the New Rule

As the Supreme Court has observed, “an agency’s power to regulate private entities must be grounded in a statutory grant of authority from Congress.” Some courts have recognized CMS’s broad authority to issue regulations under sections 1102 and 1871 of the SSA. However, in these cases, courts have typically considered CMS’s rulemaking authority in the context of another more specific Medicare or Medicaid requirement. For example, in a recent Third Circuit decision examining CMS’s regulatory authority to issue regulations interpreting the Emergency Medical Treatment and Active Labor Act (EMTALA), the court cited to section 1871 and declared that “Congress has expressly delegated authority to [CMS] to

construe Medicare-related statutes, like EMTALA, through rules and regulations” (emphasis added). In contrast, the Medicare and Medicaid Acts lack any additional provisions concerning drug price disclosures, and CMS relies solely on sections 1102 and 1871 to authorize the new rule.

In ascertaining whether Congress has authorized a specific agency rule, courts commonly engage in a two-step analysis articulated by the Supreme Court in *Chevron U.S.A., v. Natural Resources Defense Council*. First, courts analyze the language of the authorizing statutes to determine whether the statute clearly speaks to the question at issue. If, however, a statute “leaves a gap or is ambiguous,” courts then “typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute.” Nonetheless, the Court has recognized in a series of cases that *Chevron* review is inapplicable where Congress did not intend to give the agency the authority to issue binding legal rules on the issue in question.

General delegations of rulemaking authority akin to sections 1102 and 1871 may present distinct issues concerning application of the *Chevron* test. Prior to *Chevron*, in *Mourning v. Family Publications Service* and other decisions, the Supreme Court upheld the validity of rules issued under general rulemaking provisions so long as the rule was “reasonably related to the purposes of the enabling legislation.” Under this standard, courts afforded heightened discretion “to the informed experience and judgment of the agency to whom Congress delegated appropriate authority.” While some courts have continued to rely upon the *Mourning* approach as separate from the *Chevron* inquiry when interpreting general delegations of authority, the more common approach of courts has been to view *Mourning* as being relevant *only* after a court has determined as an initial matter that “Congress has indeed delegated interpretative powers to that agency” on a particular issue. Moreover, courts adopting such an approach have rejected the view that a “court is free to interpret a statute to conform to some view of its general purposes,” favoring an evaluation of agency regulations in the context of the precise language and structure of a particular statute. Accordingly, a reviewing court considering the new CMS rule would likely need to consider whether Congress intended the agency to regulate drug price disclosures in DTC advertising and whether the agency’s interpretation of sections 1102 and 1871 comport with the text and structure of the Medicare and Medicaid Acts.

An initial question concerning the CMS rule is whether Congress intended CMS to mandate drug price disclosures in DTC advertisements. In other words, does the rule present a question that Congress empowered the agency to answer? Pursuant to the so-called “major questions” doctrine, “an agency can fill in statutory gaps where ‘statutory circumstances’ indicate that Congress meant to grant it such powers,” but this rule is not followed “when the ‘statutory gap’ concerns ‘a question of deep ‘economic and political significance’ that is central to the statutory scheme.’” In these and other cases involving the major questions doctrine, the Court has declined to defer to an agency’s interpretation under *Chevron* or has simply found *Chevron* analysis inapplicable. The Supreme Court first recognized the major questions doctrine in *FDA v. Brown & Williamson Tobacco Corp.* There, the Court invalidated a final rule enabling FDA to regulate tobacco products through its general authorities over drugs because the economic consequences of the rule, coupled with numerous examples of tobacco-specific legislation that Congress enacted outside of FDA’s jurisdiction, suggested that it was Congress’s “consistent judgment to deny the FDA [the authority to regulate tobacco products].” Similarly, in *Gonzales v. Oregon*, the Court held that the U.S. Attorney General lacked authority under the Controlled Substances Act (CSA) and its implementing regulations to prohibit the distribution of controlled substances for the purpose of facilitating state-sanctioned physician-assisted suicide. The Court rejected the idea that “Congress gave the Attorney General such broad and unusual authority [to regulate standards of medical practice] through an implicit delegation” in a CSA provision requiring prescriber registration. As the Court in *Gonzales* further explained, Congress “does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.”

Relying on *Brown & Williamson*, *Gonzales*, and other Supreme Court precedent, opponents of the CMS rule have **claimed** that Congress did not intend to give CMS authority to require list prices in DTC advertisements. These critics point to a lack of clear, specific text in the Medicare and Medicaid statutes that confers authority on CMS to require this type of price disclosure, as well as any reference in these statutes to regulate this type of advertising. Critics have also argued that recent legislative **efforts** to require drug price disclosure in DTC advertising demonstrates that Congress thinks the agency currently lacks authority to implement the new rule. On the other hand, CMS has **maintained** that **various Medicare and Medicaid** provisions reflect the idea that the health care programs should be administered in a way that minimizes unnecessary health care expenditures, and the rule is in concert with this goal. Accordingly, the agency has claimed that its rule is within the scope of its authority, given the “clear nexus” between the requirements of the rule and Congress’s explicit recognition of the importance of operating Medicare and Medicaid programs in this manner.

Another issue that may be relevant to the initial question of CMS’s authority to promulgate the drug price disclosure rule is the regulatory scheme for prescription drug advertising under the **Federal Food, Drug, and Cosmetic Act** (FD&C Act). Under one general principle of statutory interpretation, *expressio unius est exclusio alterius*, courts **may determine** that the expression or inclusion of one thing in a law implies the exclusion of others. The FD&C Act generally tasks the Food and Drug Administration (FDA) with oversight of prescription drug advertising, including television advertisements. Under the FD&C Act, DTC advertisements must generally **contain** certain information about a medication’s uses and risks, and drug information must be clearly and accurately conveyed. However, the FD&C Act and accompanying **regulations** do not compel inclusion of drug price information in these advertisements. Additionally, FDA has **previously indicated** that its role in pharmaceutical advertising oversight does not include regulation of drug prices, and that the “decision to engage in public disclosure of prescription drug prices is not for the [FDA] to make.” Relying on the FDA’s role with DTC advertising, commentators **have maintained** that CMS lacks authority to regulate prescription drug television advertising, as Congress expressly gave a more limited power to regulate drug advertising to FDA under a different statute. In the preamble to the final rule, however, CMS responds that the FDA’s role in regulating prescription drug advertising does not preclude CMS from imposing a drug price disclosure requirement under Medicare and Medicaid. Specifically, the agency has **argued** that “given CMS’s role as an agency that reimburses for drugs, it is appropriate that CMS impose the price disclosure requirement, as it is the Medicare and Medicaid programs that bear the cost of drugs with excessively high prices.”

Assuming a reviewing court deems agency interpretation appropriate and proceeds with a *Chevron* analysis of the rule, the court would likely examine the language of the sections 1102 and 1871 to determine whether the text of the statute clearly authorizes the CMS rule. As noted above, should a reviewing court determine that it is ambiguous whether statutory text of the Medicare and Medicaid Acts authorizes CMS to issue the drug-pricing rule, a reviewing court could then defer to CMS’s interpretation of its statutory authority, so long as its interpretation is reasonable. CMS has generally alleged that the rule complies with the first step of the *Chevron* test because the text of sections 1102 and 1871 provide the agency with broad authority to promulgate rules that promote the efficiency of Medicare and Medicaid. The agency has also stated that the rule warrants judicial deference under *Chevron* step-two, as well as the *Mourning* case, as the rule is a reasonable means of improving the efficient administration of Medicare and Medicaid by providing beneficiaries with “relevant information” about prescription drug costs, so that beneficiaries can make informed decisions that lower costs for themselves, as well as the health care programs.

In evaluating these assertions, a reviewing court’s *Chevron* step-one analysis of sections 1102 and 1871 of the SSA could hinge on how the court construes the term “necessary” in the context of these provisions. As noted above, sections 1102 and 1871 of the SSA generally grant CMS the authority to issue regulations “necessary” to administer the Medicare and Medicaid programs. In general, courts **interpret** statutory terms in accordance with their ordinary or natural meanings, unless Congress explicitly indicates

otherwise. In the preamble to the final rule, CMS expressed that its regulation is “necessary,” because, in the agency’s view, it is a reasonable means of improving the efficient administration of the health care programs. However, opponents of the rule have generally [argued](#) that while the rule may generally help promote drug price transparency and efficient pharmaceutical markets, list price disclosure is not “necessary” (i.e., critical) to the specific functions of the health care programs themselves.

If a court reaches the second step of the *Chevron* test, it is [more likely](#) that the court would accept CMS’s argument concerning the reasonableness of its price disclosure rule. The Supreme Court has historically [concluded](#) that agencies are entitled to substantial deference in implementing policy decisions under regulatory regimes, such as those created by the Medicare and Medicaid statutes, which are “technical and complex.” A court’s analysis of the reasonableness of the CMS rule may also consider use of list price (or the WAC) as the price that must be disclosed to the public. As noted above, for many drug consumers, the WAC will not reflect the actual price that the consumer will pay out-of-pocket for a drug. For example, under the Medicaid program, beneficiaries [typically pay](#) a small co-payment for prescription drugs or nothing at all. While CMS has averred that the WAC is meaningful, in that it is an “anchor price” from which consumers can make comparisons about therapeutic options, others have [claimed](#) that publicizing the WAC will mislead consumers about the amount the consumer must pay for a drug, and consequently discourage them from discussing these medications with their health care providers or from having their prescriptions filled. Nonetheless, courts [frequently](#) adopt an agency’s views on questions of policy at the second step of the *Chevron* analysis.

Accordingly, the new CMS rule raises a number of complex issues of administrative law and statutory interpretation. And it appears that a court will soon grapple with these issues. On June 14, 2019, three pharmaceutical manufacturers and an advertising industry association filed a [lawsuit](#) challenging the validity of the CMS rule. The plaintiffs also requested that the court stay the effective date of the rule pending judicial review, and expedite review of the case. The judge in this case [has reportedly agreed](#) to act quickly, and has indicated that he will issue a decision on the motion to stay the case by July 8, 2019.

Drug Price Disclosure to Consumers and the 116th Congress

The CMS rule takes place against the backdrop of broader congressional deliberations over drug price transparency measures. Currently, the 116th Congress is considering an array of legislative proposals relating to prescription drug spending, and several of these bills include provisions designed to make drug pricing information more readily accessible to consumers. This legislation would require disclosure of drug pricing information to consumers through television advertisements or other formats. Perhaps most relevant to the CMS rule, proposed legislation would, if enacted, resolve many of the statutory questions surrounding CMS’s authority over drug price disclosures by codifying the agency’s authority. Specifically, [S. 1437](#), the Drug-Price Transparency in Communications (DTC) Act, would require that each DTC advertisement for a prescription drug or biological product for which payment is available under Medicare or Medicaid include “an appropriate disclosure of truthful and non-misleading pricing information with respect to the drug or product.” The legislation would instruct the HHS Secretary, through CMS, to determine the applicable forms of advertising and requisite price information for the disclosure.

Other bills would take a different approach to the transparency issue. Examples include [S.1664](#), the Prescription Drug Price Reporting Act, which would direct prescription drug manufacturers to submit WAC and other drug-related information to the Secretary of HHS. HHS would then have to post submitted information on a publicly available online database. Another example, [H.R. 2115](#), the Public Disclosure of Drug Discounts Act, would require the HHS Secretary to make available on the agency website specified information submitted from [pharmacy benefit managers](#), including information on rebates, discounts, and price concessions that PBMs negotiate with drug manufacturers. The [intent](#) of this bill is to allow the public to compare the price reductions that PBMs receive and the impact these

reductions have on drug prices. Unlike the advertising requirements in S. 1437 and the CMS rule, these legislative proposals would require consumers to proactively seek out drug price data from a publicly available website, and Members of Congress may consider questions of policy in evaluating the appropriate vehicle for communicating this information.

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