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CMS Issues Proposed Rule to Require Disclosure of List Price in Direct-to-Consumer Advertising for Prescription Drugs and Biological Products

On October 15, 2018, the Centers for Medicare & Medicaid Services ("CMS") released a proposed rule regarding the disclosure of pricing information in Direct-to-Consumer ("DTC") television ads for prescription drugs and biologics reimbursable by Medicare and Medicaid. The proposed rule would amend relevant Medicare and Medicaid Regulations to require DTC television ads (including broadcast, cable, streaming, and satellite communication) of prescription drug and biological products for which reimbursement is available through or under Medicare and Medicaid to include the list price, defined as the Wholesale Acquisition Cost ("WAC"), of that drug or biological product. More specifically, the proposed rule would:

- Apply to any prescription drug or biological product with a list price of at least $35/month for a 30-day supply or typical course of treatment that is distributed in the U.S. and for which payment is available under Medicare or Medicaid;
- Require television ads for such covered pharmaceuticals to contain a textual statement indicating the WAC for a typical 30-day regimen or a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or broadcast 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."
- Require that the disclosure use the most current list price as of the date of publication/broadcast and use the list price for the "course of treatment" associated with the primary indication advertised if the price is related to a "typical course of treatment" that depends on the drug's prescribed indication;
- Require that the disclosure appear at the end of the ad in a legible manner against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily; and
- Allow the Department of Health & Human Services ("HHS") to maintain a public list of drugs and biological products advertised in violation of the rule.

Notably, although the HHS Secretary would maintain a public list of drugs and biological products identified to be in violation of the rule, the proposed rule would not provide any HHS-specific enforcement mechanism for noncompliance. CMS "anticipate[s] that the primary enforcement mechanism will be the threat of private actions under the Lanham Act" for unfair competition in the form of false or misleading advertising. CMS asserts that "the Lanham Act … is the most appropriate mechanism for enforcing against deceptive trade practices."

Among other things, CMS seeks comments regarding the price disclosure statement's content, whether the regulation should apply to other forms of media, whether compliance with the rule should be a condition to payment from federal health programs, whether CMS's proposed compliance regime and reliance on private civil actions under the Lanham Act is appropriate and effective, whether WAC best reflects list price, whether a 30-day supply and typical course of treatment are appropriate metrics, and how list price disclosure may influence patient interactions with prescribers, the selection of drug products, and perceived drug efficacy. Comments are due by December 17, 2018.

Scope of CMS Authority to Issue the Rule

Despite the absence of specific authority to issue regulations related to drug pricing transparency, CMS is issuing the proposed rule pursuant to sections of the Social Security Act that provide HHS with the authority to issue regulations "for the efficient administration of functions" under the Act and "as may be necessary to carry out the administration of the insurance programs" under Medicare.

Parties commenting on the proposed rule may wish to address whether communications between manufacturers and prospective patients, which are relatively remote from CMS's insurance programs, are within the scope of CMS's rule-making authority under the cited provisions. It would appear that HHS believed that tying the proposed rule to Medicare/Medicaid, government programs in which companies choose to participate and seek reimbursement, would provide HHS with a stronger basis for asserting authority to issue this rule than trying to tie it to the authority of the Food and Drug Administration ("FDA") to regulate drug advertising and promotion under the Federal Food Drug and Cosmetic Act ("FDCA"). While the FDCA provides FDA with the authority to regulate certain aspects of prescription drug advertising and promotion, FDA arguably lacks the statutory authority to require such disclosure absent a finding that the lack of pricing information constitutes "misbranding" or is otherwise non-compliant with FDCA requirements in relation to disclosure of safety-related information.

First Amendment Considerations

Apparently anticipating that the proposed rule will elicit objections under the First Amendment, CMS takes the position that requiring the disclosure of pricing information in DTC television advertisements is consistent with First Amendment jurisprudence. Specifically, CMS asserts that regulations concerning disclosures of "factual, noncontroversial information" in commercial speech may be subject to more deferential First Amendment scrutiny. Relying on, among other precedents, the Supreme Court's 1985 decision in *Zauderer v. Office of Disciplinary Counsel*, CMS states that courts have upheld required disclosures of factual information in commercial speech where the disclosure requirement reasonably relates to a government interest and is not unjustified or unduly burdensome such that it would chill protected speech.

In considering the strength of the government's First Amendment arguments and potential challenges, a key consideration is the appropriate standard of review. The level of scrutiny that is ultimately applied would be a major factor in determining the likelihood of success of any challenge to the CMS proposed rule. Depending on the nature of the speech regulation and context, various standards of review may apply, including in order of greater to lesser scrutiny: strict or heightened scrutiny, the traditional commercial speech test (the *Central Hudson* test), and the *Zauderer* test.

One important difference between the standards is how strong the government's interest must be in order to justify the regulation. For example, if analyzed under heightened scrutiny or the *Central Hudson* test, a challenger could assert that the government has no substantial, much less compelling, interest in deterring the usage and reimbursement of prescriptions for FDA-approved products that licensed healthcare providers determine are medically appropriate to prescribe. The strength of any such asserted interest would appear even weaker in light of the fact that the pricing information required to be provided to consumers bears little to no relationship to the cost the consumer would actually experience. One could even argue that CMS is deterring FDA-approved uses through the compelled dissemination of information that is false or misleading. Notably, while to our knowledge no regulator or plaintiff has ever contended that the omission of WAC from advertising rendered that advertising false or misleading, in several instances claims have been asserted that a "list price" was, at least in context, misleading. If the regulation is required to satisfy a more demanding level of governmental interest, these weaknesses could be determinative.

Another critical difference between the standards of review is the required degree of fit between the CMS proposed rule and the objective it is attempting to achieve. If, for example, *Zauderer* applies, the government must only prove that its

method is "reasonably related" to its interest; if *Central Hudson* applies, the regulation must "directly advance" the interest and not be "more extensive than necessary." The case law is clear that the *Central Hudson* standard is significantly stricter than the *Zauderer* standard of review (which is akin to rational basis review). If *Central Hudson* scrutiny—or an even more heightened level of scrutiny—were applied, it would be easier to point to alternative options (*e.g.*, making pricing information available to consumers by providing website links) and suggest that the government was not reasonably tailoring its regulation to meet its objectives.

Lanham Act Considerations

CMS has indicated that it expects the primary enforcement mechanism for the proposed rule will be the threat of private Lanham Act challenges. While the Lanham Act can act as a private enforcement mechanism, complementing federal labeling and advertising requirements, enforcement of this proposed rule may be significantly limited due to the standing requirements and elements of a Lanham Act claim.

With regard to standing, consumers do not have standing under the Lanham Act, and challenges would need to be brought by competitors or others who can demonstrate commercial harm caused by the defendant's advertising. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1395 (2014). Competitors may also lack standing in many instances if they are not harmed by a particular advertisement's omission of list price.

Another key limitation of the Lanham Act is that, in general, omissions (*e.g.*, omission of list price) can be actionable under the Lanham Act only to the extent the advertising contains affirmative statements that, while literally true, may be misleading to an appreciable percentage of the audience in the absence of the information that has been omitted.

State Law Preemption

With respect to preemption of state laws, CMS's proposed regulations state that "[n]o State or political subdivision of any State may establish or continue in effect any requirement that depends in whole or in part on any pricing statement required by this subpart." In the preamble, CMS further explains that its proposed rule is intended to preempt state-law-based claims to enforce the new disclosure requirement as follows: "consistent with our not including any HHS-specific enforcement mechanism in this proposal, we are proposing . . . that this rule preempt any state-law-based claim which depends in whole or in part on any pricing statement required by this rule." CMS implies that, in contrast with sophisticated competitors bringing suit under the Lanham Act, allowing state-law-based claims, which can often be brought by consumers, would "increase transactional costs in defending meritless litigation" and thus undermine its "broader initiative to reduce the price to consumers of prescription drugs and biological products."

The precise scope of preemption by the CMS rule is unclear. Some state-law-based claims, such as a claim brought under California's well-known Unfair Competition Law, Bus. & Prof. Code §17200, would potentially provide a more effective avenue for challenging a competitor's omission of pricing information than the Lanham Act. *See also, e.g., Stutman v. Chem. Bank*, 731 N.E.2d 608, 611-612 (N.Y. 2000) (stating an omission can be a deceptive practice under NY General Business Law § 349); *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584, 595 (Ill. 1996) ("An omission or concealment of material fact in the conduct of trade or commerce constitutes consumer fraud [under the Illinois Consumer Fraud Act]."). Notably, however, we are unaware of such statutes ever having been invoked to challenge a pharmaceutical or biologic manufacturer's omission of list price from DTC advertising. If such a challenge were brought now, it would strongly appear that such a claim would be the kind of attempt to enforce the CMS rule that CMS seeks to preclude. The effect of the rule on existing (or future) state pricing transparency legislation is not specified, an issue on which clients may want to seek clarity.

Other Considerations

There are a number of questions regarding the impact of the proposed rule that will require further consideration in addition to those highlighted above. These additional considerations include, for example:

- The impact of failure to provide pricing information on the ability of companies to certify to compliance with law as required by a corporate integrity agreement or in other similar contexts;
- Potential False Claims Act implications of noncompliance;
- Potential Medicare/Medicaid exclusion implications of noncompliance;
- Interaction of the proposed rule with PhRMA's voluntary disclosure program announced October 15, 2018, under which member companies will (by April 2019) voluntarily include information in DTC television ads directing consumers to information about drug costs, including list price, estimated out-of-pocket costs, and availability of financial assistance; and
- FDA considerations, including (1) whether television ads would need to be resubmitted to FDA for review every time the WAC is revised and (2) the extent to which additional voluntary pricing information could be included in an advertisement without being considered misleading (*e.g.*, inclusion of competitor pricing information or information on estimated out-of-pocket costs).