care of a specialist, whereas another might benefit from remedial specialty care for a complication resulting from inadequate primary care. Although the specialists in both of these cases might report an episodic and focused relationship to the patient, the attribution of costs — and, ultimately, the assessment of each provider's performance on cost-related measures and the resulting payment adjustment — would be expected to be very different.

CMS's deliberate pace in rolling out the patient relationship codes affords an opportunity to anticipate and address these potential consequences. First, we believe the codes should be validated to verify their accuracy and reliability in routine use, with periodic auditing to help minimize the potential for moral hazard among clinicians. The resulting attribution of costs should also be validated, most likely by reviewing clinical charts. It will also be important that the use of patient relationship codes by providers who care for patients with particularly complex conditions or people of low socioeconomic status receive additional scrutiny to ensure that the codes do not inadvertently penalize such providers. Finally, we believe that the codes should be tested in conjunction with recently finalized care episode and patient-condition groups and codes,[5] thereby leveraging the opportunity to attribute the care episode itself, in whole or in part, to clinicians who are part of a multidisciplinary team. To explore these issues, CMS might consider mandating reporting in a limited geographic area, paying physicians to participate but not holding them financially liable for results. The CMS Innovation Center would be well positioned to run such a test. Underlying all these recommendations is the critical need for clinician participation during the voluntary reporting period — including communication of feedback to CMS.[4]

The relationship between clinicians and patients is central to the practice of medicine, and attempts to codify it must be approached with care. At the same time, the evolution of health care payment models toward rewarding value over volume necessitates an objective determination of the roles of various clinicians — and, ultimately, their shared accountability for costs — in the course of caring for a patient. The patient relationship categories and codes implemented under MACRA represent a first step toward this goal. Now our task should be to vet, validate, and iterate on this approach.

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Disclosing Prescription-Drug Prices in Advertisements — Legal and Public Health Issues

Stacie B. Dusetzina, Ph.D., and Michelle M. Mello, J.D., Ph.D.

On October 15, 2018, the Centers for Medicare and Medicaid Services (CMS) proposed a rule requiring television advertisements for prescription drugs and biologic products to disclose the product's price.[1] The advertisements must state in legible text the wholesale acquisition cost (WAC) for a 30-day supply or a typical course of treatment.

The rulemaking follows an un-

successful effort in Congress to include a similar measure in the fiscal year 2019 appropriations bill. The idea enjoys broad public support — in a June 2018 poll, 76% of Americans favored requiring drug advertisements to include a statement about how much the drug costs[2] — and it dovetails with moves to improve price transparency in other health care domains. But we think the proposed rule raises substantial public health and legal concerns.

Direct-to-consumer advertising is a natural target for regulation because it stimulates demand for expensive, brand-name drugs when there may be less-expensive generic drugs with similar efficacy and side-effect profiles already available, thus increasing the provision of cost-ineffective care.[3] Yet such advertising could also stimulate undertreated patients to seek medical attention and effective therapies. For example, of the 14% of people in the same poll who reported speaking with their doctor about a specific medication after hearing or seeing an advertisement, the majority (55%) received a prescription for the advertised product, but respondents also said that providers recommended other prescription drugs (54%), over-the-counter drugs (41%), or lifestyle changes (54%).[2]

The CMS proposal reflects a desire to preserve the potential benefits of direct-to-consumer advertising while curbing its ill effects. However, a potential unintended consequence of price disclosure may be to dissuade patients from seeking care because of the perception that they cannot afford treatment. For example, Trulicity (dulaglutide), a widely advertised drug for type 2 diabetes, has a WAC (or list price) of $730 per month. Patients who could benefit from diabetes treatment may assume that they cannot afford it, when in fact insured patients' costs for Trulicity may be much lower, and cheaper treatment options are available (metformin, for instance, costs $4 per month for patients who pay cash). Consequently, the proposal carries a risk of undercutting the main public health benefit of direct-to-consumer advertising: reducing rates of undertreatment.

That CMS chose the WAC as the figure that must be disclosed makes this risk especially acute. The WAC is a good estimate of what uninsured patients can expect to pay, and deductibles and coinsurance are commonly based on a drug's WAC. However, this price is typically much higher than what insured patients pay. For example, 1 month of treatment with the anticoagulant Eliquis (apixaban) has a list price of $419, but out-of-pocket prices range from $10 for commercially insured patients using the manufacturer's copayment card to $147 for Medicare beneficiaries in the Part D coverage gap (see table). Although CMS will require a statement noting, "If you have health insurance that covers drugs, your cost may be different," this wording doesn't communicate that costs to patients are probably much lower than the WAC.

CMS used the WAC for several reasons. List prices matter for many patients, and having to disclose list prices creates incentives not to raise them. Moreover, it is impracticable to state what patients will actually pay because of variation in insurance design and coverage and the fact that rebates and discounts may not be determined when advertisements are made.

The rule's use of list prices also has important legal implications. Disagreement about whether the WAC accurately represents a drug's price could affect how courts assess the rule when constitutional challenges are inevitably filed.

Despite the problems associated with requiring disclosure of list prices, the sentiment behind the proposed rule — that patients should know how much drugs will cost before they fill their prescriptions — is sensible.

Compelled disclosures in advertising impinge on commercial speech rights protected by the First Amendment. However, courts apply a deferential standard of review known as the *Zauderer* standard in challenges to disclosures of "purely factual and uncontroversial" information relating to an advertiser's products or services. Although CMS characterizes its requirement as falling squarely within *Zauderer*, there is a strong argument to the contrary.

Courts applying *Zauderer* have taken a narrow view of what constitutes a factual, uncontroversial

Prices for a 30-Day Supply or Typical Course of Treatment for the Top 10 Pharmaceutical Brands According to National Television Advertising Expenditures in 2017.*

Brand Name	Generic Name	Indication	Quantity and Dose	WAC ($)†	Price for Patients Paying Cash ($)‡	Out-of-Pocket Prices for Medicare Beneficiaries ($)§
Humira	Adalimumab	Rheumatoid and psoriatic arthritis	Two 40-mg/0.8 ml pens	4,872.03	4,846.48	259.00–1,544.00
Lyrica	Pregabalin	Nerve pain	Ninety 75-mg capsules	668.84	656.54	74.00–198.00
Xeljanz	Tofacitinib	Rheumatoid and psoriatic arthritis	Sixty 5-mg tablets	4,095.64	4,075.52	220.00–1,350.00
Trulicity	Dulaglutide	Type 2 diabetes	Four 1.5-mg/0.5 ml pens	730.20	632.06	74.00–223.00
Eliquis	Apixaban	Anticoagulation	Sixty 5-mg tablets	419.03	424.65	74.00–147.00
Keytruda	Pembrolizumab	Cancer	Three 50-mg vials	4,649.64	6,710.52	0.00–1,480.53
Xarelto	Rivaroxaban	Anticoagulation	Thirty 20-mg tablets	419.07	424.68	74.00–146.00
Taltz	Ixekizumab	Plaque psoriasis and psoriatic arthritis	One 80-mg/ml autoinjector	5,161.60	5,134.02	317.00–1,660.00
Breo	Fluticasone and vilanterol	Chronic obstructive pulmonary disease	Sixty 100-μg/25 μg blister strips	341.04	346.95	74.00–141.00
Cosentyx	Secukinumab	Psoriatic arthritis	Two 150-mg/ml Sensoready pens	4,712.38	4,687.95	260.00–1,500.00

* Data were obtained from FiercePharma. The Quantity and Dose column indicates the monthly or typical supply for indications listed.
† Data were obtained from IBM Micromedex. WAC denotes wholesale acquisition cost.
‡ Data were obtained from GoodRx.com.
§ Data were obtained using the Medicare Part D Plan Finder for ZIP code 37205 (Nashville) for patients on traditional Medicare without subsidies. Because Part D requires patients to pay different amounts as they transition across benefit phases, we identified the most and least expensive monthly prescription-fill prices for the patient on the lowest-cost plan. For Keytruda, covered under Medicare Part B, we used the 2018 average sales price for a typical dose. We assumed that patients with supplemental Part B coverage would pay nothing and those without it would pay 20% coinsurance, the standard level for Part B services.

disclosure. For example, the Ninth Circuit Court of Appeals, reviewing a required warning that drinking sugary beverages contributes to obesity, diabetes, and tooth decay, held that because the disclosure did not state that overconsumption of beverages was the problem, it was "misleading and, in that sense, untrue."[4] Similarly, the WAC is not a factually accurate representation of what a drug costs for most patients, and the disclosure omits key information. This fact sets it apart from other fee disclosures that have survived legal challenges, such as the basis for calculating attorney fees and the amount of interest charged on loans.

If a compelled disclosure doesn't qualify for *Zauderer* review, courts will apply heightened scrutiny. The most likely standard, *Central Hudson*, asks whether the government has a substantial interest that is directly and materially advanced by the speech restriction and whether the restriction is narrowly tailored to achieving that goal. Although the disclosure rule is narrowly tailored to the government's substantial interest in reducing unreasonable expenditures by CMS programs, it probably doesn't satisfy the material-advancement requirement. Courts have required the government to provide evidence that a required disclosure will effectively address the problem it targets. Graphic warning labels on cigarettes, for example, were struck down because the government's regulatory-impact analysis suggested that they would reduce the U.S. smoking rate by only 0.088%.[5] CMS offered no evidence of the likely effects of the proposed drug advertising price disclosure rule, noting only that it "may" improve consumer decision making but could also create confusion and that CMS could not quantify these effects.[1]

Three aspects of the rule undercut the government's ability to argue that it will materially improve patient decision making and reduce drug spending. First, price information does little to inform

consumer decisions if it inaccurately represents actual cost. Second, consumers can already obtain information on cash prices (which usually approximate list prices) online and their own cost from their insurer. CMS could argue that disclosing the WAC may advance the agency's interest in reducing Medicare and Medicaid spending in another way: by shaming companies into lowering list prices. But since Medicare and Medicaid don't pay list prices, this outcome seems implausible.

Third, the rule contains no meaningful enforcement mechanism — CMS plans only to list violators on its website — calling into question whether companies will comply. CMS believes that the main lever for inducing compliance will be private litigation: competitors can sue violators under the Lanham Act, which prohibits false or misleading representations in advertising or promotion. But such suits are not a robust means of enforcement. Omissions don't qualify as falsities under the law unless they create an erroneous belief among consumers. What false belief arises from not stating a product's price? Furthermore, the competitor must show that the falsity caused it to lose sales — a challenging task, since patients and prescribers may prefer one drug over another for various reasons.

Despite the problems associated with requiring disclosure of list prices, the sentiment behind the proposed rule — that patients should know how much drugs will cost before they fill their prescriptions — is sensible. The question is how best to achieve that outcome. Just before the CMS rule was announced, the main trade organization of the pharmaceutical industry, PhRMA, released its own guidelines for voluntary disclosure of the costs of advertised medicines. It proposes that advertisements direct patients to a website where the company provides information about list price as well as "average, estimated, or typical patient out-of-pocket costs." This information is more useful than the WAC alone, but "typical" out-of-pocket costs don't convey the variation in what patients pay.

We think that a better alternative would be making patient-specific cost information accessible at the point of prescribing. Some electronic health records systems now offer this feature, but it is unclear how often prescribers use it. We think that cost should become a routine part of prescribing discussions with patients, although time constraints could make it difficult to have such conversations. Providing salient cost information at the right time could help reduce drug spending while preserving patient choice, but we believe that direct-to-consumer advertising is the wrong vehicle.

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Remembering William

Britt Hultgren, B.A.

Her body swam with critically elevated levels of ammonia and bilirubin; her Model for End-Stage Liver Disease (MELD)-Na score gave her greater-than-even odds of dying within 3 months. She needed a liver transplant, but didn't qualify. As a fourth-year medical student, I had more free time than the rest of my team, so I volunteered to talk with the patient and her husband to clarify her prognosis and options. Although I felt like I'd bungled everything, the husband thanked me as I was leaving. Later, ambling down the hall, I thought about my words and gestures. What little I'd done right — a merciful silence, taking her hand, acknowledging her husband's pain