ISPOR
The professional society for health economics and outcomes research

Improving healthcare decisions

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The Honorable Alex M. Azar II
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Azar:

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is pleased to respond on behalf of its membership to the U.S. Department of Health and Human Services call for comments on "RIN 0938-AT87: Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency." We strongly agree that these are important issues to address with input from a wide variety of stakeholders, and thank the Department for
this opportunity to provide our comments.

ISPOR is a scientific and educational society with many of its members engaged in some aspect of health economics and outcomes research (HEOR) related to evaluation of pharmaceuticals. Our membership includes over 20,000 individuals across a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government (including some HHS employees), and health technology assessment bodies. The research and educational offerings presented at our conferences and in our journals are relevant to many of the issues and questions raised in this request for information.

As you will see below, we have chosen to respond only to selected questions in your call for comments. We selected those areas and questions which we feel are best informed by the research and expertise of our disciplines and our membership. This response was formulated with the assistance of ISPOR's most senior and representative Council, the Health Sciences Policy Council, and informed by a survey of our full membership. It was reviewed by and approved by our current President and myself.

ISPOR would be happy to answer any questions about our response, as well as to participate in any follow-up consultations on these issues. Please consider Richard Willke, PhD, our Chief Science Officer, as the contact person in this area.

Sincerely,

Nancy S. Berg
CEO & Executive Director

RIN 0938-AT87
Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency

ISPOR is very supportive of efforts to improve the information that patients receive about their health care, including economic information. In addition, our members have told us that they see drug spending and pricing as the top health policy issue of the coming year. This proposal to include list prices in direct-to-consumer advertising for drugs can help address both of those areas. That said, there are certain elements that deserve careful consideration to ensure that they would have the desired positive impact on patient medication behavior and health outcomes. We hope our comments on selected questions below are helpful in that regard.

1. (p. 24) whether 30-day supply and typical course of treatment are appropriate metrics for a consumer to gauge the cost of the drug.

Response: While the 30-day supply and typical course of therapy approach seems practical on its face, there are several factors that should be considered due to their potential to confuse patients. First, even for chronic/maintenance medications where a 30-day course is standard, in some cases different dosages have different costs, and dosages can be based on patient-specific factors. More importantly, however, for many medications, such as anti-infectives, chemotherapy, long-acting therapies, and others, the course of treatment can vary by indication, titration period, disease severity, patient response to treatment, and other patient-specific factors. If differences in length of treatment are the primary source of variation, one could indicate the average cost per month of treatment (or the total cost for treatment if the treatment duration is typically less than one month). If there are other major sources of variation, stating the average cost for a month or even for a "typical" course of treatment could significantly mislead the patient regarding their own expected or actual cost.

An alternative is to provide a range of costs rather than a single cost, e.g., "for most patients, a 30-day supply cost is between X and Y", or "for most patients, a course of therapy can be expected to cost between X and Y." However, defining and estimating that range would then have to be done using parameters that may vary by treatment situation (e.g., does "most" mean 90%, 95%?); for drugs with significant market experience, an empirical approach may be feasible. One would also have to study how patients interpret a range of potential costs since it is relatively uncommon for costs to be presented in this manner.

2. (p. 24) how to treat an advertised drug that must be used in combination with another non-advertised drug or device.

Response: While the need to use the advertised drug in combination with another drug or device should be disclosed to the consumer, specifying the cost of the combination can add a significant additional degree of variability and potential confusion. There may be some fixed combinations where indicating the combined cost could be reasonably reliable. However, in most cases it would seem more practical to simply state that the drug must be used in combination with another treatment and that the patient should consult their doctor or pharmacist (or insurance company) about the full cost of treatment.

3. (p.24) whether the cost threshold of $35 to be exempt from compliance with this rule is the appropriate level and metric for such an exemption.

Response: Setting a cost threshold does not seem practical for several reasons. First, as indicated in our previous answers, costs can vary considerably by patient, disease situation, and drug type. Second, ability-to-pay can also vary by patient, so even $34 could seem significant to some patients. Also, a drug with a low price may want to advertise its low price. Realistically, few prescription drugs that will be the subject of DTC ads are likely to cost less than $35 per month.

4. (p. 26-27) whether manufacturers or others submitting additional information such as list price, typical out-of-pocket cost, therapeutic alternatives, pharmacoeconomic research, and other data could be helpful for consumers and what information would be most useful.

Response: While transparency and making information available to patients is generally desirable, putting information that may need expert assistance in interpretation directly in a direct-to-consumer (DTC) advertisement may be confusing or misleading for many patients. Some of this information, like pharmacoeconomic research, is currently not generally permissible in advertising to the general public. A long-term goal could be to have such information, well-reviewed and presented at an appropriate level for patients, available on an independent website that could be cited in DTC ads.

5. p.38) What would be the effect of this potential advertising reduction on patient behavior, including as regards the information they seek out from their medical providers?

Response: Economic studies have made it clear that DTC advertising (DTCA) increases spending on prescription drugs, increases doctor visits, and increases prescribing rates [1 and references therein], so reduced advertising would presumably decrease those same things. A 2004 FDA consumer survey found that exposure to DTCA prompted 27% of Americans to make an appointment with their doctor to talk about a condition they had not previously discussed [2 and references therein]. While in some cases the patient is then prescribed the advertised drug, they are also commonly prescribed an alternative [3]. There is also evidence that "the majority of physicians (67%) and patients (54%) report that DTCA positively affects physician–patient discussions and interactions, and most agree that DTCA can prompt important discussions " [4 and references therein]. On the other hand, "in nationally representative surveys, 39% of physicians and 30% of patients felt that DTCA interferes with the physician–patient relationship", and controversy about the overall effect of DTCA on medical-decision making remains [4].

6. (p. 38) How might patient outcomes vary depending on advertising choices among competitor drug companies? For example, if only some producers of drugs that treat a particular condition cease advertising on television, are patients likely to switch between drug brands from the no-longer-advertised to the advertised? If all producers of drugs for a condition cease advertising on television, to what extent are patients likely to switch to other forms of treatment such as surgery or to forgo treatment?

Response: In terms of outcomes, if less DTC results in less drug utilization, some of that is likely to be less adherence to needed medications and the evidence is clear that this will be detrimental to patient health outcomes and is likely to increase overall health costs. On the other hand, there is also evidence that increased DTC can result in some inappropriate utilization and increase the incidence of adverse drug effects [1]. However, we did not find clear evidence about the effects of advertising choices among competitor drug companies of substitution across modes of therapy. If reducing DTC does reduce consultation with physicians as suggested by some studies (see the previous response), however, it would seem likely that patient knowledge of those other choices would often be reduced and thus they would be used less. On the other hand, for those patients who do consult with physicians, less DTC could mean that they may be less motivated to seek a particular drug treatment and thus may choose other treatment options. One suspects that the overall effect will vary by disease. Clearly more research to help understand the magnitude and incidence of these potential effects is needed.

In conclusion, we have two general comments here that are applicable across almost all of these comments. First, patients are most concerned about out-of-pocket costs. Second, most "list prices" do not represent the actual cost to the insurance plan. Given the range of insurance plans, it does not seem feasible to reliably convey either the potential out-of-pocket cost or the actual cost to the insurance plan in a brief DTC ad. It would be best to find a way to ensure that patients can differentiate between out-of-pocket costs and either actual or list prices in their decision-making – especially when value-based insurance designs deliberately keep out-of-pocket costs low in order to incent patients to take critical medications (e.g, see [3]). A negative "side effect" could be misinterpretation of costs that increases abandonment rates; a more positive outcome would be informed shared decision-making between patient and physician that results in better adherence to cost-effective medications.

Given the uncertainties present in several aspects of this plan, it may be useful to consider a pilot program, perhaps in a single therapeutic area, to gauge its effects on patients and clinicians as well as to get their feedback, before a full implementation is attempted. An alternative that could also be tested is provision of this information at an independent website that patients and physicians could reference in more depth before making treatment choices.

References

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2. C. Lee Ventola, MS. Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic? P T. 2011 Oct; 36(10): 669-674, 681-684.

3. Stacie B. Dusetzina, Ph.D., and Michelle M. Mello, J.D., Ph.D. Disclosing Prescription-Drug Prices in Advertisements — Legal and Public Health Issues. N Engl J Med 2018; 379:24; (Dec. 13): 2290-3.

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