

CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

December 17, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4187-P -- Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency

Dear Administrator Verma:

The undersigned cancer organizations of the Cancer Leadership Council appreciate the opportunity to comment on the proposed rule to require direct-to-consumer (DTC) advertisements of prescription drugs and biological products for which Medicare or Medicaid payment is available to include list price of the drug or biological product.

We support the ambitious concept of achieving transparency in health care pricing, as full and complete information about cost of care would inform patient decision-making. We have reservations about the current proposal to require inclusions of list price in DTC ads, because we do not think it will provide cancer patients meaningful information to inform their care choices or care planning. We do strongly support the suggestion to establish a separate code for doctor-patient communication that is included in the proposal, as long as that code supports a discussion of cost of care, treatment options, potential side effects of treatment, patients' quality of life concerns, and coordination of care.

The Centers for Medicare & Medicaid Services has projected very ambitious results from the requirement to include price in DTC ads. In the preamble to the proposed rule, the agency explains, "We are proposing this regulation to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs, but also unreasonable expenditures borne by Medicare and Medicaid, both of which are significant problems." In our comments below, we explain our concerns about whether the inclusion of prices in DTC ads will accomplish these ambitious goals. In addition, we offer a caution about the possibility that this plan will detract attention from other, perhaps more meaningful, efforts at enhancing health

care transparency and patient access to comprehensive information (including cost information) related to their treatment options.

In these comments, we do not address two assertions made by the agency. First, CMS asserts that the proposed rule creates a more competitive environment and the data “indicate that it will likely motivate manufacturers to be less willing to raise prices, which have dramatically increased over the past decade.”¹ Second, we do not challenge the position of the agency that this proposal is an appropriate regulation of commercial speech. Neither will we in these comments debate the merits and the risks of DTC ads for cancer drugs and supportive care medications, an active and ongoing debate in the cancer patient and provider community. Instead, we focus our comments on whether inclusion of list prices in DTC ads will empower patients.

We are not persuaded that inclusion of list prices in DTC ads will significantly benefit cancer patients, for these reasons:

- Patient cost-sharing for prescription drugs, rather than list price, is the relevant information for the patient making a treatment decision. It is the financial out-of-pocket costs of the patient that will be most important to the patient in making a treatment decision that takes into account potential financial toxicity to the patient. Understanding a patient’s direct cost-sharing will require knowing the terms of his or her insurance plan, coverage for the drug in question, and applicable cost-sharing. We understand the position of the agency that list price may matter for those patients who have high-deductible plans and who may bear the full list price of drugs until their significant deductible is met. However, even in that situation the patient must understand the terms of his or her insurance plan and not just list price in order to understand the financial impact of drug choice.
- Providing list prices in DTC ads does not achieve meaningful price transparency for cancer patients. Cancer patients often receive a recommendation of multi-disciplinary care that includes but is not limited to drug therapy. They may also be in the position of evaluating a range of drug therapies. Relying on information about prices included in DTC ads will leave patients with woefully inadequate information about the cost of their care. Although there has been substantial growth in DTC advertising of cancer drugs in the last decade, many cancer drugs are not the subject of DTC ads. This means that the proposed rule would provide list price information for only a subset of possible drug therapies, and of course the proposal does not improve the transparency of prices for other elements of cancer treatment. As a result, the proposed rule provides cancer patients limited actionable price information. Financial toxicity is a key concern for cancer patients. Providing list price of drugs without context and without accompanying

¹ On this point, the agency cites John F. Cady, “An Estimate of the Price Effects of Restrictions on Drug Advertising,” 44 *Economic Inquiry*, 493-510, December 1976, and D. Andrew August and Jane G. Gravelle, “Does Price Transparency Improve Market Efficiency? Implications for Empirical Evidence in Other Markets for the Health Sector, CRS Report 46 (July 24, 2007).

information on individual cost-sharing may cause some patients to consider deferring treatment.

- The requirement for providing list price in DTC ads should not be seen as a plan that negates the need for other efforts to improve patient access to information that will assist them in treatment decision-making that considers cost of care. In cancer care, the Oncology Care Model (OCM) demonstration project includes a requirement that participating practices develop strategies for discussing cost of care with patients. The OCM requirement has reportedly triggered new strategies for cost communication by oncology practices. An important element of OCM is that practices will be evaluated on their efforts to improve cost of care communication, among other practice improvement efforts. We will hopefully learn more about what works well in cost communication and how to replicate the best strategies. The agency has placed significant emphasis on the plan to list price in DTC ads and seems to believe that plan holds great promise for affecting drug prices. We urge that, even if this plan moves forward, the agency not abandon additional efforts related to cost of care communication that may be more useful to people with cancer.
- Patients in active treatment should not be expected to shoulder the burden of influencing pricing policies with their treatment decisions. We are well aware that every single day, patients make decisions about treatment based on the cost of care to them. Cancer patients may find that they cannot afford the cost-sharing for a drug, even if they are insured. We are not naïve about the price of drugs and the burden of cost-sharing on cancer patients. Nonetheless, we resist the assumption that patients in active treatment – in clinics, infusion centers, or cancer centers – should make treatment decisions with the intent of influencing list price. Patients may choose to become policy advocates who seek to influence public policy and drug pricing policies. However, we do not think that this proposal should assume patients in active treatment will make decisions to influence drug pricing practices, and we certainly do not think that patients should feel pressure to make such decisions.

In the proposed rule, the agency states, “In an effort to incentivize provider engagement with patients on their prescription drug out-of-pocket costs, CMS could create a new payment code, in a budget neutral manner, for doctors to dialogue with patients on the benefits of drugs and drug alternatives.” We support this suggestion, with significant refinement. The cancer community has long sought the establishment of a new payment code for cancer care planning and coordination, to incentivize provider and patient engagement in treatment decision-making, to encourage the development of a plan of care, and to foster a care coordination process. Our proposal assumes that cost of care would be among the topics that providers and patients would discuss while reviewing treatment options and a plan of care. However, it would not be the only topic.

The patients we represent increasingly articulate the need for time with their cancer care team to review treatment options and also to fully understand the side effects of treatment, including possible financial toxicity. This need could be addressed by a new service (and new code) for treatment decision-making and care planning. Such a service would also support the demand for providers to discuss with patients the information that they may become familiar with through DTC ads, along with other information and questions that arise separate and apart from DTC ads.

The undersigned organizations support transparency in health care information, including information about cost of care. We believe that several different approaches to improving cost communication should be tested and evaluated, to advance patient access to information and enhance the treatment decision-making process and ongoing care coordination.

Sincerely,

Cancer Leadership Council

CancerCare
Fight Colorectal Cancer
The Leukemia & Lymphoma Society
LUNGeity
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Prevent Cancer Foundation
Susan G. Komen