



July 23, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs, File Code CMS-9905-NC

Dear Secretary Becerra,

I am writing to you on behalf of Susan G. Komen (Komen) to provide feedback on the Request for Information (RFI) Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (RFI). We hope that this effort to collect and publicly release information about the complex financial relationships between drug manufacturers, pharmacy benefit managers (PBMs) and issuers will assist policymakers in improving access and affordability of drug coverage for patients.

Komen is the world's leading nonprofit breast cancer organization representing the millions of women and men who have been diagnosed with breast cancer. Komen has an unmatched, comprehensive 360-degree approach to fighting this disease across all fronts—we advocate for patients, drive research breakthroughs, improve access to high quality care, offer direct patient support and empower people with trustworthy information. Komen is committed to supporting those affected by breast cancer today, while tirelessly searching for tomorrow's cures. We advocate on behalf of the estimated 284,200 women and men in the United States who will be diagnosed with breast cancer and the more than 44,130 who will die from the disease in 2021 alone.

Importance of Access to Drug Therapies for Breast Cancer Patients and Survivors

Reliable access to high-quality and affordable drugs is a critical part of treating individuals diagnosed with breast cancer. Patients with breast cancer are treated with some combination of surgery, radiation therapy, and cancer drugs. Drug therapy for breast cancer includes four main categories of drugs: chemotherapy, hormone therapy, immunotherapy and targeted therapy (a cornerstone of precision medicine). These therapies include brand-name and generic drugs, biologics and biosimilars, and we anticipate further development of options in each category. Each treatment option has risks and benefits. Treatment is tailored to the biology of the tumor, stage of breast cancer and the patient's overall health and preferences. Thus, patients must have access to all four drug categories throughout the course of treatment to ensure the best outcomes.

Access to drugs is vitally important, but these drugs must also be affordable. We know that cancer treatments can be very expensive and may require long-term monitoring and follow-up care, potentially exposing patients to significant financial hardship. More and more stakeholders in the cancer community are recognizing the financial toxicity associated with adhering to treatment as prescribed, which can not only expose patients to financial ruin but also negatively affect their health if they are

forced to delay or stop treatment or make suboptimal treatment decisions due to cost. Addressing financial toxicity and how it impacts patients' treatments and overall health is key to saving lives from breast cancer.

Comments on the RFI

In general, Komen supports efforts to promote transparency around drug costs, as well as how they are affected by the relationships between various actors in the drug development, delivery, and reimbursement system. We support efforts to ensure that patients have access to all necessary information about their care options and can better understand the factors affecting their drug costs. **It will be very important, however, to ensure that the public-facing reports you release based on this data include a disclaimer that individual patient costs and out-of-pocket expenses will vary by type of insurance and where a patient is relative to their deductible and out-of-pocket maximum.** It would be counterproductive or even harmful if increased transparency dissuades patients from filling prescriptions or forego treatment that they fear they cannot afford, when their particular financial and/or insurance situations will vary. Given their high costs, breast cancer treatments could appear among plan lists of their most expensive drugs, or drugs with price increases, making this a very important issue for our community.

Komen also believes that meaningfully reducing costs and improving patient access to treatments will require systematic and comprehensive reform. We appreciate that you intend to gather information from a broad group of stakeholders and further encourage you to carefully consider and query all aspects of the drug development, delivery, and reimbursement systems in this information request. This will provide policymakers and all stakeholders a more balanced understanding of the factors affecting drug prices. **In your data collection, we also urge you to examine the distribution of any negotiated savings within this system to better understand how policy can play a part in ensuring savings are passed on to the patient.**

Finally, Komen views all policymaking related to drug costs through the lens of its ultimate impact on patients and their out-of-pocket costs. We appreciate that you intend to ask questions about what financial relationships benefit patients, as well as the impact of patient assistance programs and co-pay accumulator programs. Many patients covered by private insurance plans rely on coupons and discounted drugs in order to afford their medication and we encourage you to not only assess any potential impact these programs may have on drug costs, but also – and much more importantly for the breast cancer community – their positive impact on facilitating patient access.

Conversely, in the case of co-pay accumulator programs, in which health plans institute policies that do not count drug manufacturer copay assistance towards a patient's annual deductible or out-of-pocket maximum, we encourage you to assess the impact and harms to patient access as a result of these programs. Unfortunately, patients are often unaware of these programs until they are faced with the daunting choice of paying a pharmacy bill that could be thousands of dollars or foregoing the medication they need. **We urge you to consider this practice when determining data collection and reporting requirements.**

Conclusion

We hear from patients every day who cannot afford their treatments and firmly support efforts to lower drug costs and improve the affordability and accessibility of cancer treatments. We appreciate the

opportunity to provide these comments on your efforts to promote greater price transparency in health care and hope that it will ultimately lead to policies that increase affordability and access.

If you have any questions, or we may be of further assistance, please do not hesitate to reach out to me at mguthrie@komen.org.

Sincerely,

Molly Guthrie
Senior Director, Public Policy & Advocacy
Susan G. Komen