Via Electronic Submission

April 8, 2019

Re: RIN 0936–AA08 Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees


ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

ASCO shares the Agency’s concern regarding rising drug prices, and we are eager to work with HHS on solutions that address these concerns. ASCO’s primary objective is to ensure timely access to necessary therapies for cancer patients. Therefore, we encourage thoughtful consideration of any efforts to address the high cost of drugs to ensure continued patient access to oncology care through lower out-of-pocket costs. While we agree that transparency is an important part of the process, we are also concerned that any savings that could result from enhanced transparency and other policies may not be passed along to the patient or may result in higher premiums. Because physicians do not set or control the launch price of drugs, we confine our comments to the area where physicians do play an important role: assuring access to the most appropriate anti-cancer drugs for the patients served by ASCO members.
Re: American Society of Clinical Oncology Comments
RIN 0936–AA08 Fraud and Abuse- Rebates and Safe Harbor Proposed Rule

As the Agency considers new policies it is imperative to guard against burdening patients with increased out-of-pocket costs that impede access to life-saving and life-extending cancer drugs.

Government funded prescription drug benefits, including Medicare Parts B and D and Medicaid, were established to promote robust access to prescription drug therapies at an affordable cost to beneficiaries. We applaud the Agency’s efforts to establish new policies that support this objective, including improving patient access to cancer therapies by reducing or eliminating barriers caused by financial relationships among managed care plans, pharmacy benefit managers, manufacturers, and pharmacies. More importantly, we applaud the Agency’s goal to ensure meaningful and immediate savings to patients at the point of care.

ASCO supports efforts to ensure that patients are aware of their most cost-effective option for purchasing needed medications. In addition to the proposed rule requiring transparency related to rebates, the Agency should continue to work to enforce the new law allowing pharmacists to tell customers when their cost would be lower if they purchase prescription drugs out-of-pocket rather than using their health insurance. The Patient Right to Know Drug Prices Act and the Know the Lowest Price Act prohibit so-called "gag clauses," and allow CMS to eliminate contractual requirements that prevent pharmacists from sharing with patients their most cost-effective option for purchasing necessary medications.

These proposals must be balanced, however, with patient protections that prevent payers from compensating for potential loss of revenue by increasing premiums or other out-of-pocket costs. Shifting the burden of lower revenue to patients in this way could disincentivize maintenance of the insurance coverage that ultimately protects them from catastrophic costs.

The impact analysis provided in the proposed rule acknowledges that not all beneficiaries will experience lower costs, particularly those with fixed co-payments that do not rely on changes to list versus net prices. The proposal also concludes that “if this rule closes the gap between list and net prices but leads to fewer price concessions, all beneficiaries could experience higher premiums with only some experiencing lower out-of-pocket costs.” Shifts in costs that result in higher financial burden for patients would pose significant access issues for cancer patients and must be avoided.

The ever-changing mix of rebates and discounts make it nearly impossible for cancer care professionals to anticipate how much prescribed treatments will cost their patients. It is critical that the Agency recognize the strong connections between financial burden, access, and quality. Patients unable to pay for life-saving and life-extending anti-cancer therapies are at significant risk for non-adherence to treatment—or foregoing treatment altogether. Abandoning treatment for reasons of affordability remains a major risk in cancer treatment, and the Agency should aggressively work to prevent this tragedy.

While pharmacy benefit managers (PBMs) may have potential to generate cost savings for payers and plan sponsors, it is not clear if and how those savings are passed along to patients. PBMs assert there is no link between drug price growth and the rebates they are receiving; however, the lack of transparency around rebate arrangements prevents verification of such claims. Scarce information is available about the size and frequency of rebates PBMs receive
from manufacturers. The extent to which patients experience actual benefits of these rebates and discounts is unclear. Transparency around PBM negotiated rebates and discounts, as well as tracking how the discounts are used to lower prices for patients must be a priority. Collection and publication of data would also help the Agency and providers understand the financial arrangements for which they are being asked to contract, ultimately helping to ensure patients are able to be fully informed about price differences and ways to obtain their drugs at the lowest cost.

ASCO has serious concerns regarding any proposed utilization management policy that is driven by cost alone. We are therefore deeply concerned about utilization management decisions that are tied to rebates and discounts. Tactics such as “fail first,” or step therapy, threaten patient lives by delaying or limiting timely access to the most appropriate treatment. In some cases, PBM practices and other payer policies stray into territory that interferes with the doctor-patient relationship and disrupts care. The need for greater transparency regarding these practices is clear and we support efforts to achieve this clarity.

Thank you for the opportunity to provide feedback on this important policy to protect certain point-of-sale reductions in price on prescription pharmaceuticals and certain pharmacy benefit manager service fees. We look forward to working with you on a solution to maintain affordable access to drugs for Medicare patients. Please contact Sybil Green at Sybil.Green@asco.org with any questions.