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April 8, 2019

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: OIG-0936-P– 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
84 Fed. Reg. 25 (February 6, 2019)

Dear Secretary Azar:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed rule concerning safe harbor protection for drug rebates in Medicare and Medicaid. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

More than 15.5 million Americans with a history of cancer live in the U.S. today.[1] Since age is one of the most important risk factors for cancer many of these cancer patients and survivors likely are enrolled or soon-to-be enrolled in the Medicare program. Additionally, approximately 2.3 million Medicaid beneficiaries have a history of cancer.[2] Therefore, changes to the costs of drugs in the Medicare and Medicaid programs have a profound impact on beneficiaries who are diagnosed with cancer and for cancer survivors.

Increasingly drug therapies – particularly oral medications – play an integral role in cancer treatment. Cancer patients and survivors rely on drug therapies to treat their disease and the treatment side effects, as well as to prevent recurrence. ACS CAN is committed to ensuring that all cancer patients receive the treatment that is medically appropriate for their disease. As discussed in more detail in this

[1] American Cancer Society, *Cancer Facts and Figures* 2019. Atlanta: American Cancer Society; 2019. Available at https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf.

[2] Analysis provided to ACS CAN by Avalere Health. Funding for Medicaid patients with cancer under BCRA Discussion Draft. Analysis performed June 2017.

letter, we believe that if the changes described in this proposal are implemented and monitored carefully, this rule has the potential to make drugs more affordable for cancer patients and survivors.

Affordability of Drugs is Key for Cancer Patients and Survivors

For persons with cancer, the costs associated with treatment are staggering. In 2014, cancer patients in the U.S. paid $4 billion out-of-pocket for cancer care.[3] Cancer patients enrolled in Medicare face sizable costs including co-insurance, deductibles, the cost of drugs once they reach the coverage gap and co-insurance after they reach the catastrophic threshold, as well as all costs for uncovered services. These out-of-pocket costs are in addition to premiums most patients pay for Medicare and/or for supplemental coverage – which in some cases can be multiple hundreds of dollars every month.[4]

It is very common for cancer patients to have problems affording their medications, and research shows that high costs for cancer drugs can lead to "cost-related nonadherence" to medication regimens.[5,6,7,8] Medication nonadherence is consistently linked to the exacerbation of chronic conditions, increased health care use, and greater health system costs[9] - and is especially detrimental in cancer treatment. Therefore, public policy changes that help to lower costs for patients can have a direct bearing on their well-being.

Benefits of the Proposal

In an effort to lower costs for patients, the Department of Health and Human Services (HHS) is proposing to remove the safe harbor protection now in place that allows drug manufacturers to offer discounts to pharmacy benefit managers (PBMs), Medicare plan sponsors and Medicaid managed care plans. In its place HHS proposes allowing drug manufacturers to: give discounts to Medicare beneficiaries at the point-of-sale; and provide PBMs with flat service fees for other services provided, for example medical education, and medication monitoring.

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[3] American Cancer Society Cancer Action Network. *The Costs of Cancer: Addressing Patient Costs*, April 2017, www.acscan.org/costsofcancer.

[4] Id.

[5] Dusetzina SB et al., *Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia, Journal of Clinical Oncology,* February 1, 2014, https://www.ncbi.nlm.nih.gov/pubmed/24366936.

[6] Neugut AI et al., *Association Between Prescription Co-Payment Amount and Compliance with Adjuvant Hormonal Therapy in Women with Early-Stage Breast Cancer, Journal of Clinical Oncology,* http://ascopubs.org/doi/10.1200/JCO.2010.33.3179.

[7] Farias AJ & Du XL, *Association Between Out-Of-Pocket Costs, Race/Ethnicity, and Adjuvant Endocrine Therapy Adherence Among Medicare Patients With Breast Cancer, Journal of Clinical Oncology*, http://ascopubs.org/doi/full/10.1200/JCO.2016.68.2807#.

[8] Lee MM & Khan MM, *Gender differences in cost-related medication non-adherence among cancer survivors, Journal of Cancer Survivorship,* April 2016, Volume 10, Issue 2, pp 384-393, https://link.springer.com/article/10.1007/s11764-015-0484-5.

[9] Kennedy J & Wood EG, *Medication Costs and Adherence of Treatment Before and After the Affordable Care Act: 1999–2015,* American Journal of Public Health 106, no. 10 October 1, 2016: pp. 1804-1807. https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2016.303269.

ACS CAN supports the removal of the current safe harbor protection, and the creation of a safe harbor for point-of-sale discounts in the Medicare program[10] because the proposal:

Encourages manufacturers to provide discounts at point-of-sale, lowering out-of-pocket costs: Currently, most Part D sponsors do not pass the savings from prescription drug manufacturer rebates and price concessions to plan enrollees at the point of sale at the pharmacy. Instead, they retain these price concessions (largely in the form of manufacturer rebates). Although the retention of these rebates by plan sponsors likely help those sponsors hold down premiums, impact on out of pocket costs for patients at the point of sale are not impacted. For Part D enrollees, this has meant higher co-insurance and co-payment costs than if the rebates had been passed along at the point-of-sale. For example, if a drug has a list price of $500, and the manufacturer gives the plan sponsor a $200 rebate for the drug; the patient will pay co-insurance calculated from the $500 list price, not the $300 actual price.

HHS' proposal prohibits the payment of rebates and instead encourages discounts at the point of sale where those discounts can be shared with beneficiaries. As HHS notes, the reductions in out-of-pocket spending would most benefit two groups: 1) beneficiaries who take high-cost drugs and 2) beneficiaries with total drug spending into the coverage gap. We have noted that HHS acknowledges in the proposal that manufacturers are permitted – but not required – to give point-of-sale discounts using the newly proposed safe harbor protection. We urge HHS in its final rule to elaborate on how it will encourage plans to give these discounts, monitor the uptake of these discounts and articulate a plan for action in the event of poor uptake or other unintended consequences.

Removes an incentive to keep drug list prices high: As HHS notes, the current rebate system incentivizes drug manufacturers to keep the list prices of brand drugs high in anticipation of negotiated rebates. Patients who pay co-insurance for their drugs usually pay a percentage of the list price – not the negotiated price. Further, many cancer drugs are placed on the highest or "specialty" tier of plan formularies,[11] and CMS allows Part D plan sponsors to impose co-insurance for specialty tier drugs up to 33 percent.[12] Removing an incentive for keeping the list price high could lower the price on which beneficiary co-insurance is calculated – thus leading to lower out-of-pocket costs.

Removes an incentive for plan sponsors to steer patients to higher-rebated drugs: Under the existing safe harbor, there is an incentive for plan sponsors to encourage the use of drugs for which they receive the highest rebates – regardless of the cost to the patient. Because the patient may pay a co-insurance amount based on the list price – which doesn't incorporate rebates the plan sponsor receives – their out-of-pocket costs can be more for drugs even if the plan receives a rebate. Prohibiting rebates as proposed removes an incentive for plan sponsors to design their formularies and utilization management based on rebate amounts.

Potentially makes patient drug costs more transparent: Currently, because of the way in which the treatment of rebates interacts with the reporting of drug prices to Medicare, the drug prices posted on the Medicare Plan Finder (as reported by the Part D plan sponsors) have not always approximated the price actually charged by the pharmacy. This means that enrollees (and potential enrollees) are less able

[10] Please see Questions 3 and 4 in the last section of this document for questions about how this rule applies to the Medicaid program.
[11] Id.
[12] Kaiser Family Foundation. Medicare Part D: A First Look at Prescription Drug Plans in 2019. October 16, 2018. https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2019/

to minimize both their costs and Medicare's costs by seeking and finding the Part D plan with the lowest-cost drug or the lowest-cost drug and pharmacy combination. Prohibiting rebates and encouraging discounts that are defined in advance and given at point-of-sale should improve the accuracy of this tool and help Medicare enrollees choose the Part D plan that is the best for them.

Concerns and Questions

While ACS CAN believes this proposal has the potential to benefit cancer patients and survivors, we also acknowledge the impact of the proposed rule could be quite significant. There are several concerns and questions that ACS CAN urges HHS to carefully consider and address in the final rule.

The proposal will likely cause Part D premiums to rise: ACS CAN appreciates the tradeoff between higher premiums and lower cost-sharing for Part D enrollees that could result if HHS were to finalize this rule as proposed. Based on the analyses provided in the proposal, the net effect on beneficiary costs would be to lower their costs: while premiums are estimated to rise by $2.77 to $5.64 per member per month depending on the scenario analyzed, beneficiaries would save $3.86 to $8.01 per member per month in cost-sharing.[13] Five of the six scenarios analyzed showed a net savings for beneficiaries. We recognize that these benefits will vary depending on whether beneficiaries use high-priced drugs and how much per year they spend on drugs, but it is likely that many cancer patients and survivors will see savings.

However, rising premiums for Part D plans is a concern that HHS must take seriously. If this proposal is finalized as written, ACS CAN urges HHS to carefully monitor the effect of this policy on Part D premiums and beneficiary enrollment to ensure there are no unintended consequences to beneficiary access to this vital program.

Questions to address:

1. What, if any, impact will this change have on patients who have private health insurance? How will this change affect their premiums and cost-sharing?
2. Will plan sponsors or PBMs increase utilization management techniques like non-clinically-based prior authorization, step therapy, or quantity limits to compensate for the proposed changes? We strongly urge HHS to closely monitor plan designs to determine whether beneficiary access to medically appropriate therapies is hindered due to the imposition of additional utilization management tools as a direct result of this proposal. We note that the potential for this unintended consequence makes it all the more crucial that HHS not change its policy for the six protected classes in Medicare Part D.
3. What effect will these proposed changes have on the supplemental rebates that manufacturers offer Medicaid programs? Will this proposal actually make it more expensive for Medicaid programs to provide drugs to beneficiaries? Given the vital importance of the Medicaid program, we strongly urge HHS to ensure that Medicaid beneficiaries' access to prescription drugs is not negatively impacted as an unintended consequence of this proposal.
4. Given that Medicaid beneficiaries' cost-sharing is structured very differently than Medicare beneficiaries', Medicaid beneficiaries are not likely to see the point-of-sale benefits under this proposal that Medicare beneficiaries would. Therefore, did HHS consider exempting Medicaid managed care plan sponsors from this rule, or addressing this difference in some other way?

[13] 84 Fed. Reg. at 2358

CONCLUSION

On behalf of the American Cancer Society Cancer Action Network thank you for the opportunity to comment on the proposed changes to drug rebates in the Medicare and Medicaid programs. If you have any questions, please feel free to contact me or have your staff contact Jennifer Singleterry of our policy team at Jennifer.Singleterry@cancer.org or 202-585-3233.

Sincerely,

Lisa A. Lacasse, MBA
President