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The Honorable Daniel Levinson
Inspector General
U.S. Department of Health and Human Services
Office of the Inspector General
ATTN: OIG-0936-P
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201

Docket ID: HHSIG-2019-0001-0001


Dear Mr. Levinson:

On behalf of the National Infusion Center Association (NICA), the hundreds of thousands of patients across the nation requiring provider-administered parenteral medications, and the dedicated providers that treat them, I am pleased to submit comments in response to the Department’s proposed rule (OIG-0936-P) relating to safe harbor protections for prescription drug price reductions.

NICA is a 501(c)(3) nonprofit patient advocacy organization formed to ensure that our nation’s sickest and most vulnerable patients can access outpatient infusion and injectable medications through advocacy, education, and resource development. We represent hundreds of thousands of patients managing complex, chronic, and difficult-to-manage diseases—like autoimmune diseases—with medical benefit drugs in one of several thousand outpatient infusion facilities across the country.

There are many complex, multi-faceted challenges threatening the sustainability of our health care system. Specialty medications, particularly biological products, are incredibly expensive and list prices for these drugs continue to increase, translating to increased out-of-pocket (OOP) costs for patients and increased cost burden on payers.

Biological products are used to manage some of the most expensive conditions (e.g., autoimmune diseases, cancer), for which patients are subjected to extraordinarily high physical, emotional, and economic burden of disease. In the absence of abrupt, organic reductions in the prices of these drugs, access to care for many of our nation’s citizens will continue to rely on programs that can make these drugs more affordable. Reshaping the rebate system to drive out-of-pocket cost reductions at the point of sale may make these drugs more affordable for the people that desperately need them.
Summary

Under the current rebate system and Federal anti-kickback statute safe harbor, rebate payments by pharmaceutical manufacturers to Pharmacy Benefit Managers (PBMs) and plan sponsors are not considered to be remunerations to induce the referral of business reimbursable under any of the Federal health care programs. The purpose of this proposed rule is to update the discount safe harbor to address the modern prescription drug distribution model and ensure safe harbor protections extend only to arrangements that present a low risk of harm to the Federal health care programs and beneficiaries. To this purpose, the Department proposes to make three changes to safe harbor protections:

1. Amend the existing discount safe harbor by adding an explicit exception to the definition of “discount” such that certain price reductions on prescription pharmaceutical products from manufacturers to plan sponsors under Medicare Part D, and Medicaid MCOs would not be protected under the safe harbor;

2. Add a new safe harbor (Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products) to protect discounts between those same entities if such discounts are given at the point of sale and meet certain other criteria; and,

3. Add a second new safe harbor (PBM Service Fees) specifically designed to protect certain fees pharmaceutical manufacturers pay to PBMs for beneficial services, when those services relate in some way to the PBMs’ arrangements to provide pharmacy benefit management services to health plans.

NICA supports the reform measures outlined in this proposed rule for both the Medicare Part D and Part B programs. Additionally, we share the Department’s beliefs that excluding manufacturer rebates paid to plan sponsors from the discount safe harbor, and creating a new safe harbor for point of sale price reductions, may better align incentives among manufacturers, PBMs, and plan sponsors that may: (1) curb list price increases on beneficiaries; (2) improve transparency; and, (3) reduce the likelihood that rebates would serve to inappropriately induce business payable by Federal health care programs.

NICA submits comments in support of the proposed rebate reform measures for the following reasons:

- Under the current rebate system, rebates are not applied at the point of sale to offset the beneficiary’s cost share for prescription drugs;

- The current rebate framework may incentivize preferential formulary placement for higher-cost drugs that carry a higher associated rebate and may deter the placement of lower cost, therapeutically equivalent drugs on formularies; and,

- Rebates have been ineffective and counterproductive in driving drug price reductions and the current rebate system works to the disadvantage of beneficiaries and Federal health care programs.

Amendment to the Discount Safe Harbor

The current rebate framework may incentivize preferential formulary placement for higher-cost drugs that carry a higher associated rebate. As such, this framework may deter the placement of lower cost, therapeutically equivalent drugs on formularies.

Under the current rebate framework, there is a significant reallocation of wealth from pharmaceutical manufacturers to PBMs and plan sponsors in the form of rebates. These rebates may be a factor contributing to drug list prices increasing faster than inflation, and they may be inadvertently creating barriers to access through their influence in both formulary and benefit plan design.

Such a market distortion may be discouraging the integration and uptake of lower-cost brand name drugs, generic drugs, and biosimilar drugs in the market. If this perverse incentive does exist, rebates may be artificially holding costs high for consumers and payers as forms of cost-sharing are often based on the drug’s list price.

Pharmaceuticals in the U.S. market are expensive, particularly biological products. Often much more expensive than in other global markets. Although there are many factors that contribute to differences across global markets for pharmaceuticals, insurance design and the use of rebates in the U.S. may be contributing to an ongoing disparity between the growth in drug list prices and inflation.

If the current rebate framework is incentivizing preferential formulary placement for higher-cost drugs with higher rebates, the current rebate system may be inadvertently influencing prescription behavior and restricting access to lower-cost brand name drugs, generic drugs, and biosimilar drugs that carry a lower rebate value. This phenomenon is not limited to drugs covered under the pharmacy benefit but translates into the medical benefit as well. Within the current system, the use of rebates creates a financial incentive to make formulary decisions based on rebate potential, not the efficacy or quality of a drug. Coverage of medications, whether under the pharmacy benefit or medical benefit, should be based on quality, efficacy, and safety, not safe-harbored “kickbacks”.

Rebates have proven to be ineffective and counterproductive to driving drug price reductions. Since the safe harbor for rebates was established, drug prices have increased for the most part. In many of these years, drug prices increased at a rate beyond that of inflation (See Figure 1).

Figure 1: Historical Prescription Drug Spending Trend

Figure 1 illustrates nominal and inflation-adjusted per capita spending on retail prescription drugs, 1960-2017. (Source: Kaiser Family Foundation Analysis of National Health Expenditure Accounts)

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Figure 1 illustrates the nominal and inflation-adjusted per capita spending on retail prescription drugs between 1960 and 2017. On a per capita basis, inflation-adjusted retail prescription drug spending in the U.S. increased from $90 in 1960 to $1,025 in 2017.4

If rebates were the effective cost-savings and value-generating tool that PBMs have alleged over the years, one would expect to see a reduction in drug prices or at least a steady reduction in the rate at which drug prices increased to better align with that of inflation. It is for these reasons that NICA supports the Department’s proposal to remove protections for price reductions from manufacturers to plan sponsors under Medicare Part D and Medicaid MCOs, either directly or through PBMs acting under contract with these plan sponsors in connection with the sale or purchase of prescription pharmaceutical products, unless the reduction is price is required by law. Additionally, NICA recommends that the Department consider expanding this safe harbor amendment to price reductions from manufacturers to plan sponsors in connection with the sale of purchase of prescription medications covered under Medicare Part B as well.

New Safe Harbor for Certain Price Reductions on Prescription Pharmaceutical Products

Some of our nation’s sickest and most vulnerable patients are struggling to afford the medications they desperately need. Under the current rebate system, there is a multi-billion dollar stream of money moving from manufacturers to PBMs and plan sponsors that never make it to the consumer because these “rebates” are being used as a revenue stream for PBMs and plan sponsors instead of being applied at the point of sale to offset the beneficiary’s cost share for prescription drugs. As such, the current rebate system works to the disadvantage of beneficiaries and Federal health care programs.

Complex, chronic, rare, life-threatening, and difficult-to-manage diseases are often incredibly expensive to manage. People living with these conditions rely on expeditious and uninterrupted access to prescription medications to optimize health outcomes, maximize quality of life, and minimize the physical, emotional, and economic burden of disease. However, many of these medications, particularly biological products, are incredibly expensive and largely unaffordable for many of our nation’s citizens that desperately need them.

If rebates were instead passed through to consumers at the point of sale to reduce drug costs, we may be able to achieve a measurable reduction in patient and payer cost-burden for outpatient drugs. It is for this reason that NICA supports the proposed safe harbor that would protect point-of-sale price reductions offered by manufacturers on certain prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid MCOs.

Additionally, NICA recommends that the Department consider expanding these safe harbor protections to include point-of-sale reductions offered by manufacturers on certain drugs covered under Medicare Part B as well. Alternatively, NICA is pleased to propose a slightly different model relating to point-of-sale reductions on drugs covered under Federal health care programs: safe harbor protections for manufacturer cost-share assistance programs that provide point-of-sale reductions on prescription drugs covered under Federal health care programs (under very limited conditions). The following section outlines this proposed alternative model for the Department’s consideration.

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An Alternative Point-of-Sale Cost-Reduction Model for Consideration

Until we can make prescription drugs affordable for all Americans in the absence of insurance, it is critically important that the Department explore various cost-reductions strategies that could improve the immediate-term affordability of prescription drugs. NICA has submitted letters to the Department in the past relating to a cost-reduction strategy heavily utilized in the commercial market: manufacturer cost-share assistance programs.

By establishing a safe harbor for the extension of manufacturer cost-share assistance to beneficiaries of Federal health care programs under very limited conditions (i.e., when there is no less expensive and equally effective generic available, such as for biologics), the Department could leverage an existing pool of financial support to drive point-of-sale cost reductions for beneficiaries, improve the immediate-term affordability of prescription drugs for the vulnerable patient populations covered under Medicare and Medicaid MCOs, reduce beneficiaries’ out-of-pocket costs, and reduce the government’s cost burden. Such a cost-reduction strategy provides the prospect of improving access to care, reducing costs, improving treatment adherence, and reducing expenditures on other medical services.

For such a cost-reduction strategy to work as intended—without inducing consumption of more expensive brand products when cheaper, therapeutically equivalent generics are available—safe harbor protections could be limited to instances where no less expensive and equally effective generic is available. For instance, in the case of complex biologics for which there are no generics available. Although this strategy does not solve the overarching drug pricing issue, it would reduce patients’ out-of-pocket cost burden and could improve treatment adherence among beneficiaries that would otherwise discontinue therapy for economic reasons—a driver of unnecessary consumption of high-cost, non-drug health care services to manage symptom flares associated with an undermanaged disease.

Fixing the issue of high and rising drug prices, particularly among biologics, is an incredibly complex and arduous challenge. In the meantime, the disease continues to progress in the absence of appropriate and effective intervention. Patients with a chronic illness need consistent, uninterrupted access to prescription drugs to manage disease progression, optimize health outcomes, maximize quality of life, and minimize the physical, emotional, and financial burden of disease.

Studies have shown that spending money on the right medication can reduce the total amount spent on hospital-related (e.g., ED visits, inpatient care) or other medical costs (e.g., labs/diagnostics, surgery) through effective disease management. For example, a 2007 study found that a $1 increase in drug spending was associated with a $2.06 reduction in Medicare spending. A 2009 study found that outpatient prescription drug expenditures create “cost savings for Medicare beneficiaries” once hospital costs are considered. Similarly, a 2011 study found that “the typical new drug slows the growth of overall medical care spending”.

Every year, manufacturer cost-share assistance programs help thousands of consumers in the commercial insurance market access their medication when they otherwise could not afford the cost-share, reducing long-term health spending. These assistance programs are particularly important for people living with complex, chronic, rare, and/or life-threatening disease, like autoimmune disease or cancer, that are prescribed expensive biologics or other provider-administered parenteral specialty medications. Many of

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our nation’s sickest and most vulnerable citizens rely on these assistance programs to access this class of therapy when conventional treatments have failed. Unfortunately, in accordance with outdated guidance, these cost-share assistance programs cannot be extended to beneficiaries of Federal health care programs, like Medicare Part B, despite their promise to help patients manage disease and reduce long-term health spend.

In a Special Advisory Bulletin dated “September 2014”, the Office of Inspector General (OIG) clarified its interpretation that the Federal anti-kickback statute is implicated when manufacturer cost-share assistance covers some or all of a drug for a beneficiary of a Federal health care program when a less expensive and equally effective or generic alternative is available. These concerns are certainly valid in the case of conventional oral medications for which less expensive and equally effective generics are available. For these products, the anti-kickback statute has mitigated the Medicare’s financial burden; however, OIG’s interpretation of the anti-kickback statute’s implication for manufacturer cost-share assistance programs for drugs for which there are no less expensive alternatives available may have increased Medicare’s financial burden on non-drug health spend.

In the case of biologics, there are no generics and the only other effective alternative may be a different biological product. For the most part, biological products are comparable in price, with biosimilar biological products posing nominal cost-savings over the reference product. As such, OIG’s outdated interpretation and guidance do not account for current trends in the modern biopharmaceutical market. Consequently, every year, medically stable commercially insured patients that have relied on manufacturer cost-share assistance to access a prescription drug are facing disrupted and delayed treatment when they transition to coverage through a Federal health care program, like Part B.

There are many Medicare beneficiaries undermanaging disease because they cannot afford the medication(s) they need. These Americans face a significant challenge in managing disease progression and mitigating long-term increases in the economic burden of their disease when the disease is undermanaged. Perhaps even more concerning is that too many of these people are facing a deeply troubling dilemma: do I pay for food or my medicine?

**NICA implores the Department to consider establishing safe harbor protections for point-of-sale price reductions offered by manufacturers to consumers on certain prescription pharmaceutical products payable under Medicare Part B in the form of cost-share assistance when certain criteria are met.**

If the Department elects to pilot this alternative model, Medicare Part B may experience an increase in immediate-term cost as more beneficiaries begin consuming Part B drugs. However, any increase in cost may be heavily outweighed by long-term cost-savings associated with significant reductions in non-drug Part B spending as more beneficiaries’ conditions are appropriately managed.

NICA strongly believes that establishing such a safe harbor would: (1) increase access to health care services; (2) increase the quality of health care services being consumed; (3) increase patient freedom of choice among health care providers; (4) increase competition among health care providers; (5) increase the ability of health care facilities to provide services to medically underserved populations; (6) Decrease the long-term costs to Federal health care programs; and, (7) Decrease the potential overutilization of high-cost health care services (e.g., ED visits, imaging/diagnostics, inpatient care). Criteria could be established for this safe harbor to prevent fraud and abuse and mitigate any potential financial benefit to a

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health care professional relating to the ordering and provision of a prescription drug or referring to a particular health care provider for the provision of the ordered drug.

On behalf of NICA, I submit for the Department’s consideration this point-of-sale price-reduction model for prescription drugs covered under Part B as an alternative to expanding the proposed safe harbor protections to include point-of-sale price reductions on prescription drugs covered under Part B.

Conclusion

There are many complex, multi-faceted challenges facing the sustainability of our health care system. The affordability and accessibility of drugs continue to present the greatest challenge. Until we discover a cure for all diseases, successful disease management will rely on affordable access to pharmaceuticals. As biotechnology and our diagnostic capabilities improve, we are diagnosing complex diseases quicker and managing them more effectively. However, cost will always be a barrier to medication access in our health care system and insurance landscape. Until we solve the principal affordability problem, people will struggle to access the medications they need to manage their disease and reduce unnecessary consumption of health care services they could otherwise avoid with effective disease management.

The fact that access to our health care system requires most consumers to contract with a third party to mitigate the cost liability associated with consuming health care services underlies the magnitude of the problem and the resistance that lies ahead. Until prescription drugs become affordable for most Americans in the absence of health insurance, consumers will rely on cost-reduction strategies as a bandage to slow the bleeding of cash as they access the care they need.

Exploring safe harbor protections for point-of-sale cost-reduction strategies provides a promising prospect for immediate-term relief. Reforming the rebate framework to reduce drug costs for consumers at the point of sale is one strategy. Permitting the provision of manufacturer cost-share assistance to beneficiaries of Federal health care programs, when no lower cost and equally effective generics are available, is another strategy. Either could produce measurable reductions in consumer’s out-of-pocket costs. However, these strategies also require manufacturers to externalize revenue. As such, these strategies, in combination, may be counterproductive for long-term downward trends in drug pricing; and, individually, may not produce as significant of a reduction in OOP spending as if rebates were eliminated; however, they would not require a unanimous and organic shift in pricing practices across pharmaceutical manufacturers.

NICA supports efforts to expand access through improved affordability and transparency. We are concerned that once rebate-related revenue for PBMs and payers is reduced, these entities may explore other cost-management strategies focused on restricting access to care and provider choice (e.g., restrictive formularies limiting the number of drugs per category). As such, we urge the Department and/or Congress to establish clear guidelines, guardrails, and protections that limit the ability of PBMs and plan sponsors under Medicare Part D, Medicare Part B, and Medicaid MCOs to further restrict provider choice and patients’ access to care.

Again, what is clear is that people rely on access to medications for effective disease management and quality of life. Until we solve the broader drug pricing issue, reform measures that can make access to drugs more affordable should be explored. “Ensuring that the benefits created by pharmaceuticals not only continue, but expand, requires policies that support continued innovation from pharmaceutical
manufacturers. An important component of ensuring continued innovation is ensuring policies maintain an effective pricing environment.”

NICA applauds actions the Department has taken to address the rising cost of drugs and patient out-of-pocket costs. We support several goals outlined in the proposed rule in concept, so long as these reform measures do not inadvertently interrupt, restrict, or delay access to care. Because the extension of price reductions to consumers at the point of sale may make drugs more affordable, we encourage the Department to consider expanding the proposed rule to include safe harbor protections for point-of-sale price reductions on drugs covered under Medicare Part B as well.

Thank you for the opportunity to submit comments on this proposed rule. NICA and its Advisory Committee comprised of in-office infusion thought leaders and subject matter experts would welcome the opportunity to serve as a resource in the exploration, development, and implementation of point-of-care cost-reduction strategies to improve access to prescription drugs covered under Medicare Part B.

Should you have any questions or need more information, please feel free to contact me at brian.nyquist@infusioncenter.org or 512-402-6955.

Sincerely,

Brian Nyquist, MPH
Executive Director
National Infusion Center Association

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