July 16, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Subject: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

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 infusion providers that treat them, I am pleased to submit comments in response to the Department’s Request for Information. NICA is a nonprofit patient advocacy organization formed to ensure that our nation’s sickest and most vulnerable patients can access in-office infusion and injectable medications.

The challenges facing the sustainability of our health care system are complex and multi-faceted. 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. These products are used to manage some of the most expensive conditions (autoimmune diseases and cancer), for which patients are subjected to extraordinary OOP costs. Patients’ out-of-pocket costs continue to rise while shifts in benefit plan design produce insurance plans with reduced coverage at higher premiums.

NICA commends the administration for identifying four key challenges in the American drug market and efforts to influence sustainable change. However, there is great concern that simultaneously implementing multiple significant and sweeping reform measures—with impact to a wide breadth of our nation’s health care system—will produce significant unintended consequences, including increased cost burden for patients and payers, including Medicare.

In the American Patients First blueprint, the Administration outlined four strategies to address key challenges in the American drug market: improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs. NICA supports these strategies in concept, so long as reform measures do not interrupt, restrict, or delay access to care. As medical benefit drug spend is a significant driver of health care spend, the factors driving this increased drug spend must be sustainably and responsibly addressed to the benefit of patients, not their detriment.

Reform should first and foremost be focused on sustainable, uninterrupted access to care. Healthcare providers are in the business of providing health care. Patients rely on healthcare providers, and the
sustainability of the market, for uninterrupted access to the care they need. Responsible reform should consider market dynamics and focus on preserving and expanding access to care in the most economical care settings, like in-office infusion care settings (e.g., physician practice-based infusion suites and independent infusion centers). Reform that threatens the financial viability and/or sustainability of this critical medication delivery channel would disrupt access to care. As such, NICA implores the administration to consider the following principles that support responsible reform.

**NICA Principles for Responsible Reform**

- Address market forces and dynamics influencing increased drug list prices and high out-of-pocket costs with a focus on preserving and expanding access to care.
- Minimize the annual per capita economic burden of complex, chronic diseases (e.g., autoimmune diseases, like rheumatoid arthritis, multiple sclerosis, Crohn’s disease, ulcerative colitis, and lupus) and cancer.
  - Increase the number of **covered** therapeutic options.
  - Support patients’ ability to achieve disease remission as quickly as possible and for as long as possible.
- Improve access to care and reduce cost by supporting the expansion of lower cost, non-hospital care settings (e.g., physician practice-based infusion suites and independent infusion centers).

**Managing autoimmune diseases with medical benefit drugs**

Conditions like autoimmune diseases and cancer can be extremely costly to manage. If conventional medications (e.g., prednisone, methotrexate) do not effectively manage progression of disease, patients may rely on biological products and other intravenous and injectable specialty medications to manage disease progression. The economic burden of these diseases quickly becomes significant.

When undermanaged (e.g., when patients access to care is delayed or interrupted), the economic burden of disease increases rapidly as the disease progresses resulting in increased health care consumption. Studies have shown that the annual per capita economic burden of autoimmune disease can more than double when undermanaged. As such, utilization management strategies that commercial payors use to drive medication consumption behavior and negotiate better drug prices can significantly increase health care spending at the detriment of patients. Incorporating these strategies into Federal health care programs would drive steep increases in the cost burden of these programs.

The patients living with autoimmune diseases that rely on Medicare for coverage are some of our nation’s sickest and most vulnerable citizens relying on these government programs for the coverage they need to maximize quality of life. They are high utilizers of care and they are expensive to manage. It often takes months, or even years, to achieve remission. Once in remission, it can be a delicate balance to stay in remission. The slightest change can disrupt that equilibrium. So, delaying and/or disrupting their access to care could significantly increase financial burden on the program, rather than reduce costs.

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Coverage for biologics and specialty intravenous/injectable medications should not shift to Part D

When considering a reform provision as significant in impact as shifting coverage for provider-administered intravenous and injectable medications from Part B to Part D, it is imperative to consider long-term impacts that may outweigh any potential cost-savings realized in the short-term. Most importantly, proposed reform should not be disruptive for patients, should not delay access to subsequent treatments, and should not increase out-of-pocket costs.

Shifting coverage of drugs from the medical benefit to the pharmacy benefit will increase the cost burden for patients and Medicare. Previous analyses by Health and Human Services (HHS) regarding the impact of transitioning drugs covered under Part B to Part D suggested that such a shift, as outlined in a 2005 report to Congress, “would likely increase overall Medicare program spending by increasing spending on Part D by more than the offsetting decrease in spending on Part B”. The report also noted that most categories of Part B drugs would not be good candidates for transition to Part D, and that such a transition would be undesirable. Not all Medicare beneficiaries currently receiving medications covered under Part B have Part D coverage. Therefore, the patients currently on therapy covered under Part B that do not have Part D coverage will either lose access to the medication they need, or acquire Part D coverage, increasing their monthly cost burden independent of any changes in medication cost-share. Additionally, a recent Avalere study found that in 2016, average out-of-pocket costs were approximately 33 percent higher for new cancer therapies covered under Part D ($3,200) than for those covered under Part B ($2,400).

Furthermore, a Part B to Part D shift will send the sickest, most expensive Medicare patients from office-based care settings into hospital care settings at a significant increase in cost to the patient and Medicare. Subsequent treatments would be delayed as thousands of patients overwhelm the hospital-based infusion delivery channel. Many of these patients wouldn’t be able to afford the increase in their out-of-pocket costs, so their access to care may be disrupted. Office-based infusion providers are operating in a volatile reimbursement environment with increasingly pressurized atmosphere to operate on narrower margins. Reimbursement for infusion administration does not cover the costs associated with coordinating care for patients with autoimmune diseases. Without the drug payment, the per patient per treatment losses across their entire Medicare patient population would be unsustainable.

If providers lose money treating Medicare patients, their Medicare patients will be forced into hospital care settings, increasing out-of-pocket costs and the cost burden on Federal health care programs. Additionally, many providers cannot sustain their practice model without their Medicare patients. Therefore, this shift in the reimbursement landscape may result in the collapse of office-based infusion facilities, including physician practices, and force Medicare patients to transition into hospital-based care settings at increased cost.

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The hospital infusion delivery channel can be over 2-3 times more expensive than the office-based care setting, and hospitals do not have the capacity to meet existing demand.\(^4\) If patients are forced to transition from office settings to hospital-based care settings, there would be significant disruptions in access to care. Disruptions in care will result in symptom reemergence as diseases states flare, leading to increased spending on other drugs, physician visits, specialist visits, emergency room visits, hospitalizations and possibly more invasive surgical interventions like joint replacement or partial bowel resection.\(^5\) This significant increase in health care utilization among the most expensive Medicare patients would drive significant increases in patient out-of-pocket costs, and potentially increases in OOP costs for all Medicare beneficiaries if the program must increase premiums to mitigate this increased cost burden on the program.

If the goal of a B to D shift is to explore strategies commercial payors use to control costs and negotiate lower drug prices for expensive biologics and other IV/injectable specialty drugs, like prior authorization and step therapy, any benefits of shifting coverage for these products from Part B to Part D would be heavily outweighed by unintended consequences.

In summary, NICA is deeply concerned that shifting coverage for provider-administered intravenous and injectable medications from Part B to Part D will restrict and disrupt patients’ access to care, produce poorer health outcomes, increase out-of-pocket costs, increase Medicare spending, and reduce patients’ quality of life. A far cry from the outcome the administration is seeking to achieve. As such, we implore the administration to reconsider such an impactful reform provision and encourage you to consider engaging NICA and its advisory body comprised of the biggest players in in-office infusion who would be happy to work with the administration to explore, develop, and test alternative strategies.

**Site neutrality for physician-administered drugs would increase competition across care settings**

In the current reimbursement landscape for outpatient infusion care settings, reimbursement for provider-administered drugs is significantly higher for hospital care settings compared to non-hospital care settings.\(^6\) This site-related variability in reimbursement has distorted the competitive landscape across the infusion delivery channel in favor of hospital-based care settings. Even so, NICA has received reports from infusion providers and patients across the country that many non-340B hospitals will not administer provider-administered parenteral medications, presumably because the margins are sub-optimal to justify the opportunity cost and financial risk of investing in buying and billing medication inventory.

A site-neutral payment policy would result in a more equitable competitive landscape across all care settings in the infusion delivery channel. This change may influence a measurable reduction in Medicare spending, but may also result in fewer non-340B hospitals willing to administer provider-administered parenteral medications. The resulting increased demand on non-hospital care settings necessitates a

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sustainable landscape for non-hospital care settings that supports expansion to meet increased demand in the immediate-term as well as future demand as new products exit the biopharmaceutical pipeline and come to market.

NICA supports the concept of site-neutral payments for provider-administered drugs; however, there must be a plan in place to avoid disruptions in care for patients being treated in hospital care settings within a community that lacks non-hospital alternatives. NICA and its advisory body would welcome the opportunity to work with the administration to support implementation of a site-neutral payment model that preserves patients’ access to care.

Insufficient transparency in Pharmacy Benefit Manager (PBM) fiduciary responsibility, rebates, and fees

Incentives across the benefits landscape that favor higher drug list prices are subjecting beneficiaries to higher out-of-pocket costs. Patients requiring expensive biologics or specialty medications to manage their autoimmune conditions are particularly impacted as these incentives are making expensive medications even harder to access. PBMs claim to leverage rebates to negotiate lower drug prices, cost-savings, and value for plan sponsors and patients. However, the lack of transparency, standardized definitions, and reporting obligations make it impossible to evaluate whether PBMs are influencing a reduction or increase in drug list prices, and whether any generated savings are passed on to patients. HHS will not be able to evaluate whether PBMs’ impact is advantageous or adverse from a drug list price perspective as well as a patient access to care perspective without sufficient transparency and data sharing to determine if actual outcomes align with expected outcomes. Without enhanced transparency, it will remain unclear how these rebates effect drug pricing.

From a business perspective, a reallocation of wealth to PBMs and plan sponsors that was not included in a manufacturer’s breakeven analysis and revenue/profit projections could distort these projections, driving misalignment between actual and expected outcomes. Increasing the drug’s list price may be a strategy to accommodate an unexpectedly high allocation of rebates to get on formulary, preferential listing, etc. for a given plan year. Therefore, as long as PBM rebates and fees are based on percentage of list price, there may be incentives to favor higher list prices for drugs, and the potential for higher rebates, rather than lower prices. However, it may be possible to reset these incentives to prioritize lower out-of-pocket costs for consumers, better adherence, and improved patient health outcomes by basing rebates and fees on factors other than list prices for drugs.

Reduced out-of-pocket costs for consumers, better adherence and improved outcomes do not have to be, and should not be, mutually exclusive in our health care system. Every patient is different. To manage patients with autoimmune disease or cancer, it takes flexibility for the patient and physician to explore the entire array of treatment options, both on-label and off-label, to find what works for that patient. However, this flexibility is limited by the affordability of treatment options. If we can reduce out-of-pocket costs, and patients can find and get the right medication at the right time at an affordable cost, we will see better adherence and improved health outcomes. If we can get these patients stabilized (i.e., in remission) as quickly as possible and keep them stable for as long as possible, we will: (1) reduce the annual per capita economic burden of these diseases through better adherence and by reducing unnecessary health spending resulting from undermanagement of disease, (2) see better
health outcomes, (3) see better quality of life, and (4) see these patients remaining productive members of society for as long as possible. By supporting the expansion of non-hospital care settings, we will be able to achieve these outcomes at a reduced cost-share for patients and payers.

However, in the absence of transparency, if the current PBM rebate and fee structures are incentivizing high and increasing drug prices, beneficiary out-of-pocket spending and Federal health care program spending will continue to increase.

**Extending manufacturer cost-share assistance programs to beneficiaries of Federal health care programs may improve adherence, reduce out-of-pocket costs, and improve health outcomes**

Manufacturer cost-share assistance programs help patients access their medication when they otherwise couldn’t afford the cost-share. These assistance programs are particularly important for people living with autoimmune disease or cancer that are prescribed expensive biologics or other provider-administered IV/injectable medications. Many of our nation’s sickest and most vulnerable citizens rely on these assistance programs to access this class of therapy when conventional treatments have failed. For autoimmune patients, for which conventional treatments have failed to manage disease progression—and could not otherwise access biologics without manufacturer cost-share assistance programs—these assistance programs help them manage disease, improve health outcomes, reduce long-term out-of-pocket cost, and improve quality of life.

In the current regulatory landscape, beneficiaries of Federal health programs cannot access these manufacturer cost-share assistance programs. Commercially insured patients that have relied on manufacturer cost-share assistance to access a drug, that have become stable on the drug, are facing disrupted and delayed therapy when they transition to coverage through Medicare. Additionally, current Medicare beneficiaries that need a biologic to manage their condition but cannot afford the cost-share are undermanaging their condition. Those that cannot afford supplemental insurance will not be able to adhere to, or access, the biologic medication they need if they cannot afford their 20 percent coinsurance. Not many Americans can afford a 20 percent coinsurance on a biologic at each treatment. These Americans face significant challenge in managing disease progression and mitigating long-term increases in the economic burden of their disease if their condition is undermanaged.

In a September 2014 Special Advisory Bulletin, the Office of Inspector General (OIG) indicated 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 prevented the Medicare program from experiencing a significant increase in financial burden.

In the case of biologics, however, there are no generics and the only other effective alternative may be a different biological product. Most biological products are comparable in price. With biosimilar biological products posing nominal cost-savings over the innovator product, biological products should receive a safe harbor from the anti-kickback statute.
NICA is confident that the benefits of extending manufacturer cost-share assistance programs to beneficiaries of Federal health care programs will outweigh potential effects on list price. CMS could verify or refute the notion of increased financial burden on the program resulting from the undermanagement of autoimmune disease by looking at the cost difference between the annual per capita economic burden of autoimmune disease when effectively managed and when undermanaged—looking at autoimmune and autoinflammatory arthritis conditions, like rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and lupus; as well as psoriasis, multiple sclerosis, Crohn’s disease, and ulcerative colitis. Additionally, CMS could survey Medicare beneficiaries with these autoimmune diagnoses on whether they used manufacturer cost-share assistance to get on a biologic while covered by a commercial insurance plan but discontinued use under Medicare coverage due to financial constraints. They could also survey beneficiaries that have been prescribed a biologic while covered under Medicare but could not start because they were unable to afford the coinsurance.

**340B drug discount program is causing significant market distortion at patients’ expense**

Rapid growth of the 340B drug discount program, combined with the lax criteria for eligible entities and for an eligible patient, as well as insufficient transparency and reporting requirements for disproportionate share hospitals (“DSH hospitals”), has distorted the competitive landscape in favor of large, tax-exempt hospitals. According to the Drug Channels Institute, the program has grown by 125 percent from 2014 to 2017, and drug sales at the 340B price increased to almost $20 billion in 2017.7 With the program expansion under the ACA, the number of DSH hospitals and their child sites have exploded.8 These DSH hospitals are exempt from federal taxation, are able to obtain biologics and other expensive outpatient drugs at enormous discounts, then get reimbursed more for the same service compared to an office-based provider (e.g., physician office or infusion center). It is no surprise that the volume of outpatient medical benefit drugs acquired through the 340B program has grown substantially in recent years as well. These factors have created incredible incentives for hospitals to leverage the discount program to their financial advantage, often using 340B program revenue to drive acquisition of physician practices that administer infusions in affluent communities with a healthy proportion of well-insured patients.9 These child sites then administer these heavily discounted products to commercially insured patients and bill their insurers with a significant markup on the drug.

As a result, a growing proportion of available drug is being acquired through the 340B program, shifting an extraordinary amount of wealth from pharmaceutical manufacturers to hospitals. 340B drug sales represented almost 8 percent of the overall drug market in 2016, both branded and generic.10 From a strategic operations perspective, manufacturers will have to make up this lost revenue to maintain target profit margins to support continued investment in research and development. It would, therefore, not be surprising if manufacturers considered increasing their list prices to accommodate

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9 Carrier ER, Dowling M, Berenson RA. Hospitals’ geographic expansion in quest of well-insured patients: will the outcome be better care, more cost, or both? Health Affairs. 2012; 31(4):827-835.
unexpectedly high proportions of drug being purchased at steep discounts through the 340B program. Resulting increases in list prices would likely be realized in the commercial sector. Patients and payers bear the increased cost burden.\textsuperscript{11}

Hospital acquisition of community practices impacts not only patients, but payors as well. If acquired practices shift to bill under the hospital’s fee structure, costs of services increase, and cost-share increases for both the patient and the payor. Furthermore, the incentives for 340B hospitals to maximize their 340B program revenue may inadvertently be influencing the prescription of more medications and higher-cost medications. For patients whose condition(s) could otherwise be managed with conventional therapies, this could pose a significant increase in medical benefit drug spending among 340B DSH hospitals.

Some entities participating in the 340B discount program are held to transparency and reporting requirements to ensure that 340B savings are used to offset the cost of charity care and programs to support uninsured and vulnerable patients. DSH hospitals are not held to the same transparency and reporting requirements, so there are intense financial incentives to leverage the program for financial gain as opposed to providing charity care. According to a paper released by The Alliance for Integrity and Reform of 340B, based on an analysis by Avalere, almost two-thirds of 340B hospitals provide less charity care than the national average (2 percent of total patient costs).\textsuperscript{12} Additionally, for over one-third of 340B hospitals, charity care represents 1 percent or less of total patient costs.

NICA believes that general regulatory authority over all elements of the 340B program may materially affect the elements of the program influencing drug pricing. The program was intended to offset the cost of providing charity care and support programs for uninsured and vulnerable patients. At the very least, all 340B entities should be held to the same transparency and reporting obligations as grantees and other entities currently held to these obligations. You cannot identify whether a program is achieving its intent if you are not measuring key performance indicators (e.g., proportion of 340B revenue allocated toward subsidizing charity care and support programs for the indigent and underinsured). You cannot measure KPIs if entities are not reporting their metrics.

Changing the definition of “patients” and changing the requirements governing covered entities contracting with pharmacies or registering child sites would help to refocus the 340B drug discount program toward its intended purpose. These are two of the key issues driving unintended consequences and deviation between the program’s initial intent and what the program has become: a profit machine. Redefining an eligible “patient” will be critical to rein in some of the program abuse. Additionally, reforming requirements governing covered entities, including those involving contracting with pharmacies, registering child sites, and reporting requirements to see how this 340B revenue is allocated, will help refocus the program toward its intended purpose.


Conclusion

NICA applauds actions the administration has taken to address the rising cost of drugs and patient out-of-pocket costs. We support the concept of several provisions outlined in the American Patients First blueprint and urge the administration to ensure that access to care will not be inadvertently disrupted by subsequent reform measures. NICA implores the administration not to shift, or even consider shifting, coverage of provider-administered intravenous or injectable products from Part B to Part D. Such a shift would negatively reshape the infusion delivery landscape, undermine the sustainability of this critical medication delivery channel, increase patient out-of-pocket costs, increase Medicare spending, produce poorer health outcomes, and reduce quality of life for some of our nation’s sickest and most vulnerable patients relying on Medicare to provide affordable coverage for the health care they desperately need.

Thank you for the opportunity to submit comments on the principal issues and potential strategies outlined in the blueprint. 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 reform involving provider-administered parenteral medications. 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