NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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July 22, 2021

Re: CMS-9905-NC ("Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs")

Filed electronically via regulations.gov

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of provider-administered medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in safe, more efficient, and cost-effective alternatives to hospital care settings.

NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting. NICA thanks the Departments of Health and Human Services, Labor, and Treasury, and the Office of Personnel Management for the opportunity to provide feedback on implementation of section 204 of the *Consolidated Appropriations Act, 2021* ("CAA section 204").

We have organized our comments following the order of the questions in the request for information, and we have limited our feedback to only those questions NICA is best positioned to answer.

Definitions

> *What considerations should the Departments and OPM take into account in defining "rebates, fees, and any other remuneration"? Should bona fide service fees—for example, administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives—be included in this definition? Are there additional fees that the Departments and OPM should include in this definition? How should manufacturer copay assistance programs and coupon cards be accounted for? How should copay accumulator programs be accounted for?*

We urge the Departments and OPM to include all fees and payments in the definition of "rebates, fees, and any other remuneration". The statute provides no limiting definition and the expansive scope ("any other") indicates that Congress intended for this provision to have the broadest possible reach. This includes but is not limited to payments categorized as *bona fide* service fees.

One of the main challenges with establishing transparency in the insurance and pharmacy benefit manager (PBM) industries is that these entities have disproportionate access to information vis-à-vis the

entity at the other end of the contract (e.g., an employer). This gives the insurer or PBM enormous power to define contractual terms in the way most advantageous to itself. True transparency requires visibility of any and all money exchanged in the supply chain, regardless of how the insurer characterizes any particular revenue stream. Otherwise, insurance purchasers and regulators will be chasing never-ending redefinitions. The simplest approach – and the only that can avoid gaming – is to require disclosure of all remuneration (rebates, fees, and "any other"), which is broadly defined by the Cambridge Dictionary as payment for work or services.

In terms of manufacturer cost-share assistance programs or copay cards, understanding the role of assistance programs in facilitating access would provide valuable insight. For example, reporting the proportion of claims that involved cost-share assistance and the amount of cost-share assistance dollars, looking at pharmacy benefit and medical benefit drug claims separately. Similar reporting relating to copay accumulator programs would provide valuable insight. For example, reporting (1) the total number of claims to which copay accumulator adjustments were made, and (2) the number of assistance dollars that insurers accepted but did not count toward a beneficiary's deductible or out-of-pocket maximum. Transparency into these programs will help us quantify the proportion of patients who need these access programs to afford their medications. Additionally, required transparency reporting relating to copay accumulator programs will help us understand how much of this assistance goes directly to the patients it is intended to assist in the form of out-of-pocket costs, reduced premiums, or holding down annual premium increases, as opposed to getting absorbed by other stakeholders in the supply chain.

> *What considerations should the Departments and OPM take into account in defining the term "pharmacy"? Are there different considerations for retail pharmacies versus mail order or specialty pharmacies? Are there different considerations for prescription drugs dispensed in an inpatient, outpatient, office, home, or other setting?*

There are many considerations for drugs dispensed in different care settings, including the cost, the patient experience, safety (in the home setting), and certain potential outcomes like hospital-acquired infection. As explained in greater detail below, there are significant price differentials among the settings for medical benefit drug administration. In some cases, hospital outpatient department charges are *more than double* those of office-based administration of the same drug. This impacts overall drug spending, but it also impacts the patients whose coinsurances reflect these differentials. UnitedHealth recently studied this issue and found that administering specialty medications outside of the hospital outpatient department could save $4 billion per year. **We urge the Departments and OPM to capture site of care consumption dynamics (i.e., the number of patients receiving Part B drugs in the physician office vs HOPD), drug spending (i.e., the proportion of drug spend in the physician office vs HOPD) and pricing information by setting**.

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With regard to specialty pharmacies, any data collected should also require disclosure of ownership interests and disclosure of any restrictions on the specialty pharmacy network. Many insurers and PBMs now own their own specialty pharmacies, which has created network adequacy issues in some plans when physicians' offices are unable to comply with specialty pharmacy mandates and must end participation with that plan. Additionally, due to vertical integration among insurers, PBMs, and pharmacies, it is difficult to ascertain to what extent any savings are passed through to patients. To the extent possible, **we urge the Departments and OPM to collect these data in a way that will create transparency into the vertical consolidation and resulting patient access issues**.

> *What considerations should the Departments and OPM take into account in defining the term "therapeutic class"? How do plans and issuers currently classify prescription drugs by therapeutic class? Does the classification method rely on proprietary software, and how would the choice of therapeutic classification method influence plan and issuer operational costs?*

The fact that there is no commonly agreed upon definition of "therapeutic class" is harmful to patients because it enables insurers and PBMs to define the term in the most contractually advantageous way, regardless of clinical implications. Although we have the United States Pharmacopeia Drug Classification, this is not mandatory for payers to use in any market outside Part D. Thus, there is not one agreed upon classification system used by all insurers, which leaves the insurers to create their own. We have many examples of the problems that result from allowing insurers and their PBMs to set their own definitional rules. For example, PBMs may treat brand-name drugs as generics or generics as brands depending on what suits their invoicing needs, despite the fact that these terms are defined by the Food, Drug, and Cosmetic Act.[1]

The statute uses the term "therapeutic class of drugs" in the context of requiring disclosure of any impact on premiums from the remuneration paid by drug companies to the plan or its PBM. Specifically, the statute directs disclosure of the rebates, fees, and any other remuneration paid "for each therapeutic class of drugs." We should not rely on proprietary software owned by insurers to define therapeutic classes. Rather, **we urge the Departments and OPM to work with the Food and Drug Administration and solicit comprehensive stakeholder input in defining "therapeutic class."** Although this may not be a perfect approach, it has the benefit of delegating this effort to parties with no financial interest in the definitions, while taking into consideration the variety of stakeholder perspectives.

Entities That Must Report

[1] Linda Cahn, *Managed Care*, "When is a brand a generic? In a contract with a PBM" (Sept. 1, 2010).

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> *What role, if any, will Pharmacy Benefits Managers (PBMs) play in furnishing necessary information to plans and issuers, or to the Departments or OPM? If permitted, would plans and issuers rely on PBMs to help satisfy their reporting obligations, such as by retaining PBMs to conduct some or all of the reporting? Could PBMs obtain all the information required to be reported, including general information on the plan or coverage, such as the number of participants, beneficiaries, and enrollees; each state in which the plan or coverage is offered; monthly premiums paid by employers and by participants, beneficiaries, and enrollees; total spending on health care services broken down by type; and the impact on premiums of prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers? If not, would allowing separate reporting forms, modules, or data collection systems for PBMs and issuers and plan administrators to report such information be administratively and operationally feasible? How would separate reporting forms change the costs or burdens associated with compliance?*

This question highlights the extent of the opacity in our drug pricing system, in that the party statutorily compelled to disclose certain information must rely on other entities to provide this information to it first. The fact that a business must rely on a different business to satisfy reporting obligations highlights the intentional opacity of our drug pricing system. Not only should the Departments and OPM permit plans and issuers to rely on PBMs, but they must also *require* PBMs, including their contractors, sub-contractors, and subsidiaries, both domestic and international, to furnish all necessary and related information required for plans and issuers to satisfy their reporting obligations. Allowing insurers to provide limited data based on the fact that the PBMs (many of which are now owned by insurers) are technically different entities will further distort the already disproportionate balance of power over information in this market.

Information Required to be Reported

> *What considerations are important for plans and issuers in determining the 50 prescription drugs with the greatest increase in plan expenditures? Should the increase be measured based on the absolute increase in dollars; percentage increase in price; the increase relative to another measure, such as overall spending by the plan or issuer; or something else? What factors should the Departments and OPM consider in selecting an approach? If the Departments and OPM define the increase in proportion to the change in overall spending, should the increase be measured in comparison to total spending or only to spending on prescription drugs?*

One consideration to take into account and request data on (in addition to expenditures-related information) is the reductions in other healthcare spending these products create, such as Emergency

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Department (ED) presentation and hospitalization. This will help quantify the value of patients with high disease burden and high medical needs accessing the right drug at the right time in the most cost-effective setting. Focusing on pricing and direct drug spend data alone is akin to looking through a keyhole: it will not provide the full picture. For example, a low number of patients with a high spend tells a very different story than an exponential increase in utilization by a large number of patients.

To ultimately arrive at a system in which we price drugs rationally, we must be able to quantify the financial and economic value that these drugs provide, from the perspective of the cohorts that rely on the value these medications provide. To get the full picture, we must measure absolute increases in drug expenditures, but we must also measure spending increases *relative to several other measures*. For example, on an annual basis, we need absolute numbers related to: reporting absolute increase in dollars; percentage increase in price; rebate dollars received; average number of beneficiaries receiving the drug; proportion of drug spend in physician office vs HOPD; average number of primary care provider visits, specialist visits, ED presentations, hospitalizations; and, average *per capita* spend on ED and inpatient services for each drug.

With these data reported, drug expenditure increases could also be measured relative to: the change in beneficiaries taking the medication, change in rebate dollars from previous period, change in number of beneficiaries receiving the drug, proportion of beneficiaries receiving the drug in a physician office vs HOPD, change in number of annual PCP visits, change in number of annual specialist visits, change in number of annual labs/imaging, change in number of annual ED visits, change in number of annual hospitalizations, and average proportion of annual inpatient care. Plans and issuers must look at their beneficiaries longitudinally before they initiated the medical benefit drug treatment and after to quantify and consider the long-term cost benefits and health spend reduction associated with effectively managed chronic disease rather than only focusing on the 50 drugs with the highest gross cost.

> *What considerations are important for plans and issuers in determining the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year? Should rebates and other remuneration be measured by total dollar amount? Should rebates and other remuneration be measured in comparison to another measure, such as total spending on a drug or a unit price? If a price measure is used, which price measure should be used and why?*

While total dollar amounts are a key data point, the so-called "gross-to-net bubble" and the growth in that trend are critical to obtaining the full picture of drug spending and list price increases. According to research conducted at the University of Southern California, "Drug rebates and list prices are positively correlated: On average, a $1 increase in rebates is associated with a $1.17 increase in list price." This correlation between list prices and price concessions (which influence formulary placement) affects patients. In 2019, several pharmaceutical executives testified before Congress about the relationship

between price concessions and formulary access.[2] One executive stated that his company was discouraged from reducing certain drug prices to avoid jeopardizing their formulary access. Another explained that, after his company reduced the list price of its lead cardiovascular product by 60%, the drug lost formulary access, likely because a competitor with a higher list price could provide a bigger rebate for the PBM. This means that, not only are price concessions driving formulary design, they are discouraging drug companies from reducing their list prices, on which patient cost-sharing is often based.

The disclosure compelled by CAA section 204 will only be useful if it can help the Departments and OPM quantify the relationship between price concessions and list prices, as well as the extent to which price concessions influence formulary design. As such, **we urge you to measure rebates and other remuneration as compared to list prices—specifically, list price increases—and clear disclosure of which number is used to assess cost-sharing.**

> *PHS Act section 2799A-10, ERISA section 725, and Code section 9825 require plans and issuers to report total spending on health care services separately for hospital costs, health care provider and clinical service costs (for primary care and specialty care separately), prescription drug costs, and other medical costs, including wellness services. Which cost elements should be included in each category? Should the Departments and OPM collect prescription drug spending information separately based on the setting of care?*

The ultimate goal of drug pricing and expenditures transparency is to utilize the information to reduce spending on prescription drugs and lower beneficiary out-of-pocket costs. This makes site of care spending a critical data point. When it comes to medical benefit drugs, as noted above, the data overwhelmingly indicates that physicians' offices and ambulatory infusion centers are by far the most cost-effective setting.

For example, the Employee Benefit Research Institute (EBRI) recently studied cost differences in healthcare services by site of treatment, including for the delivery of non-oncology specialty medications. The report found that, "[I]f site-of-treatment price differentials for specialty medications were eliminated, employers and workers would save as much as 36 percent, depending on the medication."[3] In fact, for seven of the eight drugs studied, EBRI found that the hospital outpatient department had the largest allowed charges of any of the three settings (home, physician's office, or outpatient). In some cases, the hospital outpatient department charges were *more than double* those of

[2] Hearing before the House Energy & Commerce Health Subcommittee, "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain" (May 9, 2019).

[3] EBRI Issue Brief No. 525: "Location, Location, Location: Cost Differences in Health Care Services by Site of Treatment — A Closer Look at Lab, Imaging, and Specialty Medications" by Paul Fronstin, Ph.D., Employee Benefit Research Institute, and M. Christopher Roebuck, Ph.D., RxEconomics, LLC (Feb. 18, 2021).

office-based administration. This has an impact on overall drug spending, but it also impacts patients, whose coinsurances reflect these differentials. UnitedHealth recently studied this issue and arrived at the same conclusion, finding that administering specialty medications outside of the hospital outpatient department could save $4 billion per year.

Given this potential for savings, **we urge the Departments and OPM to collect spending information separately based on the setting of care.**

> *Should the Departments and OPM collect information on rebates, fees, and any other remuneration at the total level or broken out by relevant subcategories? For example, in the PBM Transparency for Qualified Health Plans (QHPs) data collection, PBMs will report information for retained rebates, rebates expected but not yet received, PBM incentive payments, price concessions for administrative services from manufacturers, all other price concessions from manufacturers, amounts received and paid to pharmacies, and spread amounts for retail and mail order pharmacies. Should the Departments use the same or similar subcategories for the reporting requirements under PHS Act section 2799A-10, ERISA section 725, and Code section 9825?*

Relevant subcategories provide better insight and transparency. The PBM Transparency for Qualified Health Plans (QHPs) data collection requires disclosure of generic dispensing rates by pharmacy type; aggregate amounts of rebates; discounts and price concessions – *excluding bona fide service fees* – that are attributable to patient utilization and those that are passed on to the plan sponsor; and, total number of dispensed prescriptions. Additionally, it requires disclosure of the "spread," i.e., the difference between the amount the insurer pays the PBM and the amount the PBM pays the pharmacy. **These reporting requirements should serve as the "floor" for CAA section 204 reporting requirements, but we urge the Departments and OPM to require additional information, since CAA section 204 has no exemptions.**

As an example of just how fungible these revenue streams are, a recent lawsuit between Express Scripts and a drug company revealed that the PBM charged an "administrative fee" almost fifteen times higher than the associated rebate for the drug at issue. Moreover, this "administrative fee" increased sharply right after the manufacturer increased the drug's price, which strongly suggests this "fee" was functionally a rebate. In a four-month period, Express Scripts invoiced almost $27,000 for "formulary rebates" while charging over $363,000 in "administrative fees."[4] This illustrates that exempting "*bona fide* service fees" creates far too big of a loophole because it could allow the majority of the money exchanging hands to be classified as such, leaving us with an incomplete and manipulated data set.

[4] *Express Scripts, Inc., et al*. v. *kaléo, Inc*., No. 17-cv-01520 (E.D. Mo. May 16, 2017).

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Are there types of rebates and price concessions that are passed directly to the participant, beneficiary, or enrollee? If so, how should they be treated? Should they be included or acknowledged in this data collection?

Due to the lack of transparency, it is difficult to identify types of rebates and price concessions that are passed through. Rebates and price concessions are intended to improve affordability of care for patients. We must track the proportion of rebates and other price concessions that are making it through to the beneficiary, not only in the form of reduced premiums but in the form of reduced cost-sharing. **We urge the Departments and OPM to require disclosure of passed-through price concessions broken down by type of pass-through, including premiums, deductibles, coinsurances, copays, and any other costs borne by beneficiaries.** Anything less will be a disservice to the patients across the country these cost-reduction mechanisms are intended to help.

This information is critical because it speaks directly to the purpose of insurance. If we find that price concessions are only applied to premium reduction, then we effectively have a system of the sickest beneficiaries – those who need high-price medications – subsidizing all beneficiaries across a plan. That is the opposite of how insurance is intended to work.

Public Report and Privacy Protections

In what ways can the Departments and OPM facilitate use of the reports by a variety of interested parties, such as government entities, academics, industry entities, and consumers and their advocates?

The goal of section 204 in directing collection of this information is for the Departments to produce a biannual public report on "prescription drug reimbursements under group health plans (or health insurance coverage offered in connection with such a plan), prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage, aggregated in such a way as no drug or plan specific information will be made public."

Notably, Congress extended an aggregation requirement to the reports that are to be published by the Departments, because those reports will be focused on industry and general plan trends, rather than any individual insurer. Thus, Congress directed the Departments to publish these reports publicly on the respective Department websites. **We urge the Departments to ensure that the reports are as granular and detailed as possible while still abiding by the statutory aggregation requirement**. Since the aggregation requirement prohibits the publication of drug-specific data, we urge the Departments and OPM to establish a clear definition of "therapeutic class," as outlined above. If each insurer can define the phrase "therapeutic class" on its own and the final aggregated report can provide no drug-specific information, then the report will be largely meaningless. As explained herein, we know that price

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concessions drive up list prices. A key next research question is to determine whether this problem is systemic or limited to drugs that share certain characteristics. Quantifying the gross-to-net bubble by therapeutic class – defined uniformly – may provide us with key insight in this regard.

With regard to the data disclosure requirements, no aggregation requirement or confidentiality limitation exists. As such, **we urge the Departments and OPM to not allow reporting entities to withhold certain data. By statute, the determination of what should be aggregated to protect confidentiality is delegated to the Departments and OPM, not the reporting entities.** A transparency provision that compels disclosure of certain information but allows for the withholding of some of the information is no transparency at all.

> *Should the public report include a comparative analysis of prescription drug costs for plans and issuers, relative to costs under Medicare or in other countries?*

A comparison to other countries will be limited in its usefulness as other countries have entirely different healthcare systems, many of which utilize a single payer system based heavily on formulary and coverage restrictions and wait times to manage utilization. However, a comparative analysis across all reporting entities would be useful. Additionally, a comparison of these data to Medicare drug spending could be useful, provided it includes out-of-pocket and premium spending trends. For purposes of such a comparison, the Medicare drug spend data should include Part B drug spending, standalone Part D plan drug spending, and Medicare Advantage plan spending (both pharmacy and medical benefit). That, in and of itself, would provide interesting data regarding similarities and differences among the different silos within Medicare that pay for prescription drug coverage.

I hope this feedback is helpful as you implement CAA section 204. If you have any questions or if I can provide any additional information, please do not hesitate to contact me.

Sincerely,

Brian Nyquist, MPH
Chief Executive Officer
National Infusion Center Association