



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Via Electronic Submission at: www.regulations.gov

January 25, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services (HHS)
Attn: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Centers for Medicare and Medicaid Services; Medicare and Medicaid Programs; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Administrator Verma:

The National Association of Chain Drug Stores (NACDS) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the proposed rule to reduce prescription drug prices for beneficiaries across the country. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Our members operate 40,000 pharmacies and include regional chains with as few as four stores as well as national companies. Chain pharmacies employ more than 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

I. Executive Summary

NACDS strongly supports CMS' proposal to cut Medicare beneficiaries' prescription drug costs by preventing the misuse of pharmacy price concessions as direct and indirect remuneration (DIR). Redefining "negotiated prices" and establishing a broad definition of "price concession" will better align marketplace incentives with the interests of Medicare beneficiaries, and lead to lower total healthcare costs. Vital to the success of these reforms will be the development and establishment of a Medicare Part D: Pharmacy Quality Incentive Program ("pharmacy quality incentive program") that is built on a standard set of pharmacy performance metrics that will drive better health outcomes and reduce the total cost of care.

The proposed changes are consistent with several of the Administration's priorities, including the goal to reduce prescription drug costs for patients; improve the Medicare program; and use "HHS programs to build a value-driven healthcare system."¹ We therefore strongly urge CMS to use its current authority to further update the Part D Program by implementing these much-needed reforms in the final rule.

As discussed in detail below, the following critical points support reform of pharmacy DIR fees, and development of a standard set of pharmacy quality metrics as part of a pharmacy quality incentive program:

- Current pharmacy DIR practices harm Medicare beneficiaries and their community pharmacies, and thwart market-based competition, by increasing beneficiary costs and decreasing drug price transparency.
- CMS has vastly overestimated taxpayer costs associated with its proposals. Pharmacy DIR fee reform and a pharmacy quality incentive program will save taxpayers billions of dollars by incentivizing medication adherence, which is proven to reduce the total cost of care while improving health outcomes.
- Beginning in plan year 2020, CMS should require that all pharmacy price concessions must be included in the negotiated price made available to beneficiaries at the point of sale, using the "lowest possible reimbursement" methodology proposed by CMS.
- This policy should be applied consistently throughout all coverage phases, including the coverage gap.
- "Price concessions" should include any payments received by, and any reductions in payments made by, a plan or its intermediaries. All payments by pharmacies to plans or their pharmacy benefit managers (PBMs), such as transaction fees, administrative fees and network participation fees, should be treated as price concessions that must be included in the negotiated price.
- CMS should further champion Medicare quality and value by establishing a pharmacy quality incentive program, which would include a standard set of performance metrics that consistently and accurately measure pharmacy performance. The program would also realign incentives to foster greater market competition by creating financial incentives to further improve quality and reduce the total cost of care.

¹ CMS, Part D Payment Modernization Model (2019), available at <https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/>

- CMS has clear authority to implement rules that eliminate problems associated with pharmacy DIR fees and promote pharmacy quality.

II. Pharmacy DIR Fees Harm Beneficiaries, Pharmacies, Taxpayers, and the Competitive Marketplace

Treating pharmacy price concessions as DIR fees, rather than including them in negotiated prices made available to Medicare beneficiaries, harms beneficiaries and pharmacies, and undermines market-based competition in Medicare. As CMS has thoroughly documented, pharmacy DIR fees increase beneficiary drug costs, and increase taxpayer costs for catastrophic coverage and low-income cost-sharing subsidies. 83 Fed. Reg. 62152, 62190-92 (Nov. 30, 2018). CMS also recognizes that pharmacy DIR fees harm pharmacies by reducing transparency and predictability of reimbursement. *Id.* at 62191. More broadly, pharmacy DIR fees undermine drug price transparency, which is necessary for efficient market competition that would reduce prescription drug costs. *Id.* at 62176. CMS has recognized the harms caused by pharmacy DIR fees for years.²

NACDS members' experiences confirm that the abuses and harms of pharmacy DIR fees are genuine. And the situation is rapidly growing worse, as abusive pharmacy DIR fees continue to grow exponentially. 83 Fed. Reg. at 62174 (pharmacy DIR fees have grown an astonishing 45,000 percent). Pharmacies are calling on CMS to eliminate these and other harms now, by implementing reforms to eliminate pharmacy DIR fees.

A. Pharmacy DIR Fees Harm Medicare Beneficiaries

Pharmacy DIR fees increase beneficiary costs and shift costs to the federal government. As CMS recognizes in the proposed rule, "when pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug." *Id.* at 62174.

Congress defined "negotiated prices" as including pharmacy price concessions to ensure that beneficiaries costs are based on true plan costs at the pharmacy. Excluding pharmacy DIR fees from negotiated prices disconnects beneficiary costs

² See, e.g., 82 Fed. Reg. 56336, 56420-21 (Nov. 28, 2017) (explaining how pharmacy DIR fees increase beneficiary costs and decrease drug price transparency necessary for competition among plans); CMS, Medicare Part D – Direct and Indirect Remuneration (DIR) (Jan. 19, 2017) (noting the negative impact of pharmacy DIR fees on beneficiary drug costs, taxpayer subsidies and plan cost-avoidance); CMS, "Fact Sheet - Medicare Part D – Direct and Indirect Remuneration (DIR)" (January 19, 2017), available at <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>.

from true costs, preventing beneficiaries from knowing how much is actually being paid.

Pharmacy DIR fees obfuscate true drug prices, thus undermining the transparency needed to allow all stakeholders to make informed decisions about how to best meet healthcare needs. As CMS points out, “consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or a plan that offers them the lowest-cost drug and pharmacy combinations.” *Id.* at 62176. NACDS agrees with CMS that

the quality of information available to consumers is even less conducive to producing efficient choices when pharmacy price concessions are treated differently by different Part D sponsors; that is, when they are applied to the point-of-sale price to differing degrees and/or estimated and factored into plan bids with varying degrees of accuracy. *Id.*

Beneficiaries are likely unaware that the increasing use of DIR fees has led to inflated drug costs. The impact of higher cost-sharing for beneficiaries not only increases out-of-pocket costs for prescription drugs, but it also negatively impacts medication adherence, leading to increased total cost of care and poorer health outcomes.

B. Pharmacy DIR Fees Harm Pharmacies

Pharmacy DIR fees force community pharmacies to conduct business in an environment of perpetual uncertainty. For months after dispensing a medication, pharmacies are unsure of their reimbursement for that drug. This uncertainty is derived from not knowing whether and how much additional money will be clawed-back at some future date due to imposed DIR fees. Unfortunately, under the current system plans exert substantial market power over pharmacies, resulting in contractual arrangements that are significantly one-sided. As explained in greater detail below, this includes leveraging program loopholes, charging creative “fees,” and imposing unachievable performance benchmarks, to name a few. As a result, pharmacies are faced with disparate payment and performance arrangements from plans, resulting in tremendous uncertainty over drug reimbursement. This unpredictable variability in the amount and timing of DIR fees provides little reimbursement transparency to community pharmacies.

As discussed in Section V below, this lack of drug reimbursement transparency is exacerbated by the lack of standardization and transparency of pharmacy performance metrics. Applying uneven and varying metrics and methodologies that do not appropriately or accurately measure pharmacy performance make it extremely difficult or near impossible for pharmacies to predict how much they will be reimbursed for dispensing prescribed medications to their patients. This lack of

business certainty acts as a powerful disincentive for pharmacies to participate in Medicare. And that disincentive is growing exponentially with the growth of pharmacy DIR fees.

The use of pharmacy DIR fees varies widely among Part D plans and PBMs. Each Part D plan may use different, vague, and unachievable metrics and performance benchmarks with inconsistent weighting, accrual calendars, and methods for fee collection. Contract terms like this are the result of what CMS calls the “one-sided nature of the pharmacy payment arrangements that currently exist.” *Id.*

One example of the unachievable nature of current pharmacy metrics is in the utilization of Generic Dispensing Rate (GDR) metrics. A pharmacy may be required to have a GDR of 95 percent or better in order to achieve the highest performance benchmark and thus qualify for the lowest pharmacy DIR fees. However, according to analysis conducted by Inmar, pharmacy data experts, only 4 percent of pharmacies actually achieve a GDR of 95 percent or higher, in which most of those pharmacies are not the traditional community pharmacies that serve Medicare beneficiaries.³ Plans and PBMs argue that they have adjusted reimbursement rates to offset pharmacy DIR fees. However, the data demonstrates that this is not the case and, in fact, reimbursement rates for pharmacies have declined since the use of DIR fees became more widespread. DIR fees are now averaging greater than 1 percent of overall prescription drugs sales, and more than 5 percent of gross profit. *Id.*

The vague and inconstant manner in which Part D plans use pharmacy DIR fees highlights the immediate need for a pharmacy quality incentive program that establishes consistent, achievable, and transparent pharmacy measures that promote better health of Medicare beneficiaries, decrease total cost of care, and reduce needless administrative burdens on community pharmacies.

C. Pharmacy DIR Fees Harm Competition

Misuse of pharmacy DIR fees not only harms beneficiaries and pharmacies, it also harms overall market competition, which is the bedrock of the Medicare drug benefit. As CMS explains in the proposed rule, “when some sponsors include pharmacy price concessions in negotiated prices while others treat them as DIR, the concept of negotiated price no longer has a consistent meaning across the Part D program, undermining meaningful price comparisons and efficient choices by consumers.” *Id.*

³ Inmar comments submitted to CMS on “Centers for Medicare and Medicaid Services; Medicare and Medicaid Programs; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P); p. 9 (January 24, 2019).

Not only is drug price transparency harmed by the misuse of DIR fees, but pharmacy quality transparency is clouded by the non-standardized and inconsistently applied measures upon which DIR fees are assessed. Without a standard set of metrics, beneficiaries, pharmacies and plans are unable to make “apples to apples” comparisons of pharmacy quality. As a result, there is not an effective means for consumers to compare plans and pharmacies within the Part D program, undercutting market competition.

We agree with CMS that “adopting policies that promote competition is an important and relevant consideration in protecting Medicare beneficiaries and the Medicare trust fund from unwarranted costs.” *Id.* To achieve this, CMS must act to address the negative impact of pharmacy DIR fees on beneficiaries, pharmacies, market competition, and the overall Medicare program.

III. CMS’ Proposals Will Reduce Costs and Encourage Competition by Promoting Medication Adherence, Increasing Drug Price Transparency, and Advancing Pharmacy Quality

CMS estimates that its proposed DIR reforms will increase government costs by a net \$13.6-\$16.6 billion over ten years. 83 Fed. Reg. at 62192-94. NACDS agrees with CMS that its DIR reform proposals will reduce federal reinsurance costs and federal low-income cost sharing subsidy costs. *Id.* However, CMS’ estimates of overall Part D cost increases do not account for expected market responses that will offset government costs.⁴

A. DIR Reform and Consistent Performance Metrics Will Reduce Overall Taxpayer Costs by Improving Medication Adherence

CMS has vastly overestimated taxpayer costs. Instituting DIR reform and a pharmacy quality incentive program will actually save taxpayers billions of dollars by promoting medication adherence, which is proven to reduce overall healthcare costs while improving health outcomes.

i. DIR Reform will Cut Overall Healthcare Costs by Lowering Beneficiary Drug Costs

Medication non-adherence—that is, patients not taking their medications as prescribed by their healthcare provider—contributes to \$100-290 billion in unnecessary healthcare expenditures every year as a result of increased

⁴ As CMS has noted in the past, its cost estimates do not account for “behavioral changes” by beneficiaries, plans, pharmacies and others. *See* 82 Fed. Reg. at 56428 fn.54.

hospitalizations and other avoidable, expensive medical services.⁵⁻⁷ A systematic literature review of 79 studies conducted in 2018 revealed the adjusted total cost of non-adherence across multiple disease groups ranged from \$949 to \$52,341.⁸ A 2017 white paper found that the direct medical costs and consequences related to not taking medication as prescribed is estimated to be 7 to 13 percent of national health spending annually – approximately \$250 billion to \$460 billion in 2017, translated to a potential cost to taxpayers of \$6 trillion over 10 years.⁹ And a 2016 cost-benefit analysis concluded that between one and two thirds of medicine-related hospitalizations are caused by poor adherence. Improving adherence could result in annual per-person savings ranging from \$1,000 to \$7,000, depending on the disease state.¹⁰ Multiple, credible sources have drawn the same conclusion: medication non-adherence is a costly, preventable problem that dramatically affects total cost of care.

DIR reform will improve medication adherence by making prescription drugs more affordable for Medicare beneficiaries, which in turn will help reduce the unnecessary costs associated with non-adherence. These savings will offset CMS' estimate of increased government costs.

CMS concludes that including pharmacy price concessions in negotiated prices will reduce beneficiary cost sharing by \$14.8 billion. 83 Fed. Reg. at 62192 A wide variety of rigorous studies demonstrate that reducing patient drug costs increases medication adherence (that is, patients are more likely to take their medications as prescribed by their physicians). Medication adherence, in turn, both improves patient health and reduces overall healthcare costs.¹¹

⁵ Rosenbaum L, Shrank WH; “Taking Our Medicine - Improving Adherence in the Accountability Era;” *New England Journal of Medicine*; Aug. 22, 2013

⁶ Network for Excellence in Health Innovation; “Bend the Curve: A Health Care Leader’s Guide to High Value Health Care;” 2011.

https://www.nehi.net/writable/publication_files/file/health_care_leaders_guide_final.pdf

⁷ The NCPIC Coalition; “Enhancing Prescription Medicine Adherence: A National Action Plan;” 2007.

<http://www.bemedwise.org/docs/enhancingprescriptionmedicineadherence.pdf>

⁸ Cutler RL, et al; “Economic Impact of Medication Non-Adherence by Disease Groups: A Systematic Review;” *BMJ Open* 2018;8:e016982. doi:10.1136/ bmjopen-2017-016982

<https://bmjopen.bmj.com/content/bmjopen/8/1/e016982.full.pdf>

⁹ “A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination;” *Prescriptions for a Healthy America*; October 2017.

<https://static1.squarespace.com/static/589912df1b10e39bd04eb3ab/t/59f0e439edaed84e6822d9bd/1508959306380/P4HA+WhitePaper+E-DigitalFinal+1017.pdf>

¹⁰ Patterson JA, et al; “Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies;” *American Journal of Managed Care*; 2016. <https://www.ajmc.com/journals/issue/2016/2016-vol22-n9/cost-benefit-of-appointment-based-medication-synchronization-in-community-pharmacies>

¹¹ Conversely, as CMS notes in the proposed rule, “[n]umerous research studies suggest that higher cost-sharing can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.” 83 Fed. Reg. at 62176.

Beneficiary drug costs significantly impact medication adherence. A literature review of 160 studies revealed that an increase in patient share of medication costs is directly associated with a significant decrease in medication adherence.¹² Beneficiaries with chronic disease and low-income status are particularly sensitive to the impact of cost sharing.¹³ In sum, reducing beneficiary drug costs encourages patients to take medically necessary medications as prescribed by their physicians.

Studies also demonstrate that the total cost of healthcare decreases significantly when patients take their medications as prescribed. For example, patients who are adherent to their medications have more favorable health outcomes such as reduced mortality and use fewer healthcare services, especially hospital readmissions and ER visits, leading to reduced healthcare costs.¹⁴ Similarly, a 2014 study funded by the National Institutes for Health examined data from a large, diverse sample of Medicare beneficiaries, and concluded that obtaining prescription drug insurance through Part D was associated with an 8 percent decrease in the number of hospital admissions, a 7 percent decrease in Medicare expenditures, and a 12 percent decrease in total resource use.¹⁵ Additional studies of patients being treated for specific disease states such as diabetes,¹⁶ high cholesterol,¹⁷ and Parkinson's Disease¹⁸ offer additional support for the connection between improved adherence and lower healthcare costs.

¹² Eaddy MT, et al; "How Patient Cost-Sharing Trends Affect Adherence and Outcomes;" *Pharmacy & Therapeutics*; January 2012. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/>

¹³ Adams, A., et al. (May 2001). The Case for a Medicare Drug Coverage Benefit: A Critical Review of the Empirical Evidence. *Annual Review of Public Health*, Vol. 22, No. 1. Retrieved December 20, 2018, from: <https://www.annualreviews.org/doi/10.1146/annurev.publhealth.22.1.49>

¹⁴ Braithwaite S, et al; "The Role of Medication Adherence in the U.S. Healthcare System;" *Avalere Health*; June 2013.

http://www.avalerehealth.net/research/docs/20130612_NACDS_Medication_Adherence.pdf

¹⁵ Kaestner R, et al; "Effects of Prescription Drug Insurance on Hospitalization and Mortality: Evidence from Medicare Part D;" *National Bureau of Economic Research Working Paper Series*; 2014.

<https://www.nber.org/papers/w19948.pdf>

¹⁶ The Pennsylvania Project evaluated a pharmacy-based medication adherence initiative across 283 pharmacies. The intervention, which included pharmacist-led screening for medication non-adherence and counseling for those at an increased risk, led to statistically significant improvement in medication adherence for all medication classes that were studied, and an annual per patient cost savings of \$241 for improved adherence to oral diabetes medications and \$341 related to improved adherence to statin medications. Pringle JL, et al.; "The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs;" *Health Affairs*; August 2014.

<https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.1398>

¹⁷ One study found significant savings due to improved adherence to diabetes medications – or per beneficiary savings of approximately \$5,000 in medical spending. The potential for population-wide savings from improved medication adherence for patients with diabetes is illustrated by the fact that only approximately half of Part D reported good medication adherence. Stuart, BC, Dai, M, Xu, J, Loh, FH, Dougherty, SJ; "Does Good Medication Adherence Really Save Payers Money?;" *Medical Care*; 2015;53(6):517-523.

¹⁸ Research has also demonstrated that medication adherence reduces the use of acute and post-acute care services. For example, a study of beneficiaries being treated for symptoms of Parkinson's Disease found

In addition to the above studies, the Congressional Budget Office (CBO) reviewed several studies and concluded that “a 1 percent increase in prescription drug use would cause spending for medical services to fall by roughly one-fifth of 1 percent,” and these cost savings “begin in the same year as the change in prescription drug use.¹⁹ Thus, the CBO concluded that although improved medication adherence may increase costs in the Medicare Part D program, these costs are offset by significantly decreased medical costs. These overall healthcare savings occur because patients who take their medications as prescribed avoid expensive hospitalizations and other medical services. *Id.*

ii. Establishing a Pharmacy Quality Incentive Program Built on Standardized Performance Metrics Will Reduce Healthcare Costs

Developing standardized pharmacy performance metrics through a pharmacy quality incentive program would also reduce the total cost of care by aligning incentives for pharmacies, plans, and PBMs to further improve medication adherence. Medication adherence is one of the most cited areas where community pharmacies can play a role in improving health outcomes and reducing costs. Community pharmacists routinely collaborate with other healthcare providers, health systems, and caregivers to positively address patient outcomes and mitigate rising healthcare costs. Initiating and implementing a successful medication adherence program depends on the realignment of perverse program incentives.

The Pennsylvania Project serves as one recent example of a large-scale community pharmacy demonstration study that evaluated the impact of medication adherence on five chronic medication classes.²⁰ The Project involved 283 pharmacists who screened 29,042 patients for poor adherence risk and provided brief interventions to patients with increased risks. The intervention group experienced statistically significant improvements in adherence across all medication classes. Further, the study demonstrated a significant reduction in per patient annual healthcare spending for patients taking statins (\$241) and oral diabetes medications (\$341). Based on these findings, the study concluded that such pharmacy adherence

that medication adherence was associated with a 14% lower risk of hospitalization, a 33% lower risk of skilled nursing facility episodes, 17% lower risk of home health episodes, and an estimated \$2,200 in reduced health care costs over 19 months. Wei, YJ, Palumbo, FB, Simoni-Wastila, L, et al. Antiparkinson Drug Adherence and Its Association with Health Care Utilization and Economic Outcomes in a Medicare Part D Population. *Value in Health*. 2014;17(2):196-204.

¹⁹ Congressional Budget Office; “Offsetting the Effects of Prescription Drug Use on Medicare’s Spending for Medical Services;” 2012. <https://www.cbo.gov/publication/43741>

²⁰ Pringle JL, et al., “The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs,” *Health Affairs* (Aug. 2014), available at <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.1398>

programs would reduce costs for a plan with 10,000 members by \$1.4 million each year and could also be expected to increase the plan's star rating.

While the Pennsylvania Project is a prime example of how pharmacy patient care programs improve adherence and reduce costs, no standardized quality program to improve adherence currently exists for the Part D program. Instead, plans develop and apply inconsistent and varying performance metrics, especially related to adherence, leading to arbitrary and incompatible demands on pharmacies across plans and preventing the full benefit of these initiatives for patients.

A standard set of metrics would apply consistent performance metrics to pharmacy adherence programs, ensuring that a pharmacy can implement medication adherence programs across plans that consistently improve medication adherence and reduce overall Medicare costs. CMS should develop a set of standard quality metrics for medication adherence and other pharmacy programs to align quality standards that reflect evidence-based strategies to best improve beneficiary health and reduce overall Medicare costs. To advance health outcomes further, CMS should establish a pharmacy quality incentive program that encourages plans to implement consistent pharmacy quality programs designed to drive better medication optimization and health outcomes.

In summary, reducing beneficiary drug costs through DIR reform, and improving quality by developing a pharmacy quality incentive program built on consistent performance metrics, will improve medication adherence. Better adherence, in turn, will both improve patient health outcomes and reduce total cost of care. These substantial cost savings should be accounted for in CMS' estimates of the overall savings that will be generated by its DIR reform proposals.

B. Other Behavioral and Market Responses to DIR reform will Further Reduce Costs

CMS estimates that beneficiary and taxpayer costs associated with plan premiums may increase. However, these estimates do not account for expected market responses and behavioral changes that will generate savings. Medicare plans have a primary interest in maintaining competitive premiums to attract beneficiaries, so it is reasonable to expect that plans will take action to reduce or eliminate potential increases in premiums.

Last year, the consulting firm Milliman released an important report that analyzed the impact of including all pharmacy price concessions and half of manufacturer rebates in negotiated prices at the point-of-sale.²¹ The report included robust, realistic models based on changes in behavior that would likely result from DIR

²¹ Milliman, "Reducing Part D Beneficiary Costs Through Point-of-Sale Rebates" (January 16, 2018).

reform. Milliman concluded that “the net impact of potential behavioral changes and market responses could be to reduce spending for all stakeholders, with overall government savings of \$8 to \$73 billion over ten years.” *Id.* at p. 1.²²

For example, plans would likely work to maintain competitive premiums by reducing costs in other areas, such as by further encouraging use of generics that reduce drug costs. As Milliman points out, “this change in strategy could result in overall lower spending for all stakeholders and could potentially offset some of the increase in government costs expected to occur...” *Id.* at p. 7. Plans may also shift to lower cost medications by implementing innovative plan designs, such as adjusting cost sharing for preferred and non-preferred drugs to encourage utilization of lower cost drugs.

The greatest impact on plan and government costs may come from a focus on lower cost specialty drugs. Under current practices, high-cost specialty drugs are often subject to percentage-based pharmacy DIR fees, which accentuate the harm to beneficiaries by dramatically increasing cost sharing for those drugs. Including these pharmacy DIR fees in negotiated prices would eliminate an incentive for plans to favor these high cost specialty drugs, creating further incentives for plans to focus on lower cost specialty alternatives. As the Milliman report notes, “[s]pecialty medications in particular could be a focus when adjusting formulary strategies, because these products have the highest POS costs.” *Id.* at p. 8. A sharper focus on lower-cost alternatives to high cost specialty drugs would likely reduce costs for all stakeholders.

In summary, reducing beneficiary cost-sharing through DIR reform, and encouraging adherence programs through a pharmacy quality program built on standard set of performance measures, will lead to better medication adherence and more beneficiaries taking their medication as prescribed. Better adherence will lead to better health outcomes and a significant reduction in costs for the government through the avoidance of more costly future medical treatment.

IV. All Pharmacy Price Concessions Should Be Included in Negotiated Prices

NACDS supports the proposed revisions to the treatment of pharmacy price concessions in Medicare. Implementing the proposal will eliminate the harm caused by excluding pharmacy price concessions from negotiated prices and will generate savings for Medicare beneficiaries and taxpayers.

²² Although the Milliman models were based on reforms to the treatment of pharmacy and manufacturer price concessions, the current proposal to reform pharmacy price concessions will lead to the same types of behavioral changes by plans and PBMs that would yield cost savings for the government.

A. NACDS Supports the Revised Definition of “Negotiated Price”

NACDS agrees with the CMS proposal to delete the existing regulatory definition of “negotiated prices” and adopt a new definition of “negotiated price” as the lowest amount a pharmacy will receive as reimbursement for a covered drug from a plan. The “reasonably determined” exception is a regulatory loophole that plans have exploited to increase beneficiary drug costs. CMS should close that loophole completely.

Problems associated with pharmacy DIR fees are the result of the “reasonably determined” exception in the current definition of “negotiated prices.” Pursuant to that exception, plans artificially inflate negotiated prices made available to beneficiaries by refusing to subtract “contingent” pharmacy price concessions “that cannot reasonably be determined at the point-of-sale.” 42 C.F.R. § 423.100. As CMS notes in the proposed rule, plans have applied the “reasonably determined” exception much more broadly than the agency intended. 83 Fed. Reg. at 62177. CMS has the authority to address the abuse of the “reasonably determined” exception by plans.

Using this authority, CMS should eliminate the reasonably determined exception. Instead, all pharmacy price concessions should be reflected in the negotiated price that is made available to beneficiaries at the point of sale and reported to CMS on a prescription drug event (PDE) record.

As CMS notes, the use of pharmacy DIR fees has exponentially increased in recent years, and there is every reason to believe this trend will continue unless CMS acts now. When looking at the last 15 quarters and expectations for 2019, DIR fees will continue to increase, with pharmacy DIR fees expected to range between 6.0 percent and 6.39 percent of Medicare Part D sales during 2018.²³

If all pharmacy price concessions were included in negotiated prices at the point-of-sale, pharmacies would know what prices they are selling the product for and how much it cost them, just like any other business. When pharmacy DIR fees are clawed-back retroactively, as is currently the case, pharmacies lack control over their own revenues and profitability, creating undue financial risk and business operation challenges.

The proposal to base beneficiary cost sharing on the “lowest possible reimbursement” will produce direct savings for beneficiaries at the pharmacy

²³ Inmar comments submitted to CMS on “Centers for Medicare and Medicaid Services; Medicare and Medicaid Programs; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P); p.5 (January 24, 2019).

counter. In addition, it will give community pharmacies transparency into the total concessions they provide during the plan year.

NACDS agrees with CMS that contingent incentive payments to pharmacies should not be reflected in the negotiated price. Including contingent incentive payments in the negotiated price would create perverse incentives for beneficiaries to use lower performing pharmacies. As CMS notes, including the amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at “high performing” pharmacies that receive incentive payments. 83 Fed. Reg. at 62178.

CMS notes that it is “considering for a future year, which could be as soon as 2020, adopting a new definition of ‘negotiated price’” as well as related DIR reforms. **NACDS strongly recommends that CMS move forward as quickly as possible with such changes by incorporating pharmacy DIR fee reform into a final 2020 Part D rule.** As discussed above, these reforms are needed immediately to provide relief to beneficiaries and community pharmacies, and to encourage drug price transparency and market competition that is the bedrock of the Medicare Part D program. Without such reform, we expect beneficiaries will continue to see no relief in their out-of-pocket costs. In addition, we expect abuses to continue with few changes, as there is little recourse for community pharmacies to oppose current practices. The proposed changes are not new and should not catch plans off guard. Rather, CMS has highlighted these problems and potential reforms on numerous occasions over the years. Now is the time for CMS to move beyond talking about drug pricing reform and start implementing drug pricing reform by eliminating pharmacy DIR fees. Any further delay in correcting the many problems that CMS has identified with pharmacy DIR fees will only exacerbate the situation.

In the proposed rule CMS requests comment on a “considered alternative to the lowest possible reimbursement approach that would require Part D sponsors to apply less than 100 percent, e.g., 95 percent or more, of pharmacy price concessions at the point of sale.” 83 Fed. Reg. at 62179. NACDS supports the revised definition of “negotiated price” as proposed by CMS, because it will have the greatest positive impact on beneficiaries and the Medicare program as a whole. Additionally, NACDS believes that requiring that 100 percent of pharmacy price concessions must be included in the negotiated price will minimize the potential for plans to abuse the system by exploiting potential gaps in the program, as CMS has noted is happening with the “reasonably determined” exception. In addition, anything less than 100 percent will not resolve pharmacies’ uncertainty about total reimbursement amounts, therefore limiting the potential to best serve beneficiaries. Thus, we urge CMS to ensure that 100 percent of pharmacy price concessions are included in negotiated prices at the point-of-sale.

Finally, because the proposal calls for negotiated prices to reflect the lowest possible reimbursement the pharmacy can receive, CMS should include safeguards to ensure that pharmacies are not reimbursed for less than drugs actually cost. We fear that such potentially improper actions could harm Part D beneficiaries by driving pharmacies out of the program. We encourage CMS to include safeguards that plans provide adequate reimbursement to meet their Medicare program access requirements. Maintaining beneficiary access and reducing barriers to care is a fundamental pillar of the Part D program and is of vital importance to Medicare beneficiaries. A program without safeguards in place to prevent below-cost reimbursement threatens that fundamental pillar and will potentially lead to disruption in continuity of care, increased risks of poor health outcomes, and more costly complications. Safeguards can be put in place without impeding plans' ability to design and structure plan benefits that meet the needs of beneficiaries while keeping prescription drug costs to a minimum. To ensure this, CMS should also establish a protocol for the reporting of inappropriate activities by plans related to inadequate pharmacy reimbursement.

B. Any Definition of "Price Concession" Must Be Comprehensive and Include All Remuneration and Cost Savings, Including Pharmacy Transaction Fees

NACDS supports CMS in the development of a definition for "price concession." NACDS agrees that the definition should be broad enough to account for the various types of concessions currently utilized within the Part D program, and to account for future types of concessions that may be used in the program. Without clear definitions of what constitutes a "price concession" and what should therefore be included in the negotiated price, NACDS is concerned that plans will find loopholes to reclassify or redefine pharmacy price concessions in a manner that excludes them from negotiated prices, thereby increasing beneficiary drug costs.

CMS is also considering a definition that would include any form of discount, direct or indirect subsidy, or rebate received by the plan or its intermediary contracting organization from any source, that serves to decrease the costs incurred by the plan. NACDS supports the intent of the definition, but offers the following revisions for consideration:

Price concession means any form of discount, direct or indirect subsidy, ~~or~~ rebate, fee paid by a pharmacy or deducted from payments to a pharmacy, or any other remuneration received directly or indirectly by the Part D sponsor or its intermediary contracting organization from any source, that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: discounts, chargebacks, rebates, cash discounts, transaction fees, network participation fees and other administrative fees collected from

pharmacies, free or reduced cost goods contingent on a purchase, coupons, free or reduced-price services, and goods or services in kind.

These suggestions align with the goal of creating a broad definition that is meant to capture all types of price concessions.

The proposed revisions above include pharmacy transaction fees, network participation fees, and any other fees that plans charge pharmacies. Pharmacies share the concern expressed by the data experts at Inmar that these fees, which are significant and growing, are being collected from pharmacies but are not accounted for in negotiated prices or elsewhere. NACDS appreciates CMS issuing a reminder to plans that pharmacy fees should be subtracted from negotiated prices when they are deducted from payments made to pharmacies. But without a more definitive requirement by CMS, plans may separately invoice pharmacies in an attempt to continue to artificially inflate beneficiary costs. Therefore, as reflected in our proposed revisions to the “price concession” definition, NACDS strongly recommends that CMS should close all such loopholes by requiring plans to include all pharmacy fees in negotiated prices. Pharmacies are paid to dispense medications to Medicare beneficiaries, so any direct or indirect payments collected from pharmacies reduce plan drug costs and should be reflected in negotiated prices.

C. Excluding Pharmacy Price Concessions from Negotiated Prices Is Inconsistent with The Social Security Act And CMS Rules

Under the current rule’s “reasonably determined” exception, Medicare plans exclude contingent pharmacy price concessions from negotiated prices provided to Medicare beneficiaries if the price concessions “cannot reasonably be determined at the point-of-sale.” 42 C.F.R. §423.100. However, Congress intended for all pharmacy price concessions to be included in negotiated prices. Other provisions of the current rule also require negotiated prices to reflect “total” pharmacy price concessions and prohibit plans from recouping payments from pharmacies after the point-of-sale. Because the “reasonably determined” exception is inconsistent with the statute and other provisions of the CMS rule, NACDS asks CMS to eliminate the “reasonably determined” exception.

i. Federal Law Requires Inclusion of All Pharmacy Price Concessions in Negotiated Prices

The Social Security Act requires that all pharmacy price concessions must be included in negotiated prices provided to Medicare beneficiaries at the point-of-sale. The statute states that plans “shall provide enrollees with access to negotiated prices used for payment for covered Part D drugs,” and those negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D

drugs....” Social Security Act § 1860D–2(d), codified at 42 U.S.C. § 1395w-102(d). The repeated use of “shall” in the statute demonstrates that the law mandates inclusion of pharmacy price concessions in negotiated prices. Nothing in the law purports to authorize the current rule’s “reasonably determined” exception to this statutory mandate.

Congress made clear that all pharmacy price concessions must be included in negotiated prices provided to beneficiaries at the point-of-sale. The official Conference Report accompanying the enacted law demonstrates that the law requires that negotiated prices must include “all” pharmacy price concessions. House Conference Report No. 108-391, p. 438 (Nov. 21, 2003) (“Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or direct or indirect remunerations), regardless of the fact that no benefits may be payable.”).²⁴

The rationale for requiring negotiated prices to include all pharmacy price concessions is clear: Beneficiary cost sharing at pharmacies should be based on actual drug costs at pharmacies, not artificially inflated amounts that do not reflect true drug prices paid to pharmacies. Congress used the term “cost sharing” because it intended beneficiaries to pay a portion of the genuine “cost” of a drug. There is no reason to believe that Congress intended beneficiary “cost sharing” to be based on an artificially inflated dollar figure that is not what the beneficiary’s drugs actually cost at the pharmacy. As CMS notes, excluding pharmacy price concessions from negotiated prices artificially inflates beneficiary cost sharing, and makes it more difficult for beneficiaries to know “the actual cost for a drug.” 83 Fed. Reg. at 62174.

Excluding pharmacy price concessions from negotiated prices is inconsistent with the statute and Congressional intent to include “all” pharmacy price concessions in negotiated prices. “Negotiated prices” that exclude pharmacy price concessions obviously are not the true prices that plans have negotiated with pharmacies, and thus are not genuine negotiated prices that the statute requires plans to offer to beneficiaries.

ii. CMS Correctly Understands That the Statute Calls for Inclusion of Pharmacy Price Concessions in Negotiated Prices

As discussed above, the statute reflects Congressional intent to include all pharmacy price concessions in negotiated prices. CMS has previously suggested that the

²⁴ See also House Report No. 108-178(I), p. 184 (June 25, 2003) (“all PDP plans will be required to make available to their enrollees the benefit of all price discounts.”); House Report No. 108-178(II), p. 154 (July 15, 2003) (“Both standard coverage and actuarially equivalent coverage would offer access to negotiated prices, including applicable discounts.”).

statute's requirement that negotiated prices "shall take into account" price concessions might not require plans to include non-pharmacy price concessions in negotiated prices. In 2005 CMS adopted a rule that formerly allowed plans to include in negotiated prices only price concessions "that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale." 70 Fed. Reg. 4194 (Jan. 28, 2005). However, CMS clarified that this rule allowed plans to exclude from negotiated prices only manufacturer rebates and other "non-pharmacy" price concessions. *See* 79 Fed. Reg. 1918, 1972-74 (Jan. 14, 2014) (emphasis added); *see also* 79 Fed. Reg. 29844, 29876 (May 23, 2014).²⁵ Thus, from the beginning CMS understood that pharmacy price concessions should be included in negotiated prices as required by the statute.

Nevertheless, plans began to artificially inflate beneficiary costs by excluding pharmacy price concessions from negotiated prices. CMS realized that excluding pharmacy price concessions from negotiated prices increases costs and decreases price transparency. *See* 73 Fed. Reg. 28555, 28563 (May 16, 2008) (describing how plans' refusal to include price concessions in negotiated prices harms beneficiaries and taxpayers). Therefore, CMS began to take steps to ensure that pharmacy price concessions are included in negotiated prices, consistent with the statute.

In 2009, CMS revised its rule to state that negotiated prices are the prices that pharmacies "will receive, in total, for a particular drug." 74 Fed. Reg. 1494, 1543 (Jan. 12, 2009). This requirement remains in clause (1) of the current rule's definition of "negotiated prices." The requirement that negotiated prices must reflect the amount that a pharmacy "will" receive "in total" indicates that pharmacy price concessions must be included in negotiated prices, regardless of when those price concessions are realized. CMS adopted this regulatory revision to "increase 'price transparency' by ensuring that only the actual drug price is used to determine beneficiary cost sharing and report drug costs to CMS." *Id.* at 1506 (emphasis added); *see also* 73 Fed. Reg. 28556, 28564 (May 16, 2008) (CMS intended "to require that Part D sponsors base beneficiary cost sharing on the price ultimately received by the pharmacy or other dispensing provider.") (emphasis added).

In 2013, CMS reiterated that "negotiated prices ... must be the amounts ultimately paid to the pharmacy," and it is the agency's "intent that negotiated prices transparently reflect all the price concessions that a pharmacy has agreed to up-front on a per-drug-claim basis."²⁶ Thus in 2014 CMS again revised the "negotiated prices" definition to address the fact that plans were still harming beneficiaries by excluding pharmacy price concessions from negotiated prices. CMS found that "the

²⁵ In contrast, when CMS adopted that rule it observed that the statute does require plans to include at least "some" price concessions in negotiated prices – i.e., pharmacy price concessions. 70 Fed. Reg. at 4244.

²⁶ Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, pp. 164-65 (April 1, 2013), *available at* www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf

exclusion of pharmacy price concessions from the negotiated price thwarts the very price competition that the Congress intended,” and causes a host of other problems for beneficiaries and taxpayers. 79 Fed. Reg. 29844, 29877 (May 23, 2014). CMS also explained that it did not intend to allow plans to exclude pharmacy price concessions from negotiated prices. 79 Fed. Reg. 1918, 1872-74 (Jan. 14, 2014).

As CMS revised the rule in 2014, the agency concluded that “the best interpretation of statutory intent is that all pharmacy price concessions must be reflected in the negotiated price.” *Id.* at 1973 (emphasis added). CMS proposed to interpret the statute:

such that negotiated prices are the amounts that a network pharmacy receives in total for covered Part D drugs, and that these prices must reflect all price concessions from network pharmacies. Therefore, any other negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and (DIR) referenced in the statute would be those price concessions offered by sources other than network pharmacies (or their intermediary contracting organizations). In practice, this means prescription drug manufacturers.

Id. This statutory interpretation promotes competition and “align[s] beneficiary and taxpayer interests in minimizing costs.” *Id.*

As a result, CMS proposed to revise clause (2) of the rule’s definition of negotiated prices to clarify that negotiated prices “[a]re inclusive of all price concessions and any other fees charged to network pharmacies.” *Id.* at 2062. In the final version of the 2014 rule, CMS unexpectedly added the “reasonably determined” exception to clause (2), even though it was not included in the proposed rule. 79 Fed. Reg. at 29962. Importantly, despite adding the “reasonably determined” exception, CMS never altered its conclusion that “the best interpretation of statutory intent is that all pharmacy price concessions must be reflected in the negotiated price.”²⁷

Since it adopted the 2014 rule, CMS has continued to interpret the statute as authorizing the agency to mandate inclusion of all pharmacy price concessions in negotiated prices. In 2017, CMS concluded that “requiring that all pharmacy price concessions be applied at the point of sale would ensure that negotiated prices ‘take into account’ at least some price concessions and, therefore, would be consistent with the plain language of section 1860D–2(d)(1)(B) of the Act.” 82 Fed. Reg. at

²⁷ The PBMs that manage Medicare drug benefits recently affirmed to a federal court that in 2014 “CMS revised the definition of ‘negotiated prices’ to require that all price concessions from pharmacies be reflected in ‘negotiated prices.’” See Brief of Appellant Pharmaceutical Care Management Association (PCMA), p. 33 (May 16, 2017), in *PCMA v. Rutledge*, 8th Cir. No. 17-1629. As PCMA acknowledges, the rule reflects “a deliberate policy choice” by CMS “to capture the ‘true price’ of a drug in the ‘negotiated prices.’” *Id.* at p. 32 (emphasis added).

56427. CMS reiterates this exact same interpretation of the statute in the current proposed rule. 83 Fed. Reg. at 62177. *See also* 83 Fed. Reg. 16440, 16616 (April 16, 2018) (“we believe the statute provides us with discretion to require that Part D sponsors apply ... all pharmacy price concessions they receive to the price of a Part D drug at the point of sale.”).

Overall, CMS has a long history of interpreting the Social Security Act as requiring plans to include pharmacy price concessions in negotiated prices made available to beneficiaries at the point-of-sale. NACDS agrees with CMS that all pharmacy price concessions should be included in negotiated prices, in accordance with statutory requirements, and thus supports the change proposed in this rule.

iii. Other Provisions of the CMS Rule Require Negotiated Prices to Include All Pharmacy Price Concessions

Under the “reasonably determined” exception, plans increase beneficiary costs by excluding contingent pharmacy price concessions from negotiated prices. 42 C.F.R. § 423.100 (negotiated prices “[a]re inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale”). The Obama Administration adopted this exception in 2014 because it thought there “may” be “some” pharmacy price concessions that should be reported as DIR, and thus there was “room for further discussion with industry” on that issue. 79 Fed. Reg. at 29878.

CMS originally believed that the “reasonably determined” exception would be a “narrow exception,” and plans would have to include virtually all pharmacy price concessions in negotiated prices. *Id.* CMS now understands that is not the case, as plans have inflated beneficiary costs by exponentially increasing the amount of pharmacy price concessions that are excluded from negotiated prices.²⁸

As discussed above, allowing plans to exclude pharmacy price concessions from negotiated prices is inconsistent the Social Security Act and CMS’ longstanding interpretation of that statute. Excluding pharmacy price concessions also contradicts two other provisions of the CMS rule that defines “negotiated prices.”

First, clause (1) of the rule defines negotiated prices as prices that a pharmacy “will receive, in total, for a particular drug.” 42 C.F.R. § 423.100. The requirement that negotiated prices must reflect the “total” reimbursement paid to the pharmacy

²⁸ *See* 83 Fed. Reg. at 62174 (45,000% growth of pharmacy price concessions excluded from negotiated prices); 82 Fed. Reg. at 56426 (“We now understand that the reasonably determined exception we currently allow applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards these types of contingent pharmacy payment arrangements, and, as a result, this exception prevents the current policy from having the intended effect on price transparency, consistency, and beneficiary costs.”)

indicates that no pharmacy price concessions should be excluded from negotiated prices. In addition, the requirement that negotiated prices must reflect the amount that a pharmacy “will” receive indicates that pharmacy price concessions must be included in negotiated prices regardless of whether those price concessions are imposed before or after the point-of-sale. Clause (1) does not say that negotiated prices are the preliminary prices that pharmacies are paid at the point-of-sale; it says that negotiated prices are the “total” prices that the pharmacy “will” receive. CMS has repeatedly informed plans that the purpose of clause (1) is to ensure that negotiated prices reflect “actual” drug prices that are “ultimately” paid to pharmacies.²⁹ If a pharmacy receives \$10 from a plan but is subsequently required to return \$2 to the plan, the actual “total” price that the pharmacy will ultimately be paid is \$8, not \$10. In contrast, under the reasonably determined exception plans inflate beneficiary costs by claiming that the “negotiated price” is \$10, not \$8. Thus, the reasonably determined exception, as currently applied by plans, is inconsistent with clause (1).

Second, clause (5) of the rule requires that negotiated prices paid to pharmacies “[m]ust not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.” 42 C.F.R. § 423.100. CMS promulgated clause (5) because plans were forcing pharmacies to return a portion of negotiated prices after the point-of-sale. CMS adopted clause (5) when it “heard from pharmacies that some sponsors apply dispensing fees to claims when they are adjudicated at the point of sale but require that these fees later be rebated back to the sponsor and deducted from payment remittances. Such practices again misstate the negotiated price.” 79 Fed. Reg. at 29877 (emphasis added). That is exactly what is happening when plans fail to subtract pharmacy price concessions from negotiated prices: Plans pay pharmacies at the point-of-sale and report those payments as “negotiated prices,” but then plans subsequently recoup from pharmacies – that is, plans force pharmacies to “rebate back” – part of those negotiated prices. These plan practices are inconsistent with clause (5) and should be halted immediately.

Clauses (1) and (5) are consistent with the statutory requirement that pharmacy price concessions must be included in negotiated prices. In contrast, the “reasonably determined” exception, as currently applied by plans, is inconsistent with both of those clauses and the statute. CMS should eliminate the “reasonably determined” exception and replace it with language consistent with both the statute and the other provisions of its rule.

²⁹ See 74 Fed. Reg. at 1506 (CMS adopted clause (1) to “increase ‘price transparency’ by ensuring that only the actual drug price is used to determine beneficiary cost sharing and report drug costs to CMS.”); *id.* (the rule requires plans to use “the price ultimately received by the pharmacy ... as the basis for calculating beneficiary cost sharing”); 73 Fed. Reg. at 28564 (clause (1) was intended “to require that Part D sponsors base beneficiary cost sharing on the price ultimately received by the pharmacy or other dispensing provider.”) (emphasis added).

D. All Pharmacy Price Concessions Should Also Be included In Negotiated Prices During the Coverage Gap

Excluding pharmacy price concessions from negotiated prices is particularly harmful to beneficiaries during the coverage gap. The beneficiary pays an even larger share of the “negotiated price,” and then the plan claws back from the pharmacy and keeps for itself some or all of the beneficiary’s money.

NACDS strongly supports the inclusion of all pharmacy price concessions in the negotiated price for prescriptions dispensed in the Medicare Part D coverage gap. Allowing plans to exclude a portion of pharmacy price concessions would result in contracting and operational challenges for CMS, plans, pharmacies, and drug manufacturers, and would also reduce savings and drug price transparency for beneficiaries.

If CMS decides not to require the inclusion of all pharmacy price concession in the negotiated price during the coverage gap, plans could take advantage of this loophole and continue to artificially inflate beneficiary drug costs during the coverage gap. Additionally, allowing for the differential treatment of DIR during the coverage gap would require CMS to develop and provide guidance on how claims straddling the coverage gap phase would be adjudicated. Such claims would pose operational challenges for plans and pharmacies.

Treating pharmacy DIR fees differently in the coverage gap would also lead to less savings and more confusion for beneficiaries. The exclusion of any pharmacy price concessions from the negotiated price during the coverage gap would result in increased cost-sharing for beneficiaries. The operational and contracting challenges for plans, retail pharmacies and CMS, combined with the increased costs and confusion for beneficiaries far outweigh any small reduction in government costs that may result from the exclusion of pharmacy DIR from the negotiated price during the coverage gap phase of the Part D program.

NACDS agrees with CMS that the agency has authority to require plans to include all pharmacy price concessions in negotiated prices during the coverage gap. The statute incorporates by reference a regulatory definition of “negotiated price” that is codified at 42 C.F.R § 423.2305. There is no need to amend this definition. Instead, CMS may interpret and apply this definition to require plans to include all pharmacy price concessions in the negotiated price provided to beneficiaries at the point of sale.

Clause (1) of the coverage gap definition of “negotiated price” is identical to clause (1) of the definition of “negotiated prices” that applies outside the coverage gap. *Compare* 42 C.F.R § 423.2305 *with* 42 C.F.R § 423.100. Clause (1) defines negotiated

price as the price that a pharmacy “will receive, in total, for a particular drug.” The requirement that the negotiated price must reflect the amount that a pharmacy “will” receive means that pharmacy price concessions must be included in the negotiated price, regardless of whether those price concessions are imposed before or after the point-of-sale. Likewise, the requirement that the negotiated price must reflect the “total” reimbursement that will be paid to the pharmacy indicates that no pharmacy price concessions should be excluded from the negotiated price.

If a pharmacy receives \$10 from a plan but is subsequently required to return \$2 to the plan, the “total” price that will be paid to the pharmacy is \$8, not \$10. Therefore, under clause (1) of the coverage gap definition of negotiated price, plans must include all pharmacy price concessions to ensure that the negotiated price reflects pharmacy reimbursement “in total.” As CMS states, the agency has authority to include all pharmacy price concessions in the negotiated price during the coverage gap “because such concessions necessarily affect the amount that the pharmacy receives in total for a particular drug.” 83 Fed. Reg. at 62179 (emphasis added).³⁰

Clause (2) of the coverage gap definition states that the negotiated price “[i]s reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale”. This same provision was previously included in the definition of negotiated prices that applied outside the coverage gap. CMS has made clear that this language applies only to “non-pharmacy” price concessions, such as manufacturer rebates. *See* 79 Fed. Reg. 1918, 1972-74 (Jan. 14, 2014) (emphasis added); *see also* 79 Fed. Reg. 29844, 29876 (May 23, 2014).³¹

In fact, that is the only way to read clause (2) consistent with clause (1). Clause (1) requires the negotiated price to equal the “total” reimbursement that the pharmacy will receive, so it would be contradictory to read clause (2) as allowing plans to elect to exclude pharmacy price concessions that clearly affect total pharmacy reimbursement. The better and more consistent reading of these two provisions is that clause (1) requires plans to include all pharmacy price concessions in negotiated prices, while clause (2) allows plans to exclude non-pharmacy price concessions from negotiated prices.

³⁰ *See also* 74 Fed. Reg. at 1506 (CMS adopted clause (1) to “increase ‘price transparency’ by ensuring that only the actual drug price is used to determine beneficiary cost sharing and report drug costs to CMS.”); *id.* (the rule requires plans to use “the price ultimately received by the pharmacy ... as the basis for calculating beneficiary cost sharing”); 73 Fed. Reg. at 28564 (clause (1) was intended “to require that Part D sponsors base beneficiary cost sharing on the price ultimately received by the pharmacy or other dispensing provider.”) (emphasis added).

³¹ In contrast, when CMS adopted this language the agency observed that the statute does require plans to include at least “some” price concessions in negotiated prices – i.e., pharmacy price concessions. 70 Fed. Reg. 4194, 4244 (Jan. 28, 2005).

E. Detailed Claim Level Data Will Support Drug Price Transparency

As part of DIR reform, CMS should take additional steps to increase drug price transparency by allowing network pharmacies to validate that “negotiated price” adjustments are consistent with network contracts on a timely basis. This will also provide CMS greater insight into adjustments by creating detailed records that could be used during auditing of plans.

Specifically, we believe that CMS should require plans to include consistent claim level detail in the electronic remittance advice that accompanies reimbursement payments to pharmacies. The claim level detail should include consistent and pre-established fields needed to properly identify the claim including the Claim Authorization Number, date of service and payment remittance, ingredient cost reimbursed, dispensing fee reimbursed, total payment amounts with the Network ID used to price the claim, the specific dollar amounts, and the appropriate qualifier codes for each payment adjustment including any fees or incentive payments.

NACDS believes this can be accomplished through the following regulatory language:

42 CFR 423.520 - Prompt payment by Part D sponsors.

(I) Payment and pricing information of a claim by the Part D sponsor (or its intermediaries) to a network pharmacy shall in a timely manner properly allocate all pricing components including the Network Reimbursement ID used to price the claim, any fees, price concessions, discounts, incentives or any other forms of remuneration that affect payment and pricing of the claim as part of the claim adjudication response at the point-of-sale. All aforementioned items – Network Reimbursement ID, fees, price concessions, discounts, incentives, or any other forms of remuneration that affect payment and pricing of the claim shall each be identified in a predetermined line item in the remittance advice that is a national standard. The Part D sponsor shall include suitable claim-level detail on the electronic remittance advice that accompanies each payment. This claim-level detail shall include, in an industry standardized format, all fields needed to properly identify the claim, including the Claim Authorization Number, date of service, date of payment remittance, ingredient cost

reimbursed, dispensing fee reimbursed, payment amounts including the Network ID used to price the claim, the specific dollar amounts and the appropriate qualifier codes for each payment adjustment including fees, price concessions, or incentives.

V. CMS Should Establish A Pharmacy Quality Incentive Program Utilizing A Standard Set of Metrics

NACDS strongly urges CMS to establish a *Medicare Part D: Pharmacy Quality Incentive Program* as part of CMS' DIR reform efforts to promote the health of beneficiaries. CMS should signal the creation of such a quality program in this final Part D rule, with the expectation that the program could fully begin in 2021. At a minimum, CMS must set forth a standard set of well-defined performance measures beginning in the 2020 plan year and a corresponding assessment process to promote better health of Medicare beneficiaries and reduce needless and excessive administrative burdens on community pharmacies.

CMS Proposal: CMS proposes consideration of the “option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements. We request commenter feedback on whether these metrics could be designed to provide pharmacies with more predictability in their reimbursements while maintaining plan’s ability to negotiate terms. Additionally, we seek comment on the most appropriate agency or organization to develop these standards...”³²

NACDS supports CMS' recent efforts to align the Medicare program with several of the Administration's policies and direction on healthcare quality, value, transparency, integrity, accountability and care coordination, including the recently announced Part D Payment Modernization Model.³³ We further applaud the Administration's efforts to implement such policies and transition toward value-based models in Medicare, promoting an accountable and competitive marketplace, while realigning incentives to yield improved health outcomes and total cost of care savings for Medicare.

To further advance the Administration's policies, CMS' DIR reform initiative should be tethered to the development of standardized pharmacy performance metrics, as

³² 83 Fed. Reg. at 62179.

³³ Part D Payment Modernization Model. *Centers for Medicare and Medicare Services*. 2019. <https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/>

the first step in establishing a pharmacy quality incentive program. Such an initiative would represent an important, innovative strategy synergistic with the efforts described in the Part D Payment Modernization Model to enhance the Part D Program by: (a) re-aligning Part D incentives toward better quality and health; (b) lowering total cost of care spending; (c) supporting care coordination and transparency across settings; and (d) reducing the excessive and needless administrative burdens presently placed on community pharmacies.

Such a reform initiative is also consistent with and can help further the Administration's policies³⁴⁻³⁷ including:

1. Promote the transition towards value and health outcomes while minimizing the burden of reporting;
2. Hold healthcare providers accountable for a set of population-health metrics while fostering collaboration across the healthcare continuum;
3. Establish measures that are meaningful to providers and patients that help them assess quality and value, with the goal of improving both; and
4. Create federal policies based on "the needs those on the front-line serving patients, seeking to improve quality and health outcomes of beneficiaries they serve."³⁸

While CMS has made significant strides implementing these policies in Medicare Parts A and B, the same reforms have not been implemented in Medicare Part D. To

³⁴ "Meaningful Measures Framework;" *Centers for Medicare and Medicaid Services*.

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>

³⁵ The administration should ensure that delivery system reform models, which aim to hold providers accountable to a set of population-health metrics and total spending, foster collaboration across the systems... The administration should seek to develop measures that are meaningful to providers and patients, and help them assess quality and value, "Reforming America's Healthcare System through Choice & Competition Report (page 112);" U.S. Department of Health and Human Services, U.S. Department of the Treasury, U.S. Department of Labor; 2018. <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>.

³⁶ CMS Quality Strategy;" *Centers for Medicare and Medicaid Services*; 2018.

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy.html>

³⁷ "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs;" *Executive Orders - Budget & Spending*; 2017. <https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/>

³⁸ Administrator Verma emphasized the agency's aim to listen and be responsive to healthcare stakeholders by having federal policies be guided by the needs of those on the front-line serving patients. "CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit;" *Centers for Medicare and Medicaid Services – Press Release*; 2017. <https://www.cms.gov/newsroom/press-releases/cms-administrator-verma-announces-new-meaningful-measures-initiative-and-addresses-regulatory-reform>

make a full transition toward improving quality and health, the Part D program needs this same innovation.

Fragmentation of medical and pharmacy benefits can prevent optimal health outcomes for Medicare beneficiaries. Absent appropriate program quality measures and corresponding incentives aimed at driving better health outcomes and reducing total costs of care, substantial system disfunction and unnecessary spending will continue to occur. Failure to implement a pharmacy quality incentive program by 2021 could unintentionally magnify the existing conflict between drug cost containment and the goal of improving health outcomes. Without a pharmacy quality incentive program, standalone Part D plans lack proper financial incentives to offer pharmacy quality and performance programs. We therefore strongly urge CMS to facilitate movement toward greater value by creating a pharmacy quality incentive program to ensure quality and value are essential pillars of the Part D program.³⁹

A pharmacy quality incentive program would also strongly encourage plans and pharmacies to collaborate and better engage beneficiaries enrolled in Part D plans in accessible, convenient care settings. Likewise, Medicare beneficiaries would have the opportunity to be more engaged with their trusted pharmacists to improve their health and wellbeing. Establishing a pharmacy quality incentive program that rewards quality, value and improved health outcomes will motivate participating entities to reduce total cost of care expenditures and ensure judicious stewardship of federal healthcare dollars. Accordingly, we urge CMS to finalize the concept of a quality program in this final 2020 rule, with the expectation that a full program could commence in 2021.

At the first step in establishing a quality incentive program, CMS must establish for the 2020 plan year a standard set of metrics that measure pharmacy performance and quality. **Establishing a set of performance measures would begin to realign incentives to encourage implementation of evidence-based interventions that promote clinically meaningful outcomes for beneficiaries while also incentivizing robust pharmacy care quality.** Specifically, through the implementation of a standard set of metrics, community pharmacy could undertake an even more substantial role to improve medication optimization, facilitate care coordination, reduce medical errors, advance population health, and empower and

³⁹ The proposed action is consistent with CMS' Value Based Transformation (VBT) vision to advance value-based payment and care. This policy focuses on patients as consumers, providers as accountable patient navigators, payment for outcomes, and prevention of disease. See "Physician-Focused Payment Model Technical Advisory Committee Value Considerations for Model Development and Testing Fact Sheet," (2018), available at <https://innovation.cms.gov/Files/fact-sheet/ptac-value-fs.pdf>.

motivate beneficiaries to achieve better health outcomes. A set of standard metrics can be developed by 2020.

Research and experience demonstrates that community pharmacies should be recognized as alternative care sites.⁴⁰⁻⁴² In fact, community pharmacies have evolved into patient-centered healthcare destinations offering a wide range of accessible and affordable clinical care services including chronic care management and disease state monitoring, smoking cessation programs, transitions of care coordination, minor ailment care, immunization screening and administration, chronic and acute disease screening, mental health services, medication management, health and wellness programs, lifestyle counseling, and more. Additionally, pharmacy care interventions have been shown to substantially mitigate downstream healthcare costs⁴³⁻⁴⁷ and the value of community pharmacy can be leveraged through cross-sector collaboration and partnerships⁴⁸⁻⁴⁹ with

⁴⁰ “The Pharmacy’s New Role in Providing Healthcare Services;” *PM3260 Magazine*. January 23, 2014. <https://www.pm360online.com/the-pharmacys-new-role-in-providing-healthcare-services/>

⁴¹ Larkin PJ; “A Pharmacy Forum: Becoming A Health and Wellness Destination;” *Winsight Grocery Business*; April 2016. <https://www.winsightgrocerybusiness.com/pharmacy-forum-becoming-health-wellness-destination>

⁴² Barrett, J; “Pharmacists Play Key Role in the Future of Health Care;” *Pharmacy Times*; June 2017. <https://www.pharmacytimes.com/conferences/ashp-summer-2017/what-role-do-pharmacists-have-in-the-future-of-health-care>

⁴³ Total mean direct medical costs decreased by \$1,200 to \$1,872 per patient per year compared with baseline. Cranor CW, Bunting BA, et al; “The Asheville Project: Long- Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program;” *Journal of the American Pharmacists Association*; 2003. <https://www.sciencedirect.com/science/article/pii/S1086580215300073?via%3Dihub>

⁴⁴ Milosavljevic A, et al; “Community pharmacist-led interventions and their impact on patients’ medication adherence and other health outcomes: a systematic review;” *International Journal of Pharmacy Practice*; 2018. <https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462>

⁴⁵ Lee JK, et al; “Effect of a Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure, and Low-Density Lipoprotein Cholesterol: A Randomized Controlled Trial;” *Journal of the American Medical Association*; 2006;296(21):2563-2571. <https://jamanetwork.com/journals/jama/fullarticle/204402>

⁴⁶ Fikri-Benbrahim N, et al; “Impact of a community pharmacists’ hypertension-care service on medication adherence;” *Social and Administrative Pharmacy*; 2013. <https://www.ncbi.nlm.nih.gov/pubmed/23391845>

⁴⁷ Brennan TA, et al; “An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients;” *Health Affairs*; January 2012. https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2011.0931?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed

⁴⁸ Increased collaboration between ACOs and plans may facilitate better and more affordable drug treatment options for beneficiaries by encouraging the use of generic prescription medications, where clinically appropriate, or reducing medical errors through better coordination between health care providers and plans. 83 Fed. Reg. at 68030.

⁴⁹ ACOs that employ or contract with pharmacists are better at managing medication costs while delivering value. MacDonald JV; “ACO Hospitals Increasingly Seek Help from Pharmacists. Drug Topics;” December 2018; Volume 162, Issue 12. http://www.drugtopics.com/aco/aco-hospitals-increasingly-seek-help-pharmacists?elq_cid=5857498&elq_mid=4939&rememberme=1

other entities to further improve patient outcomes.⁵⁰⁻⁵² This is especially relevant to Medicare beneficiaries in the current landscape of an aging population, increased chronic disease, and projected physician shortage, reinforcing the need for improved care coordination and innovative care delivery models.⁵³⁻⁵⁴ Such action would positively impact the health of Medicare beneficiaries, and preserve the value and integrity of the Part D Program, while ensuring a transparent and rigorous quality and cost performance Part D delivery model. The following outlines the specific benefits that CMS and Medicare beneficiaries would realize under a pharmacy quality incentive program.

A. Advance Quality, Value, and Improved Health Outcomes

Just as CMS has taken the lead on developing a standard quality program for physicians (MIPS/APMs, etc.), a similar effort would greatly benefit the Part D program and help advance the movement towards value and a system focused on health outcomes. The proposed pharmacy quality incentive program would represent innovation aimed at yielding better quality, outcomes, savings and improvement activities through the advancement of pharmacy care and care coordination.⁵⁵⁻⁵⁶ Such a program would standardize roles and performance measures to foster better care, while addressing profound business uncertainty by aligning program incentives. Incentive payments would support higher quality and health outcomes. Additionally, the program's construct would also ensure that high performing pharmacies are not disadvantaged by unintentionally driving beneficiaries from high performing to lower performing pharmacies.

⁵⁰ Van Boven JFM, et al; "Medication monitoring and optimization: a targeted pharmacist program for effective and cost-effective improvement of chronic therapy adherence;" *Journal of Managed Care & Specialty Pharmacy*; August 2014. <https://www.jmcp.org/doi/10.18553/jmcp.2014.20.8.786>

⁵¹ Vegter S, et al; "Improving Adherence to Lipid-Lowering Therapy in a Community Pharmacy Intervention Program: A Cost-Effectiveness Analysis;" *Journal of Managed Care & Specialty Pharmacy*; July 2014. <https://www.jmcp.org/doi/10.18553/jmcp.2014.20.7.722>

⁵² Spence MM, et al; "Evaluation of an Outpatient Pharmacy Clinical Services Program on Adherence and Clinical Outcomes Among Patients with Diabetes and/or Coronary Artery Disease;" *Journal of Managed Care & Specialty Pharmacy*; October 2014. <https://www.jmcp.org/doi/10.18553/jmcp.2014.20.10.1036>

⁵³ Dexter PR, et al; "Preparing for an Aging Population and Improving Chronic Disease Management;" *AMIA Annual Symposium Proceedings*;" 2010. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3041380/>

⁵⁴ Gritters J; "The Cost of Long Wait Times;" *Athena Health: Insight*; 2017.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3041380/> <https://www.athenahealth.com/insight/cost-long-wait-times>

⁵⁵ Mechanic RE, et al; "Medical Group Responses to Global Payment: Early Lessons From the Alternative Quality Contract in Massachusetts;" *Health Affairs*; 2011. <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0264>

⁵⁶ Larson BK, et al; "Insights from Transformations Under Way at Four Brookings-Dartmouth Accountable Care Organization Pilot Sites;" *Health Affairs*; 2012. <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.1219>

A pharmacy quality incentive program is an integral component of the DIR fee reform proposal because it would provide the right program incentives to advance quality and value of pharmacy care for beneficiaries enrolled in Part D plans. Without a pharmacy quality incentive program, plans lack incentives to offer the best possible pharmacy care to beneficiaries.

NACDS is firmly committed to a pharmacy quality incentive program that includes upside and downside risk. Our expectation is that this performance program would include a significant glide path from a one-sided reward model to incremental upside and downside risk models in later years. Such an approach would be consistent with incentives built into the CMS' MIPS and APMs programs for physicians. Providing financial arrangements in the early years to reward community pharmacies directly for their performance would foster significant financial investment in exceptional pharmacy care quality and care coordination programs. Program metrics should be developed by CMS, in consultation with stakeholders, and these metrics should be tailored to pharmacy type, drug dispensed, and disease states being managed; directed toward value; and measure only those medications dispensed by the pharmacy.

NACDS is committed to advancing a quality program that improves outcomes for beneficiaries, reduces administrative burden for community pharmacies, and drives value in care. CMS could work with stakeholders and quality experts to establish the requisite program construct that includes a methodology to advance pharmacy-level performance, data collection and reporting, among other things. It also would include developing a set of metrics; attribution rules for determining which patients belong to which pharmacy (visit-based; assignment-based, et al.); methods for collecting composite scores, and methods for calculating achievable benchmarks and comparator groups.

In addition to defining "pharmacy incentive payments," CMS also would need to set forth standardized pharmacy quality measures and performance standards (likely based on existing, vetted quality measures such as those noted in Exhibit A) that serve as the basis for incentive payments. Such measures should be based on pharmacy-specific, proven and achievable criteria, and would take into account the drugs dispensed, and the disease state being managed. Furthermore, a definition for specialty pharmacy must also be established in regulation to ensure measures are appropriate for pharmacies that dispense specialty medications and provide related services to patients taking specialty medications. This effort would further demonstrate the quality services provided by pharmacists and could dovetail into other federal quality programs such as provider status and MIPS (see Appendix B).

The biggest advantage of constructing a pharmacy quality incentive program would be the realignment of program incentives to advance health outcomes for Medicare beneficiaries through better frontline medication optimization care. Medication optimization services delivered by community pharmacies are central to the care of beneficiaries. Nearly all Americans (91.7 percent) live within 5 miles of a community retail pharmacy. In 2017, more than 73 percent of prescriptions dispensed in the US were filled at retail pharmacies. Face-to-face interactions with beneficiaries at the point-of-dispensing medications to counsel and educate on adherence is critical to achieving national-scale improvements in health outcomes and lowered costs.^{57,58} In the age of convenience – with 24-hour and drive-through pharmacies – pharmacists understand the need for timely and effective prescription and healthcare information.

The national payment mechanism for pharmacies is limited to the dispensing of a medication product, without regard to clinical services that optimize patient care. Pharmacists routinely counsel patients on new medications as part of the dispensing process, but innovative, new payment models are needed to support pharmacists as they delve deeper into preventive services, chronic care management, medication optimization, and other valuable services. Today, limited opportunities exist for pharmacies to be compensated for such clinical services in federal programs, which imposes a major barrier on pharmacy participation in innovative federal value-based models. Not only would recognition of pharmacists as healthcare providers improve access to care, but it would also lead to reduced healthcare costs. The implementation of a pharmacy quality incentive program would help support the value and sustainability of pharmacy in healthcare, with accountability for helping plans drive true value through the improvement of health outcomes and reduction of downstream costs. Therefore, we urge the agency to

⁵⁷ Patients who participated in brief face-to-face counseling sessions with a community pharmacist at the beginning of statin therapy demonstrated greater medication adherence and persistency than a comparison group who did not receive face-to-face counseling. The intervention group had statistically greater Medication Possession Ratio (MPR) than the control group every month measured. Taitel M, Jiang J, Rudkin K, Ewing S, Duncan I; “The impact of pharmacist face-to-face counseling to improve medication adherence among patients initiating statin therapy;” *Patient Prefer Adherence*; 2012;6:323-9. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3340117/>

⁵⁸ A systematic review was conducted using 51 studies determining the optimal modes of delivery for interventions to improve adherence to cardiovascular medications. Among person-dependent interventions (nonautomated phone calls, in-person interventions), phone calls showed low success rates (38%). In-person pharmacist interventions were effective when held in a pharmacy (83% successful) but were less effective in clinics (38%). Cutrona SL, Choudhry NK, et al; “Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence;” *AJMC*; December 2010. https://www.ajmc.com/journals/issue/2010/2010-12-vol16-n12/ajmc_10dec_cutrona929to942?p=1

delineate a clear path forward in this final rule by adopting a set path towards implementing such a program.

B. Reduce Total Healthcare Spending and Beneficiary Costs

One of the key aspects of a quality program would be the collection of standardized data and information for total system cost assessments and for continuous improvement measures. As CMS has noted when outlining concerns with DIR fees, current practices by plans may result in inaccurate reporting to Medicare about totals costs, and cost-shifting that inappropriately drives up expenses for the government and beneficiaries. One way that a quality incentive program could help mitigate these problems is to ensure that complete and accurate program information is transparently reported to CMS. CMS could use that information to monitor critical program elements and hold entities accountable.

The pharmacy quality incentive program can further help motivate best practices that are shown to help reduce total costs of care and ensure efficiency within the Part D program. As in other CMS quality programs, standard pharmacy quality measures can be targeted to improve value, drive health outcomes, minimize system waste or impact total cost of care. Moving to standardize and broadly implement best practices reduces program fragmentation and can better prevent excessive total cost of care spending.

C. Promote Integrity, Transparency and Accountability

The substantial opaqueness and lack of standardization of pharmacy performance metrics within the Part D program has impeded the pursuit of program quality and value. Currently, plans implement inconsistent and sub-optimal metrics, resulting in considerable Part D program variations with respect to what metrics, methodologies, approaches, and processes are employed by each plan. For instance, only 4 of the top 7 PBMs use medication adherence to calculate DIR fees, and the weighting of a medication adherence metric, if employed, also varies from 20% to as high as 85% of the score.⁵⁹ Likewise, at least 3 of the top 7 PBMs/plans exclude medication therapy management (MTM) as a metric for DIR assessment whereas others may include the HEDIS measure of high-risk medications in the elderly metric as part of an assessment.⁶⁰ Some plans also may or may not include a generic drug rate metric and/or formulary compliance measure. The referenced measures

⁵⁹ Inmar comments submitted to CMS on “Centers for Medicare and Medicaid Services; Medicare and Medicaid Programs; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P); p.8 (January 24, 2019).

⁶⁰ *Id.* at pp. 7-8.

all may have significant merit in a standardized program, but as evidenced above, the current system allows plans to set up arbitrary and inconsistent metrics.

Without consistent measures and metric definitions, not only are pharmacies adversely impacted but patients lack clear guidance on what performance actually means for their health and well-being. Metrics are not being used in a way to drive improvement or provide meaningful information to beneficiaries, but instead are employed arbitrarily and inconsistently. CMS has worked to make measures meaningful for physicians and other health entities, by standardizing what and how performance is measured so that accurate comparisons can be made. Yet the opposite is occurring in the current pharmacy environment, and the divergent metrics employed by plans lead to more confusion and inconsistent care for patients.

For example, something as simple as the classification of a product as a brand or generic for purposes of assessing a generic effective rate metric can be skewed. In fact, some plans fail to define brand and generic drug products in accordance with the Federal Food, Drug and Cosmetic Act, which sets forth FDA's approval criteria for brand and generic products. Instead, some plans classify a product as a generic or brand based on what may generate the most financial benefit to them. Such actions by plans make it exceedingly hard for community pharmacies to successfully track and execute against certain cost-effective generic metrics. Yet, to make matters worse, some plans may go even further by setting unrealistic, generic effective rate performance standards given the mix of drug products dispensed in a traditional community pharmacy and the percentage of available FDA approved generics for the medications dispensed.⁶¹ Such metrics may not always be based on beneficiaries' best interests, but instead may exist for plans to generate additional revenues through pharmacy DIR fees.

Numerous metric performance variations therefore exist within the Part D program, resulting in isolated quality plan initiatives.⁶² Because program quality measures are meant to apply equally across plans and a target population, a lack of standardization and harmonization of metrics fosters misunderstanding about how such metrics and performance results are to be used. It also inhibits the ability for

⁶¹ *Id.* at p. 9.

⁶² Adopting uniform standards across all Federal programs would facilitate administering the programs as a comprehensive system, which in turn, facilitates ease of operations for Part D plans and PBMs and results in cost savings. PCMA, "Re: Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule [CMS-4182-P];" January 2018; Page 134.

CMS to compare results across entities and plans and hinders the ability to adequately identify and act upon areas of needed improvement.^{63,64}

In sum, CMS must provide oversight and infuse clear expectations and quality into the Part D program by implementing a pharmacy quality incentive program that links quality to improved patient care and includes a standardized set of quality and value performance standards. The lack of standard metrics therefore undermines the integrity of the program, the value of quality information to beneficiaries, and the Administration's goals related to healthcare quality, transparency, affordability, care coordination and accountability.

D. Reduce Administrative Burden and Costs

Tremendous resources are necessary to build corporate systems and capabilities to report performance metrics for the hundreds of Part D plans in which community pharmacies participate.⁶⁵ This administrative burden is magnified substantially by the differences in and complexity of pharmacy DIR fee accrual calendars, measurement cycles and assessment systems for the top 7 PBMs.⁶⁶ Managing disparate DIR accrual and assessment systems, and reporting on variations of metrics, results in overwhelming administrative burdens and financial costs on community pharmacies. This heavy burden diverts important resources away from implementing first-rate quality of care initiatives and shifts the burden towards

⁶³ Disparate specifications can create confusion with interpreting measure performance results across settings or patient populations and choosing measures for implementation. These measures can also increase data collection burden...Conflicting results that may occur due to differences in measure specifications may be confusing to consumers making decisions about selecting healthcare providers and providers of healthcare services making decisions about quality improvement efforts. "Guidance for Measurement Harmonization;" *National Quality Forum*; 2011.

http://www.qualityforum.org/Publications/2011/05/Guidance_for_Measure_Harmonization.aspx

⁶⁴ The health care system demands simplification and harmonization of measurement, enhancement of system-wide adaption of real-time health care provider engagement and streamlined innovation around what are known as "measures that matter." Czekai AM; "Transforming Health Care Quality Measurement and Reporting;" *American Health Policy Institute*; 2017.

<http://www.americanhealthpolicy.org/Content/documents/resources/Transforming%20Health%20Care%20Quality%20Measurement%20and%20Reporting.pdf>

⁶⁵ "2019 National Medicare Part D Plan Statistics;" *Q1 Medicare*; Last Accessed December 28, 2018.

https://q1medicare.com/PartD-2019MedicarePartD-PlanStatistics.php?utm_source=partd&utm_campaign=NavLink&utm_medium=LeftNavi

⁶⁶ Inmar comments submitted to CMS on "Centers for Medicare and Medicaid Services; Medicare and Medicaid Programs; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P); pp.13-16 (January 24, 2019).

investing heavily in pharmacy accounting, management and operational systems to monitor complex and varying DIR fees.⁶⁷

Focusing on a standardized set of pharmacy quality measure as a first step in establishing a pharmacy quality incentive program would significantly reduce the needless, overwhelming administrative burden on community pharmacies. Implementing a transparent and accountable pharmacy quality incentive program with measures that are consistent, achievable, and proven to make meaningful impacts on quality and value are most essential to reduce system inefficiencies and improve care of Medicare beneficiaries.⁶⁸ Thus, we welcome the opportunity to work with CMS to develop and execute a pharmacy quality incentive program that best serves beneficiaries, improves healthcare quality and total cost of care while at the same time reducing the excessive administrative burden on community pharmacies. Such an initiative will further demonstrate CMS' dedication to lead on quality,⁶⁹ and will be consistent with removing government burdens that impede value-based transformation and quality, aligning with ideas in Executive Order (EO) 13771, Reducing Regulation and Controlling Regulatory Costs,⁷⁰ and CMS' Patients over Paperwork Initiative.⁷¹

E. Performance-Based Pharmacy Networks

The PBM sector has expressed concern that including pharmacy price concessions at the point of sale would limit the ability of plans to maintain preferred pharmacy networks.⁷² NACDS submits that pharmacy networks can however be upheld

⁶⁷ "The Core Quality Measures Collaborative;" *American Academy of Family Physicians*; Last Accessed December 28, 2018. <https://www.aafp.org/practice-management/improvement/measures/core-quality-measures-collaborative.html>

⁶⁸ The administration should ensure that delivery system reform models, which aim to hold providers accountable to a set of population-health metrics and total spending, foster collaboration across the systems... The administration should seek to develop measures that are meaningful to providers and patients and help them assess quality and value. "Reforming America's Healthcare System through Choice & Competition Report;" *U.S. Department of Health and Human Services, U.S. Department of the Treasury, U.S. Department of Labor*; 2018; page 112. <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>

⁶⁹ "CMS Quality Strategy;" *Centers for Medicare and Medicaid Services*; 2018. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy.html>

⁷⁰ "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs;" *Executive Orders - Budget & Spending*; 2017. <https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/>

⁷¹ "Patients Over Paperwork;" *Centers for Medicare and Medicaid Services*; 2018. <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html>

⁷² PCMA, "Re: Medicare Program Contract Year 2019 Policy and Technical Changes to the

through the establishment of a pharmacy quality incentive program. Preferred pharmacy networks could be built on high-quality performance of community pharmacies rather than on price concessions alone,⁷³ recognizing the tremendous value that pharmacies can and do contribute to plans and to the lives and health of beneficiaries. As part of such a program, preferred pharmacies could still offer lower copays to beneficiaries in conjunction with plans through new quality and performance-based arrangements.

The concept of creating high-performance pharmacy networks focused on improving patient health outcomes and reducing costs has been the subject of an CMMI research grant.⁷⁴ This research shows that practitioners see value in this type of pharmacy care as a way to improve patient outcomes.⁷⁵ Early results of the program also show improved adherence and significant reduction in ER visits and hospital admissions.⁷⁶ However, as seen through the experience of other value-based initiatives (such as the ACO Medicare Shared Savings Program) making substantial impact takes refinements, time and improves with experience.⁷⁷ In sum, a pharmacy quality incentive program provides one of several means to design performance-based networks that reduce system costs and drive quality and health outcomes.

F. At a Minimum, CMS must Develop a Standard set of Metrics Beginning in the 2020 Plan Year

While the clearest incentives for change and improvements to the Part D program would be achieved through a comprehensive quality incentive program, creating a set of standardized measures would begin to address some of the existing problems.

Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule [CMS-4182-P];” *Pharmaceutical Care Management Association*; January 2018; page 180.

⁷³ “2014 Premiums and Star Ratings for Medicare Part D Prescription Drug Plans with Preferred Pharmacy Networks;” *Avalere Health*; December 2013. <https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-12-09-13-avalere-premium-and-stars-analysis-final-2.pdf>

⁷⁴ “Community Pharmacy Enhanced Services Network;” Last Accessed January 16, 2019. <https://www.communitycarenc.org/what-we-do/supporting-primary-care/pharmacy/cpesn>

⁷⁵ A majority of respondents thought that enhanced pharmacy services are valuable, with more than 85% of practice responders agreeing that partnering with an enhanced-service pharmacy can help to improve patient health outcomes. Fay AE, et al; “Care team perspectives on community pharmacy enhanced services;” *Journal of the American Pharmacists Association*; May 2018.

https://www.communitycarenc.org/sites/default/files/2018-08/CPEsn_in_Journal_of_the_American_Pharmacists_Association.pdf

⁷⁶ “Community Pharmacy Enhanced Services Network – For Payors;” Data from 2010. <https://cpesn.com/payors/>

⁷⁷ Feore J, Sullivan G; “Experienced Medicare Accountable Care Organizations Generate Savings;” *Avalere*; September 2018. <https://avalere.com/press-releases/medicare-accountable-care-organizations-generate-savings-as-experience-grows>

CMS' experience with federal quality programs has taught stakeholders the need for more standardization, certainty and stability with respect to quality and performance metrics.⁷⁸ Standardization provides greater opportunity for quality improvement by reducing the frequency of metric changes and variations of processes. Standardization also ensures accurate and helpful comparisons across stakeholders so that entities can target areas for improvement and can implement changes that drive value. It also leads to a decreased burden on health care providers and to the realization of quality improvement opportunities that matter most to patients.⁷⁹

Variations in metrics over time and across plans creates undue burden and uncertainty for pharmacies, and do not serve beneficiaries' best interests. In contrast, by focusing on a standard set of quality measures, pharmacies would compete to satisfy well-defined, evidence-based metrics that improve patient care outcomes and reduce costs. The spirit and intent of the need for standardization and longevity of standards within the Part D program is captured in the following comment by the Pharmaceutical Care Management Association (PCMA), the association of PBMs that manage Medicare drug benefits, which aptly states this concept:

PCMA has indicated that it has concerns with constant changes to the Star Ratings measures, especially cut points and methodology. Part D plan sponsors need more stability to make long-term plans to improve measures and then to execute on those plans. While individual changes to the Star Ratings measures may be appropriate when evaluated in a vacuum, constant changes to the Star Ratings measures may be counter-productive to overall improvement in beneficiary care.⁸⁰

While the content of the exact points is somewhat different, the need for program consistency, stability and certainty is abundantly clear.

⁷⁸ PCMA, "Re: Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule [CMS-4182-P];" January 2018; Page 44.

⁷⁹ Dunlap NE, et al; "Observations from the Field: Reporting Quality Metrics in Health Care (Theme #5)," *National Academy of Medicine*; 2016. <https://nam.edu/wp-content/uploads/2016/07/Observations-from-the-Field-Reporting-Quality-Metrics-in-Health-Care.pdf>

⁸⁰ PCMA, "Re: Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule [CMS-4182-P];" Page 44.

A standard set of measures would provide CMS with the ability to assess and appropriately measure performance across the entire Part D program. It also would put a stop to the arbitrary nature of how some plans define and benchmark pharmacy performance. Moving to a transparent and standard set of metrics would provide pharmacies with greater certainty, enabling pharmacies to further invest in programs that advance pharmacy quality. A standard set of measures also coincides with the spirit of HHS' Meaningful Measures initiative,⁸¹ requiring the assessment of core issues that are vital to providing high-quality care and improving patient outcomes.

G. CMS Has Authority to Develop Metrics and Establish a Pharmacy Quality Incentive Program

CMS has authority under the Medicare statute and regulations, as well as its broad demonstration power, to develop a standard set of pharmacy performance metrics as the first step in establishing a pharmacy quality incentive program. This authority aligns with ongoing CMS efforts to ensure high quality care for Medicare beneficiaries and protect the Medicare Trust Fund.

i. CMS has Authority Under Medicare Parts C and D

CMS's authority to administer the Medicare Part D program includes oversight of plan access, quality, and beneficiary protections. Relevant statutory text provides CMS with the authority to use performance programs and measures to ensure compliance, noting: "performance measures established by the Secretary pursuant to subparagraph A(ii) shall include at least measures for" cost, quality programs, customer service and benefit administration, and claims adjudication. 42 U.S.C. § 1395w-111(g)(5)(b) (emphasis added). This language provides CMS authority to establish additional metrics beyond those specifically listed in the statute.

Even more specific authority related to pharmacy measures is provided in the statutory and regulatory requirements for Medication Therapy Management Programs (MTMPs) and quality assurance programs. See 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.125(d). Specifically, when adopting MTMP regulations, CMS contemplated creating specific pharmacy measures along with minimum MTMP requirements to ensure programs are operating effectively for Medicare beneficiaries. CMS noted that, while it did not identify specific MTMP or pharmacy measures in its 2005 final Part D rule, it could do so in future rulemaking:

⁸¹ "Meaningful Measures Framework;" *Centers for Medicare and Medicaid Services*; Last Accessed January 16, 2019. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>

[W]e intend to work with industry and other stakeholders to develop a comprehensive strategy for evaluating plan performance that collectively considers multiple standards and services affecting the cost and quality of drug therapy. As industry practices evolve, including the expected expansion of electronic prescribing, we believe meaningful performance measures can be identified that will validate best practices and provide benchmarks that will spur further program and system improvements. Accordingly, we will work with industry to identify new standards for quality and performance that could eventually become plan requirements.

70 Fed. Reg. 4194, 4277 (Jan. 28, 2005) (emphasis added). CMS clearly understands that it has the authority to develop a comprehensive strategy for evaluating plan performance. Although CMS did not finalize other pharmacy standards in 2005, the agency noted that it has authority to create a platform as well as pharmacy measures in the future:

[W]e intend to utilize the Medicare Prescription Drug Benefit as a platform for driving the quality improvement of prescription drug therapy. We require plans to report details on their respective MTMPs, and we intend to collaborate further with industry to develop measures that can be used to evaluate programs and establish appropriate standards.

Id. at 4280 (emphasis added). Given the experience garnered from many years of administering the Part D program, CMS now has such knowledge to reform Part D to establish a pharmacy quality incentive program built on standardized quality measures.

CMS has additional authority to establish standardized pharmacy measures under its Star Rating system for Medicare Advantage and Part D plans. CMS originally established a Star system as part of its broad statutory requirements to disseminate information to beneficiaries to help them make informed plan choices. 42 U.S.C. §§ 1395w-21(d) & 22(e); 42 U.S.C. §1395w-101(d). Congress then expanded this system to include bonus payments and other benefits for high performing Medicare Advantage plans. Under the Star Rating system, CMS selects measures and data “based on its relevance and importance such that the ratings can meet the needs of beneficiaries using them to inform plan choice.” 83 Fed. Reg. 16,440, 16,520 (Apr. 16, 2018). Consequently, measures can be broadly established to help educate consumers about issues related to their Part D benefit, including pharmacy quality.

In particular, CMS has adopted Star Rating measures that are already directly tied to pharmacy performance. Measures related to medication adherence, diabetes treatment, and appropriate use of high-risk medications all rely on pharmacy data

or pharmacy interventions, and these measures can account for a significant portion of a health plan's current Star Rating.⁸² CMS has also clarified that it has the authority to adopt new Star Measures, amend existing measures, or entirely remove measures through its rulemaking process. Furthermore, CMS has noted that it can make technical or more minor changes through its Annual Call Letter.⁸³ Overall, CMS can use its Star Rating system to adopt standardized pharmacy quality measures or refine existing measures. Such actions would be fully consistent with existing CMS actions and the agency's overall approach to ensuring quality in prescription drug and Medicare Advantage plans.

PCMA acknowledges that CMS has authority to regulate Medicare pharmacy performance measures. PCMA, on behalf of its member PBMs, is challenging a North Dakota law that "requires PBMs to utilize benchmarks set by an unbiased, nationally-recognized entity when evaluating pharmacy performance, and it regulates the fees PBMs may levy on pharmacies due to their deficient performance." *PCMA v. Tufte*, 326 F. Supp. 3d 873, 893 (D.N.D. 2018). PCMA argued that this state law was preempted by 42 U.S.C. § 1395w-104(c), which as discussed above empowers CMS to establish pharmacy quality and performance measures used in the Medicare program. PCMA agrees that CMS has "reserved for itself the role of partnering with private industry to identify the optimum performance measures" for pharmacies in the Medicare program. 326 F. Supp. 3d at 892, quoting PCMA. In fact, PCMA notes that "CMS already regulates the area of pharmacy performance" in Medicare.⁸⁴ Although neither NACDS nor the court agreed with PCMA that the North Dakota quality measures law is preempted,⁸⁵ we do agree with PCMA that CMS has authority to adopt Medicare pharmacy performance standards. CMS can and should exercise that authority, by adopting standardized measures that properly assess and improve quality and performance.

ii. CMS has Demonstration Authority

CMS also has broad demonstration authority to develop a pharmacy quality program. As background, CMS already operates numerous quality reporting programs for various healthcare stakeholders (*e.g.*, hospitals, physicians, nursing homes, home health centers), and has noted that such value-based reforms align

⁸² CMS. Medicare Star Ratings. <https://www.medicare.gov/find-a-plan/staticpages/rating/planrating-help.aspx?AspxAutoDetectCookieSupport=1> As an example, the Star measure entitled "Members Who Had a Pharmacist (or Other Health Professional) Help them Understand and Manage Their Medications."

⁸³ See *e.g.*, CMS. Letter to Medicare Advantage Organizations, Prescription Drug Plans Sponsors and Other Interested Parties Re: Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond (Nov. 12, 2015), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf>

⁸⁴ Memorandum In Support Of PCMA's Motion For Summary Judgment in *PCMA v. Tufte*, p. 32 (Jan 19, 2018).

⁸⁵ The court granted summary judgment against PCMA on the preemption issue. 326 F. Supp. 3d at 894.

with the agency's overall quality strategy to improve outcomes and reduce costs.⁸⁶ While many of these programs are now codified in statute, the agency has often used its demonstration authority to first test value-based arrangements before they are fully enacted into law (*e.g.*, the hospital quality incentive demonstration, the physician group practice demonstration, health information technology related programs, and most recently the Part D Payment Modernization Model among others).

Section 402 of the Social Security Act authorizes the Secretary to develop and engage in demonstration projects “to determine whether, and if so which, changes in methods of payment or reimbursement for health care and services under health programs established by the Social Security Act ... would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services.” 42 U.S.C. § 1395b-1(a)(1)(A). Importantly, this authority is not specific or limited to a type of provider, supplier, or other stakeholders, but instead has generally been interpreted expansively. CMS has also used this authority in the context of prescription drugs in its Medicare Advantage Quality Bonus Payment Demonstration, which CMS initiated before implementing the MA Star Rating program.⁸⁷ Under Section 402, CMS could reasonably conduct a similar demonstration that focuses on pharmacy quality measures to determine if such a program would “increase the efficiency and economy” of services provided to Medicare beneficiaries under Part D. Such a program could address concerns CMS has already identified with DIR, as noted in its January fact sheet that outlines implications for beneficiary cost-sharing, Medicare subsidy payments, and plan liability.⁸⁸

Since 2010, CMS has largely moved its demonstration programs under the Center for Medicare and Medicaid Innovation, which has extensive authority to conduct different types of payment and incentive programs. Congress created the Innovation Center to “test innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care furnished to individuals” in Medicare and Medicaid. 42 U.S.C. § 1315a(a)(1). This authority is actually broader than Section 402, since it allows programs to avoid budget neutrality requirements and successful models can be expanded via rulemaking rather than legislative action. While the Innovation Center has mainly focused on fee-for-service Medicare, it recently published a Request for Information

⁸⁶ CMS Value-Based Programs at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html>

⁸⁷ See 75 Fed. Reg. 71,190, 71,220 (Nov. 22, 2010); *see also* CMS, Fact Sheet; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Demonstration on Quality Bonus Payments, Nov. 10, 2010.

⁸⁸ See CMS, Fact Sheet, Medicare Part D – Direct and Indirect Remuneration (DIR) (January 19, 2017), <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>

(RFI) seeking a new direction for its programs. The RFI included a focus on Prescription Drug Models, stating that “CMS wants to test new models for prescription drug payment, in both Medicare Parts B and D and State Medicaid programs that incentivize better health outcomes for beneficiaries at lower costs and align payments with value...[m]odels that contemplate novel arrangements between plans, manufacturers, and stakeholders across the supply chain, including, but not limited to innovative value based purchasing arrangements, and models that would increase drug pricing competition while protecting beneficiaries’ access to drugs are of particular interest.”⁸⁹ The RFI request specifically contemplates a potential Innovation Center model focused on pharmacy quality metrics.

VI. DIR Fee Reform and a Pharmacy Quality Program do not Violate the Non-Interference Clause or Institute a Prohibited Pricing Structure, and are a Logical Outgrowth of Multiple CMS Proposals

A. The Proposals are Entirely Consistent with the Non-Interference Clause

The Social Security Act provides that “to promote competition” in Medicare, CMS “may not interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors” or “institute a price structure for the reimbursement of covered part D drugs.” 42 U.S.C. § 1395w-111(i). Applying the statute’s definition of “negotiated prices” and developing quality metrics will not interfere with negotiations or mandate a price structure for reimbursement. On the contrary, the proposals will “promote competition” by increasing transparency of costs and quality for beneficiaries and all market participants.

NACDS supports CMS’ “long-standing position” that the prohibition against interference in contract negotiations does not prohibit CMS from engaging in “the implementation or enforcement of statutory requirements.” 79 Fed. Reg. at 29874. As CMS notes, “there are numerous statutory provisions that require us to directly intervene in the contractual relationship between Part D sponsors and network pharmacies,” such as the “interpretation of what ‘access to negotiated prices’ means....” *Id.*, quoting 42 U.S.C. § 1395w-102.

CMS has simply proposed to implement statutory provisions regarding access to negotiated prices and utilization of quality metrics. As discussed at length elsewhere in these comments, the Social Security Act authorizes CMS to promulgate rules for “negotiated prices” and “quality programs.” *See, e.g.*, 42 U.S.C. §§ 1395w-102, 1395w-104. It would be nonsensical to argue that the non-interference clause prohibits CMS from interpreting and enforcing these and other provisions of the

⁸⁹ CMS. Request for Information: Innovation Center New Direction, available at <https://innovation.cms.gov/Files/x/newdirection-rfi.pdf>

statute that CMS is charged with implementing. Congress did not specifically grant CMS authority to implement these and dozens (if not hundreds) of other statutory mandates, only to withdraw that authority via the non-interference clause.

Similarly, NACDS supports CMS' conclusion that the "price structure" prohibited by the statute refers to mandating particular dollar amounts or price indices, and does not prevent CMS from implementing statutory requirements "to regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes" and "establishing rules for consistent treatment of drug costs in the program." 79 Fed. Reg. at 29875. CMS has not proposed to mandate particular reimbursement amounts or particular price indices. Plans and pharmacies would be free to negotiate particular reimbursement rates and price concessions associated with purchasing drugs and satisfying performance metrics. Requiring plans to comply with the statute by including pharmacy price concessions in negotiated prices and promoting quality by developing pharmacy quality metrics as authorized by the statute, does not force plans to pay any particular amounts to pharmacies.

Far from violating the non-interference clause, the CMS proposals will "promote competition" as required by the non-interference clause. As CMS notes, the non-interference clause imposes a "duty to act" on CMS "to promote competition in the private market for part D drugs." 79 Fed. Reg. at 29874. CMS has thoroughly documented the considerable anticompetitive effects of not including pharmacy price concessions in negotiated prices. *See, e.g.*, 82 Fed. Reg. at 56421 (lack of transparency and differential plan treatment of pharmacy price concessions harms competition among plans); 83 Fed. Reg. at 62176 (expressing concerns about the impact of current plan practices on competition among plans and pharmacies); 79 Fed. Reg. at 29877 ("the exclusion of pharmacy price concessions from the negotiated price thwarts the very price competition that the Congress intended with respect to how private plans would compete with other plans on both premiums and negotiated prices."). Similarly, developing a program built on a standard set of pharmacy quality metrics would promote competition by increasing transparency related to pharmacy quality, enabling beneficiaries and plans to make "apples to apples" comparisons when choosing pharmacies. The CMS proposals do not interfere with competition; they promote competition.⁹⁰

⁹⁰ CMS' analysis of the non-interference provision when it amended the definition of "negotiated prices" in 2009 remains true today: "Our proposed changes to the definition of negotiated prices do not interfere with the negotiations between Part D sponsors and pharmaceutical manufacturers and pharmacies, nor do they institute a price structure for reimbursement of covered Part D drugs. While Part D sponsors will be required to use the price ultimately received by the pharmacy (or other dispensing provider) as the basis for calculating beneficiary cost sharing and reporting drug costs, Part D sponsors will not be required to use a particular pricing approach in their contractual agreements with PBMs." 74 Fed. Reg. at 1506.

B. The Reforms Satisfy Rulemaking Requirements and are a Logical Outgrowth of Multiple CMS Proposals

NACDS urges CMS to finalize proposals to revise the definition of “negotiated prices” and develop a pharmacy quality incentive program in its final CY 2020 Part D rule. The agency has the clear authority to do so and has complied with the notice and comment rulemaking requirements under both the Administrative Procedure Act (APA) and the Social Security Act (SSA), and these policies would be a logical outgrowth of the current detailed proposed rule.

CMS uses notice and comment rulemaking to promulgate rules governing payment for Medicare services. 42 U.S.C. § 1395hh(a)(2). A final rule may take effect without additional notice and comment rulemaking if it is a “logical outgrowth” of a regulatory proposal. 42 U.S.C. § 1395hh(a)(4). Here, CMS has not only followed the rulemaking process but has gone to extra lengths to provide repeated notice to stakeholders, and has included sufficient detail to ensure stakeholders are aware of and can comment on the proposed policy changes.

i. CMS Provided Sufficient Notice and Received Voluminous Public Comments

As discussed above, over many years CMS has provided notice and sought comments on proposals to include pharmacy price concessions in negotiated prices. Over just the past two years, CMS has provided notice and sought comments on several occasions.

In 2017, CMS formally addressed and provided notice to interested parties of these potential policy changes with a fact sheet⁹¹ notifying stakeholders about problems with pharmacy DIR, followed by a proposed rule with a “Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale.” 82 Fed. Reg. 56419 (Nov. 2017). In the RFI, CMS solicited comments on how it could include pharmacy price concessions in negotiated prices, and in response CMS received “many timely comments”⁹² from a myriad of stakeholders, including pharmacies, pharmacy associations, beneficiary advocacy groups, plans and PBMs. This request specifically explained that CMS is considering a policy change that could require all price concessions to be included in negotiated prices, giving stakeholders clear notice of the potential policy change put forward by the agency.

⁹¹ CMS, Medicare Part D – Direct and Indirect Remuneration (DIR) (Jan. 19, 2017), available at <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>

⁹² 83 Fed. Reg. at 62175.

The Administration then continued to highlight these policy proposals in subsequent documents that provided additional opportunities for public comment, including the Administration’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.⁹³ This much-publicized document once again highlighted the 2017 RFI and asked for additional public comments on how to reduce cost-shifting and related drug pricing issues.

Only after public input from these numerous comment periods has CMS moved forward with a more detailed proposal via its normal rulemaking cycle—outlining the change in this formal proposed rule, seeking public comment, and working to finalize its proposal in a final regulation. While the specific issue of quality metrics was first formally addressed in this proposed rule, this still follows the APA rulemaking process and satisfies legal requirements for adequate notice and comment. Furthermore, and as outlined in more detail in our comments on establishing a pharmacy quality incentive program, NACDS believes that developing metrics as part of a broader quality program would most directly address the problem CMS seeks to resolve. Absent such incentives, we believe that many of the concerns will continue to occur and limit the effectiveness of this proposal. Consequently, the agency has worked to find a comprehensive solution to pharmacy DIR fees in this rule and has not only met but exceeded its legal requirements in both providing notice and seeking input from stakeholders.

ii. The Proposals Are Adequately Detailed and Specific

The proposals are also sufficiently detailed. CMS has included the terms or substance of the proposals, the subjects, and issues involved. *See* 5 U.S.C. § 553(b)(3). Courts have consistently upheld final rules as logical outgrowths of proposals “where the NPRM expressly asked for comments on a particular issue or otherwise made clear that the agency was contemplating a particular change.”⁹⁴ Here, the proposed rule includes a comprehensive explanation of the problem, the text of the revised definition of “negotiated prices,” the reasoning for seeking this change, and explicit examples of how the new definition would be applied. Furthermore, the agency explicitly seeks comments on this proposal, providing specific notification for stakeholders.

With respect to a pharmacy quality incentive program, this requirement is inherently part of the broader and more detailed proposal addressing DIR, providing the same comprehensive background for stakeholders. While adopting such a program was not explicitly included in the initial RFI, CMS has clearly met the

⁹³ American Patients First: The Trump Administration Blueprint to Lower Patient Out-of-Pocket Costs. May 2018. Available at <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>

⁹⁴ *See* CSX Transp. Inc. v. Surface Transp. Bd., 584 F.3d 1076, 1081 (D.C. Cir. 2009) (citing Owner–Operator Indep. Drivers Ass’n v. Fed. Motor Carrier Safety Admin., 494 F.3d 188, 209–10 (D.C. Cir. 2007)); Portland v. EPA, 507 F.3d 706, 715 (D.C. Cir. 2007).

legal requirements in this proposed rule by stating and soliciting feedback on how to “develop a standard set of metrics from which plans and pharmacies would base their contractual agreements” and what entities could help develop such standards. 83 Fed. Reg. at 62179. This fully satisfies legal requirements by notifying interested parties what to comment on, and stakeholders can “reasonably anticipate” what policies may be adopted.⁹⁵

NACDS also expects that CMS would seek additional input and guidance from stakeholders in fully developing any such program, potentially by using sub-regulatory guidance that could include additional opportunity for input from stakeholders. This rule would simply allow the agency to take the initial step in implementing a program for this space. Stakeholders could then provide additional feedback when actual measures are developed, tested, and fully applied.

Furthermore, any “logical outgrowth” concern is diminished in this context because NACDS is asking that CMS finalize its proposals, rather than requesting that the agency reverse or significantly alter its proposals. Because there is no need for a significant departure from what CMS has proposed (which is the concern in many logical outgrowth cases), stakeholders are fully aware of and able to comment on the proposal. This is not a situation “where interested parties would have had to divine the agency’s unspoken thoughts, because the final rule was surprisingly distant from the [a]gency’s proposal.”⁹⁶

CMS has therefore satisfied both the APA and the SSA requirements and should finalize its policy on this topic in the CY 2020 Part D final rule. The numerous opportunities to provide input from stakeholders as well as the detailed proposal in the current rule and prior proposals have fully apprised all interested parties fairly, so they can submit comments and anticipate regulatory changes.

VII. General Medicare Part D Comments

A. Broader Use of Prior Authorization and Step Therapy, New Formulation and Drug Price Increases Exceptions

CMS is proposing to provide Part D plans with a number of utilization management tools designed to drive the utilization of lower cost drugs. Specifically, CMS is proposing to allow plans: (1) to use prior authorization for protected class drugs or to determine use for protected class indications or both, (2) to exclude from their

⁹⁵ See *Anne Arundel County v. EPA*, 963 F.2d 412, 418 (D.C. Cir. 1992).

⁹⁶ See *Environmental Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (internal quotation marks and citations omitted).

formularies a protected class single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration, and (3) to exclude from their formularies any single-source drug or biological product that is a protected class drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation.

NACDS supports efforts to curb the rising costs of prescription drugs but cautions HHS that any actions it takes must be balanced with ensuring access to needed prescriptions drugs for Medicare beneficiaries. Plans should only be allowed flexibility to make changes to the treatment of protected class drugs and manage drugs through exception processes to the extent that doing so does not reduce drug coverage. Limiting access to prescription drugs can have unintended consequences, including decreased medication adherence, which further leads to poorer health and increased costs down the road. The impact of medication adherence on improving patient health and lowering overall medical costs is addressed in more detail above in Section III of our comments responding to Pharmacy DIR reform.

In order to ensure beneficiary access and adherence is not jeopardized, NACDS recommends that any changes in utilization management of protected classes be based on clinical parameters focused on the best treatment for the patient. Specifically, we recommend CMS consider the following parameters in allowing plans more flexibility with respect to utilization management tools:

- Only apply to new starts *and* only if guided by drug-selection assay criteria (e.g. genotypic assay),
- Not apply to products that show improved adherence, convenience, or tolerability profile, and
- Apply only to non-protected class indications.

We believe implementing such protections will help ensure beneficiaries will continue to have access to the treatments they need to best address their healthcare needs.

Ensuring access to needed medications is particularly crucial for the most vulnerable beneficiaries, such as those being treated with antiretrovirals (ARVs) and antineoplastics. The treatment of those with HIV and cancer presents unique challenges not present with other patients and therapies within the Part D program. For example, patients with HIV are now living longer than ever before due to advances in clinically superior treatment options, however, challenges such as evolving HIV population demographics and increases in costs for HIV treatment contribute to suboptimal adherence to drug regimens and risk of ARV resistance.

Similarly, the use of individualized and targeted therapy, tumor-agnostic therapy, CAR T-cell, gene and other therapies for cancer patients have greatly improved the specificity of treatment as well as long-term outcomes and survival. This has only increased the importance of immediate access to a wide array of therapies, as any delay can have catastrophic effects. Traditional utilization management tools are of limited usefulness due to the individualized and targeted nature of modern cancer treatments that do not have other clinically interchangeable options.

The unique challenges that patients living with HIV/AIDS and cancer face must be balanced with traditional utilization management tools and approached in a manner that ensures access to a broad array of treatment options. These challenges require that effective treatment options be available among the six protected drug classes. HHS must ensure any changes to drug management or drug formularies do not come at the cost of patient access and medication adherence, and especially so for vulnerable patient populations.

B. Prohibition Against Gag Clauses in Pharmacy Contracts

CMS is proposing to implement a provision of the “Know the Lowest Price Act of 2018” (P.L. 115- 262) that prohibits plans from restricting their network pharmacies from informing their plan enrollees of the availability of prescription drugs at a cash price that is below what that the enrollee would be charged (either the cost sharing amount or the negotiated price when it is less than the enrollee’s cost sharing amount) for the same drug under the enrollee’s plan. CMS states that the measure will become effective with the plan year starting January 1, 2020.

NACDS applauds CMS for moving forward in implementing a prohibition on plans from using what is colloquially known as “gag clauses” in network pharmacy contracts. The prohibition of gag clauses in contracts among plans, Medicare Advantage plans, PBMs, and pharmacies will enhance patient access to medications, enable pharmacists to have improved relationships with patients, and keep healthcare costs for patients to a minimum. We look forward to working with you to implement this important requirement.

C. Part D Explanation of Benefits

CMS is proposing to require that plans include the cumulative percentage change in the negotiated price since the first day of the current benefit year for each prescription drug claim in the explanation of benefits (EOB) and is requesting stakeholder feedback on operationalizing this in the EOB to best serve beneficiaries.

NACDS agrees that providing beneficiaries with necessary information to make informed choices about their health care, including making determinations about whether a prescription is covered under their plan is a valuable goal and could help

reduce costs and lead to better health. However, the usefulness of the information is time sensitive and providing this information after a prescription has been filled, such as through the EOB or through an end-of-the-year annual statement, may allow a beneficiary to make a more informed choice going forward, but misses the opportunity to make an immediate change, as could be done if the information was provided at the point of prescribing.

To this end we encourage CMS to focus on proposals that allow the prescriber to make a coverage determination and access cost information at the point of prescribing. Providing information at the point of prescribing will allow the beneficiary to work with his or her prescriber to find alternative or lower cost solutions and avoid unnecessary delay and potential lapses in therapy.

D. Electronic Prescribing and the Part D Prescription Drug Plan

NACDS strongly supports CMS' integrating a patient-specific real-time benefit tool (RTBT) into the Part D benefit to drive lower prescription drug spending and minimize beneficiary out-of-pocket costs. Beneficiaries often arrive at the pharmacy counter with little or no insight as to what a medication will cost them, which can lead to overuse of unnecessarily expensive medications and the underuse of essential medications. As previously noted, medication adherence has a profound impact on health outcomes and total cost of care. Thus, we strongly agree with CMS that "reducing medication cost also yields benefits in patients' medication adherence" and that "increasing patient cost-share for a medication [is] associated with a significant decrease in medication adherence." 83 Fed. Reg. at 62165.

The integration of a RTBT into the Part D benefit, which provides decision support elements described in the proposed rule (i.e., clinically appropriate formulary alternatives and utilization management requirements such as step therapy, quantity limits, and prior authorization requirements) will give providers and beneficiaries the information needed to make better informed choices on their healthcare treatment.

While appreciating CMS' efforts to improve access to clinically appropriate and cost information, NACDS cautions CMS that RTBTs must be designed to provide information in a manner that allows the prescriber to make a determination about whether a prescribed drug is covered by the beneficiary's insurance plan without fear of "steering" a beneficiary to certain pharmacies or to mail order. This could be accomplished by requiring the beneficiary to select his or her pharmacy of choice prior to the prescriber utilizing the RTBT to access the enrollee cost-sharing information. Moreover, we believe that the RTBT must provide sufficient information to the prescriber and pharmacy to facilitate clinical decision making that will inform prescribers and pharmacists to assist in determining optimal patient medication regimens.

We further caution CMS that RTBTs do not presently take into consideration pharmacy-level cost-containment programs, such as \$ 4.00 generic programs, nor patient assistance programs. Moreover, absent system safeguards, RTBTs can inadvertently drive physician prescribing of expensive, therapeutically alternatives that are subject to high rebate arrangements between PBMs and manufacturers. Such results would needlessly drive up the overall spending of the Part D program. We therefore request that CMS ensure that the following additional elements be required in RTBTs:

1. Preserve patient's right to pharmacy selection at the outset;
2. Ensure accurate and complete patient's out-of-pocket costs at formulary and pharmacy levels;
3. Avoid unintended economic costs to taxpayers and beneficiaries associated with steering patients to therapeutic alternatives that are subject to "spread pricing" due to excessive list prices and rebates;
4. No commercial messaging within RTBT transmissions; and
5. Ensure information integrity, fairness and accuracy among others.

Finally, NACDS encourages CMS to pause their proposed timeline for January 1, 2020 implementation. This would allow CMS to address the concerns raised above as well as work with NCPDP on a more appropriate timeline to complete standards development for such a solution. CMS' aggressive timeline due to a lack of standardization may cause additional confusion among prescribers with each plan offering their own proprietary solution.

VIII. Conclusion

NACDS strongly urges the Administration to use its authority to implement comprehensive reform of pharmacy DIR fees in the final rule by adopting a new definition of "negotiated price" and a broad definition of pharmacy price concessions, and by developing a pharmacy quality incentive program built on a standard set of quality metrics. These reforms are needed immediately to provide relief to community pharmacies from the use of overly-burdensome and inconsistent fees in Medicare. This reform package will not only be vital to reducing beneficiary costs but will provide the transparency and consistency needed to enable community pharmacies to continue serving their local Medicare beneficiaries.

In addition, we appreciate the opportunity to comment on general Part D matters, including our concerns about proposals to limit beneficiary access to protected drug classes, our support for a prohibition on pharmacy "gag clauses," and our recommendations for making relevant prescription drug coverage information

more readily available to beneficiaries, prescribers, and pharmacies through such resources as RTBTs.

Thank you for your consideration. We look forward to working with CMS in implementing these very important reforms.

Sincerely,

STEVEN C. ANDERSON, IOM, CAE
President & Chief Executive Officer

EXHIBIT A: Metrics that Can Be Influenced by Pharmacy Care

The current Part D STARS measures include medication adherence for diabetes, hypertension, and cholesterol medications, in addition to the use of statins in patients with diabetes and the CMR completion rate.⁹⁷ Yet, these metrics were validated at the health plan level. Additionally, other clinically meaningful measures have been utilized in value-based pharmacy programs including: medication optimization (meaning that the patient is on the right drug, the right dose, the right formulation, and considers safety and efficacy of the drug), blood pressure control, blood sugar control, depression, cholesterol goals, high risk medications in the elderly, asthma control based on rescue inhaler use, total costs of care, hospitalizations, emergency department visits, readmissions, medication reconciliation, med synchronization, patient satisfaction, and offering text message service reminders for patients.

The following Table provides an overview of existing quality measures, illustrating potential future opportunities for measuring pharmacy quality. The use of more clinically advanced pharmacy measures promotes value and encourages program innovation.

<i>MIPS Performance – Quality Measures</i>	<i>Part C/ D Stars</i>	<i>NQF#</i>	<i>MIPS Quality</i>	<i>ACO#</i>	<i>HEDIS</i>	<i>CPC+</i>
<i>Medication Reconciliation Post-Discharge</i>	C20	0097	46	12	Yes	-
<i>Documentation of Current Medications</i>	-	0419	130	-	No	-
<i>30-Day All Cause Readmission After Discharge</i>	C21	1789	HCPR6	8	Yes	156
<i>Adherence for Diabetes Medications</i>	D11	-	-	-	No	-
<i>Poor Diabetes Control (A1c >9%)</i>	-	0059	1	22/27	Yes	122
<i>ACE/ARB in Coronary Artery Disease and Diabetes</i>	-	0066	118	33	Yes	-
<i>LDL Management in Diabetes</i>	-	-	2	23	Yes	-
<i>Adherence for Hypertension (ACE/ARB)</i>	D12	-	-	-	No	-
<i>Persistence of Beta Blocker Treatment</i>	-	0070	7/8	31	Yes	-
<i>Functional Status Assessments for Congestive Heart Failure</i>	-	Q377	377	-	No	-
<i>ACE/ARB in Heart Failure</i>	-	0081	5	-	No	-
<i>Antiplatelet Therapy in Coronary Disease</i>	-	0067	6	-	No	-
<i>Controlling High Blood Pressure</i>	C16	0018	373	28	Yes	165
<i>Improvement in Blood Pressure</i>	-	Q373	373	-	No	-
<i>Screening for High Blood Pressure</i>	-	Q317	317	21	No	-

⁹⁷ Fact Sheet – 2019 Part C and D Star Ratings. Table 12. Data from October 10, 2018.
https://www.bettermedicarealliance.org/sites/default/files/2019_Star_Ratings_Fact_Sheet_2018_10_09.pdf

<i>Anti-platelet Therapy in Ischemic Vascular Disease</i>	-	0068	204	30	No	164
<i>Statin Therapy for the Prevention and Treatment of Cardiovascular Disease</i>	-	Q438	438	42	Yes	347
<i>Adherence for Cholesterol (Statins)</i>	D13	-	-	-	No	-
<i>Influenza Immunization</i>	C03	0041	110	14	Yes	147
<i>Pneumococcal Vaccination Status for Older Adults</i>	-	0043	111	15	Yes	127
<i>Immunizations for Adolescents</i>	-	1407	240	-	Yes	-
<i>Penicillin Allergy: Appropriate Removal or Confirmation</i>	-	-	AAAAI18	-	No	-
<i>Tobacco Use: Screening and Cessation</i>	-	0028	226	17	Yes	138
<i>Unhealthy Alcohol Use: Screening & Brief Counseling</i>	-	2152	431	-	Yes	-
<i>Tobacco Use and Help with Quitting</i>	-	Q402	402	-	No	-
<i>Initiation & Engagement of Substance Abuse or Dependence Treatment</i>	-	-	305	-	Yes	139
<i>Evaluation or Interview for Risk of Opioid Misuse</i>	-	Q414	414	-	No	-
<i>Use of Opioids from Multiple Providers</i>	-	-	-	-	Yes	-
<i>Use of Opioids at High Dosage</i>	-	-	-	-	Yes	-
<i>Weight Assessment and Counseling for Nutrition and Physical Activity – Child</i>	-	0024	239	-	Yes	-
<i>Falls: Risk Assessment</i>	-	0101	154	13	Yes	-
<i>Falls: Screening for Future Fall Risk</i>	C18	0101	318	13	Yes	139
<i>Use of High-Risk Meds in the Elderly</i>	-	0022	238	-	Yes	-
<i>Potentially Harmful Drug-Disease Interactions in the Elderly</i>	-	-	-	-	Yes	-
<i>Depression Utilization of the PHQ-9 Tool</i>	-	0712	371	18	Yes	160
<i>Maternal Depression Screening</i>	-	Q372	372	-	No	-
<i>Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment</i>	-	1365	382	-	No	-
<i>Adult Major Depressive Disorder (MDD): Antidepressant Medication Management</i>	-	0104	107	-	No	-
<i>Adherence to Antipsychotic Medications</i>	-	0105	9	-	Yes	-
<i>Optimal Asthma Control</i>	-	1879	383	-	Yes	-
<i>Medication Management for People with Asthma</i>	-	Q398	398	-	No	-
<i>Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation</i>	-	1799	311	-	Yes	122
<i>Chronic Obstructive Pulmonary Disease (COPD): Long Acting Beta Agonist</i>	-	0091	51	-	Yes	-
<i>Annual Hepatitis C Virus (HCV) Screening for Active Injection Drug Users</i>	-	0102	52	-	No	-
<i>One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk</i>	-	Q387	387	-	No	-
<i>Tuberculosis (TB) Prevention for Patients</i>	-	3059	400	-	No	-
	-	Q337	337	-	No	-

If CMS decides to establish a standard set of metrics that include new metrics to be developed, we suggest that such metrics should be developed by an established measure developer:

- (1) with experience developing measures for Medicare Part D,
- (2) that serves as a neutral convener of all relevant stakeholders on this issue, including health plans, pharmacy benefit managers, chain and independent pharmacies, government agencies, specialty pharmacy providers, pharmacist practitioner organizations,
- (3) that develops measures through a fully-transparent consensus-based process, and
- (4) that is willing to steward these measures on behalf of CMS, including completing necessary maintenance at least annually.

EXHIBIT B: Establishment of a Pharmacy Quality Incentive Program Could Inform Other Federal Quality Programs

The proposed pharmacy quality incentive program aligns with the goals of other federal incentive programs, like the Part D Payment Modernization Model. The program could also inform collaborations or alliances within other federal value-based programs, including programs for Accountable Care Organizations (ACOs) where pharmacy care and care coordination are urgently needed. Many top priority quality metrics for ACOs can be impacted by medication optimization. And, using the Agency for Healthcare Research and Quality (AHRQ) National Guidelines Clearinghouse, it has been estimated that there are 79 clinical quality metrics for which pharmacists have or should have primary responsibility as the health professionals most closely involved in service delivery. As one may expect, many of those quality measures involve medication management, adherence, and medication safety.⁹⁸

The success of a Medicare Part D pharmacy quality incentive program could also inform the MIP Program. The MIP program does not recognize pharmacists as providers, yet community pharmacy could be an ideal partner for physicians to achieve established quality measures. Consider the following:

- “Quality MIPS” measures account for 50% of the MIPS Composite Score, and 25% of these are related to medications,
- “Improvement Activities” measures account for 15% of the total score, and 25% of these are related to medications, and
- “Promoting Interoperability” measures account for 25% of the MIPS composite score and 20% of these are related to medications.⁹⁹

Further, two MIP measures specifically mention pharmacists, including metrics around medication reconciliation after discharge in the quality category, and population management of medications in the clinical improvement category.¹⁰⁰ Similarly, many APM quality metrics are dependent upon improvements affected by optimized medication use as well. These include metrics regarding controlling high

⁹⁸ Carmichael J, Gurbinder J, Nguyen PA; “Healthcare Metrics: Where do Pharmacists Add Value?;” *American Journal of Health System Pharmacy*; 2016;73:1537-47.
<https://www.ncbi.nlm.nih.gov/pubmed/27521240>

⁹⁹ “Payment Methods in Outpatient Team-based Clinical Pharmacy Practice, Part 2: MACRA for Pharmacists;” *American College of Clinical Pharmacy*; October 2017.
https://www.accp.com/docs/positions/misc/Practice_Advancement_Issue_Brief.pdf

¹⁰⁰ “A Whirlwind Tour of Value-Based Payment Models- with Pharmacists as your guide;” *Pharmacy Today*; June 2018. [https://www.pharmacytoday.org/article/S1042-0991\(18\)30783-7/fulltext](https://www.pharmacytoday.org/article/S1042-0991(18)30783-7/fulltext)

blood pressure, comprehensive diabetes care, preventive care, tobacco use, and more. Even though the list of healthcare providers within the MIP program was expanded to include nurse practitioners, dentists, podiatrists, optometrists and others, CMS failed to fully recognize the valuable contribution of community pharmacists to work with physicians to engage patients extensively in convenient, accessible settings.

Community pharmacists are among the advanced healthcare professions with doctorate-level education and years of clinical training. Yet, like some other professionals, they lack “provider” designation in the Social Security Act. As such, Medicare services provided by physical therapists, dieticians, and others are rightfully covered; however, the services provided by pharmacists are needlessly omitted. The absence of the provider designation creates challenges in integrating community pharmacy into sustainable, innovative delivery of care models. However, community pharmacists are the medication experts in the U.S. healthcare system. Given that medication is the primary medical intervention in the U.S. to treat most diseases and conditions, community pharmacists can improve outcomes and save avoidable healthcare dollars. Pharmacists have the skillset to provide patient care services and medication related support. Tying both critical components together allows pharmacists to more actively contribute toward reducing total cost of care to our healthcare system. This great potential could be realized through the establishment of a pharmacy quality incentive program and/or provider status designation for pharmacists.