



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

March 7, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4192-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted via www.regulations.gov

Re: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P)

Dear Administrator Brooks-LaSure:

The National Association of Chain Drugs Stores (“NACDS”) thanks the Centers for Medicare and Medicaid Services (“CMS”) for the opportunity to comment on the *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule* (CMS-4192-P) (hereinafter the “proposed rule”).

I. Executive Summary of NACDS’ Position on the Proposed Rule

NACDS writes in support of CMS’ proposal to reduce prescription drug prices for Medicare Part D patients by adopting a revised definition of “negotiated price” for a covered Part D drug that would include all pharmacy price concessions (also known as “pharmacy direct and indirect remuneration” or “pharmacy DIR fees”) at the point of sale. NACDS support is premised on the simple fact that the proposal will better align marketplace competition with the interests of Medicare patients, and lead to lower total healthcare costs, including lower out-of-pocket costs for beneficiaries. This reform promotes better medication adherence, mitigation of health disparities, and in turn, better health outcomes. Of utmost importance: ***this proposal is a win for the nation’s Medicare patients***. In fact, requiring pharmacy price concessions in the negotiated price is expected to reduce beneficiary costs by \$21.3 billion over 10 years, or approximately 2 percent.¹

This proposal is also a step in the right direction to meaningfully reform pharmacy DIR because it offers transparency for pharmacies operating in the program. ***For the past eight years, all branches of the federal government have considered opportunities for DIR fee reform***, including:

- The Department of Health and Human Services (“HHS”) and CMS have long analyzed the need for pharmacy DIR reform, which stemmed from a change CMS made in 2014 to the “negotiated price” definition. This change led to the proliferation of Part D plans’ usage of pharmacy DIR fees (also known as “pharmacy price concessions”).

¹ 87 Fed. Reg. 1842, 1849 (Jan. 12, 2022).

- In 2017, CMS under the Obama Administration left the industry with a stark warning of a growing trend: total DIR grew about 22 percent per year, with gross drug costs and DIR growing most dramatically since 2013.²
- In 2018, a proposal from CMS sought to address pharmacy DIR fees' exponential growth; and illuminated that the problem had become more concerning: pharmacy price concessions, net of all pharmacy incentive payments, had grown an extraordinary 45,000 percent between 2010 and 2017.
- And still, in this 2022 proposed rule, CMS' has once again shed a light on the seismic problem: 1) from 2018 to 2020, pharmacy price concessions increased by 50.4 percent; 2) pharmacy price concessions, net of all pharmacy incentive payments, grew more than 107,400 percent between 2010 and 2020; and 3) performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and pharmacy benefits managers ("PBMs"), behind only manufacturer rebates.
- Congress introduced several pieces of legislation that would address pharmacy DIR reform. Most recently, the *Pharmacy DIR Reform to Reduce Senior Drug Costs Act* (S. 1909/H.R. 3554) was introduced in the current 117th Congress.³
- Pharmacy efforts to achieve pharmacy DIR fee reform extended into the judicial sphere when some independent pharmacies sued HHS over the 2014 language.⁴

NACDS supports the Administration's work on the transparency aspect of pharmacy DIR reform and urges CMS to finalize the rule for contract year 2023.

Still, as retail pharmacies continue their commitment to serve Medicare patients, NACDS knows our advocacy efforts do not end with transparency of pharmacy DIR fees. First, we know that pharmacy DIR fee transparency should include guardrails to successfully effectuate the proposed reform to best serve Medicare patients, including important operational and forward-thinking considerations. Second, and in tandem with pharmacy DIR fee transparency, ***NACDS continues to advocate, as we have for the past eight years, that comprehensive pharmacy DIR reform must include the standardization of pharmacy price concessions and incentive payments that are currently based on performance measures.*** Therefore, NACDS urges CMS to act on the following:

- A. CMS should finalize the proposal because the resulting transparency is a critical, overdue step in the right direction for patients and pharmacies in the Medicare Part D program.
- B. CMS should implement the regulatory guardrails to successfully effectuate the proposed reform, including:

Guardrail 1: CMS should evaluate whether reimbursement reflected at the point of sale could impact beneficiaries' access to pharmacies.

Guardrail 2: CMS should also apply the negotiated price definition to the coverage gap.

Guardrail 3: CMS should ensure that the proposed rule can be swiftly operationalized for contract year 2023.

² CMS, Fact Sheet, Jan. 19, 2017, available at <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>.

³ H.R.554 – 117th Congress (2021-2022): Pharmacy DIR Reform to Reduce Senior Drug Costs Act, H.R.3554, 117th Cong. (2021), <https://www.congress.gov/bills/117/congress/house-bill/3554>; S.1909 –117th Congress (2021-2022): Pharmacy DIR Reform to Reduce Senior Drug Costs Act, H.R.3554, 117th Cong. (2021), <https://www.congress.gov/bills/117/congress/senate-bill/1909/text>.

⁴ *National Community Pharmacists Association v. Azar* (filed Jan. 15, 2021), Complaint for Declaratory and Injunctive Relief, available at <https://ncpa.org/sites/default/files/2021-01/NCPA-v-Azar-Complaint.pdf>.

Guardrail 4: CMS should support pharmacies' need to ensure cash flow capabilities through standardized, transparent, predictable, and relevant performance measures.

Guardrail 5: CMS should conduct a thorough analysis on the direct impact such proposal will have on pharmacies and potentially patient access.

- C. CMS should implement standardized pharmacy measures to effectuate comprehensive pharmacy DIR reform that best serves Medicare patients and improves healthcare quality, equity, and reduce preventable spending.**
- D. CMS should finalize the proposed rule because CMS has the requisite legal authority to promulgate and finalize this proposal.**

In sum, we appreciate the opportunity to provide our comments and look forward to our continued work with CMS on comprehensive pharmacy DIR reform.

II. Detailed Response

CMS initially developed the concept of direct or indirect remunerations ("DIR") upon the enactment of the Medicare Modernization Act of 2003. DIR was originally intended as a way for CMS to track the annual amount of rebates and price adjustments from manufacturers and pharmacies so that it could appropriately base prescription drug reimbursement on the lowest price.⁵ However, the use of DIR has grown far beyond CMS' intention and now encompasses a wide variety of price concessions (or "DIR fees") including costs for pharmacies to participate in a Part D preferred network, price reconciliations based on contractual rates, compliance fees for contract-based performance metrics, or a combination of these fees.

Part D plans and their pharmacy benefit managers ("PBMs") now utilize these fees to recoup millions of dollars from pharmacies on medications that have already been dispensed to patients. Pharmacies routinely report that DIR fees are charged back to them months after the point of sale and that a lack of transparency in contracts removes the ability for pharmacies to accurately estimate how much money will be owed to the plan or PBM.

Moreover, as CMS has come to realize, DIR fees result in increased out-of-pocket costs, driving patients more rapidly into the Medicare Part D coverage gap where they become responsible for a greater portion of prescription costs. This is because the structure of the Medicare Part D program incentivizes plan sponsors to report pharmacy price concessions as DIR, rather than including them in negotiated prices made available to Medicare beneficiaries.

Over the years, CMS has thoroughly documented the various concerns with pharmacy DIR fees, including how such fees increase beneficiary drug costs and taxpayer costs for catastrophic coverage and low-income cost-sharing subsidies.⁶ CMS has also recognized that pharmacy DIR fees harm pharmacies by reducing transparency and predictability of reimbursement.⁷ More broadly, pharmacy DIR fees undermine drug price transparency, which is necessary for efficient market competition that would reduce prescription drug costs.⁸

Experiences of regional and national chain pharmacies confirm that the abuses and harms of pharmacy DIR fees are real and the situation is rapidly growing worse, as abusive pharmacy DIR fees continue to grow

⁵ See CMS, Fact Sheet, Jan. 19, 2017, available at <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>.

⁶ 87 Fed. Reg. 1842, 1911-1914; 83 Fed. Reg. 62,152, 62,190-92 (Nov. 30, 2018).

⁷ 83 Fed. Reg. at 62,191.

⁸ 87 Fed. Reg. at 1911-1914.

exponentially.⁹ NACDS welcomes CMS' proposal to begin reforming pharmacy DIR fees and urges CMS to finalize the proposed change.

A. CMS should finalize the proposal because the resulting transparency is a critical, overdue step in the right direction for patients and pharmacies in the Medicare Part D program.

Under the proposed rule, CMS would eliminate the “reasonably determined” exception presently found under 42 C.F.R. § 423.100. CMS would do this by removing the existing definition of “negotiated prices”¹⁰ and replacing it with the modified term “negotiated price,” which CMS would define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract. CMS states this would mean that all pharmacy price concessions would need to be included in the negotiated price. CMS also proposes a specific definition of what is considered a pharmacy price concession. However, the change would specifically exclude any incentive payments made to pharmacies.

For the reasons detailed in this section, NACDS supports CMS' proposal to delete the “reasonably determined” exception and the existing regulatory definition of “negotiated prices” and adopt a new definition of “negotiated price” as the lowest amount a pharmacy could receive as reimbursement for a covered drug under its contract.

1. NACDS supports the proposal because it could improve the beneficiary experience, foster health equity, and improve health outcomes, while also lowering overall healthcare costs.

As CMS recognizes in the proposed rule, “[r]equiring pharmacy price concessions in the negotiated price is expected to reduce beneficiary costs by \$21.3 billion over 10 years, or approximately 2 percent.”¹¹ NACDS supports this change because it benefits the patients that pharmacies serve and is in alignment with Congress' intention for the Medicare beneficiary experience, including lower out-of-pocket prescription drug costs, improved health, and reduced overall healthcare costs.

Congress defined “negotiated prices” as including pharmacy price concessions to ensure that beneficiaries' costs are based on true plan costs at the pharmacy. Excluding some pharmacy price concessions from negotiated price disconnects beneficiary costs from true costs, preventing beneficiaries from knowing how much is actually being paid. As CMS has recognized in the past, “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.”¹² NACDS agrees with CMS in that:

[T]he 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.¹³

Beneficiaries are likely unaware that the increasing use of pharmacy DIR fees has led to needlessly inflated out-of-pocket drug costs. Worse still, the negative impacts of higher cost-sharing are endured by beneficiaries

⁹ 87 Fed. Reg. at 1909 (pharmacy DIR fees have grown an astonishing 107,400 percent).

¹⁰ 42 C.F.R. § 423.100.

¹¹ 87 Fed. Reg. at 1948.

¹² 83 Fed. Reg. at 62,176.

¹³ *Id.*

beyond the pharmacy counter. In fact, higher out-of-pocket costs have been repeatedly connected to patients not taking their medication as prescribed – either not picking up their medication in the first place because they cannot afford the co-pay or picking up the medication, but taking it inappropriately to make their supply last longer such as cutting pills in half or skipping doses to stretch out their supply.¹⁴ A literature review of 160 studies illustrated that an increase in patient share of medication costs is directly associated with a significant decrease in medication adherence.¹⁵ Low income beneficiaries living with chronic conditions are particularly sensitive to the impact of cost-sharing.¹⁶

For many chronic conditions, patients may not immediately feel the impact of skipping their medications, but medication non-adherence leads to serious consequences in poorer health outcomes and higher downstream spending. When medications are not taken as prescribed, patients do not receive the expected, optimal benefit. For costly chronic conditions, such as diabetes, heart failure, hypertension, or cardiovascular disease, for example, non-adherence may lead to worsening of the condition and the need for more costly medications and treatments in the future; or worse, an emergency department visit for an avoidable heart attack or heart failure exacerbation.

Experts agree that medication non-adherence leads to undue and preventable suffering for patients, suboptimal health outcomes, increased total cost of care, and wasted spending. Specifically, patients not taking their medications as prescribed by their healthcare provider contribute to \$100 billion to \$290 billion in unnecessary healthcare expenditures every year as a result of increased hospitalizations and other avoidable, expensive medical services.¹⁷ Additionally, a systematic literature review of 79 studies conducted in 2018 revealed the annual adjusted total cost of non-adherence per person across multiple disease groups ranged from \$949 to \$52,341.¹⁸ A 2017 report 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.¹⁹ A 2016 cost-benefit analysis concluded that up to two thirds of medicine-related hospitalizations are caused by poor adherence.²⁰

The adverse health impacts and staggering costs of non-adherence can be meaningfully addressed. Specifically, research repeatedly demonstrates that the total cost of healthcare *decreases significantly* when patients take their medications as prescribed, and patients are more likely to take their medications as prescribed when their out-of-pocket drug costs are lower. For example, patients who are adherent to their medications are less likely to die from their health conditions and are less likely to visit the emergency room, or be readmitted to the

¹⁴ Kaiser Family Foundation, Mar. 1, 2019, available at <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>.

¹⁵ Eaddy MT, et al., *How Patient Cost-Sharing Trends Affect Adherence and Outcomes*, Pharmacy & Therapeutics, Jan. 2012, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/>.

¹⁶ Adams, A., et al., *The Case for a Medicare Drug Coverage Benefit: A Critical Review of the Empirical Evidence*, Annual Review of Public Health, Vol. 22, No. 1, May 2001, Retrieved Dec. 20, 2018, available at <https://www.annualreviews.org/doi/10.1146/annurev.publhealth.22.1.49>.

¹⁷ Rosenbaum L, Shrank WH, *Taking Our Medicine - Improving Adherence in the Accountability Era*, New England Journal of Medicine, Aug. 22, 2013; Network for Excellence in Health Innovation, *Bend the Curve: A Health Care Leader's Guide to High Value Health Care*, 2011, available at https://www.nehi.net/writable/publication_files/file/health_care_leaders_guide_final.pdf.

The NCPIE Coalition, *Enhancing Prescription Medicine Adherence: A National Action Plan*, 2007, available <http://www.bemedwise.org/docs/enhancingprescription-medicintheadherence.pdf>.

¹⁸ 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, available at <https://bmjopen.bmj.com/content/bmjopen/8/1/e016982.full.pdf>.

¹⁹ *A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination*, Prescriptions for a Healthy America, October 2017, available at <https://static1.squarespace.com/static/589912df1b10e39bd04eb3ab/t/59f0e439edaed84e6822d9bd/1508959306380/P4HA+WhitePaper+E-DigitalFinal+1017.pdf>.

²⁰ Patterson JA, et al., *Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies*, American Journal of Managed Care, 2016, available at <https://www.ajmc.com/journals/issue/2016/2016-vol22-n9/cost-benefit-of-appointment-based-medication-synchronization-in-community-pharmacies>.

hospital, leading to reduced healthcare costs.²¹ Also, reducing out-of-pocket costs for patients has a demonstrated impact on mitigating health disparities and promoting equity. For example, a study found that providing full drug coverage increased medication adherence, particularly in nonwhite patients, and it reduced the rates of major vascular events or revascularization by 35% and reduced total healthcare spending by 70%. The authors concluded that lowering copayments for medications for cardiovascular disease can have a meaningful impact on racial and ethnic disparities.²²

Furthermore, improving adherence has been demonstrated to result in annual per-person savings ranging from \$1,000 to \$7,000, depending on the disease state.²³ 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.²⁴ Additional studies of patients being treated for specific disease states such as diabetes,²⁵ high cholesterol,²⁶ and Parkinson's Disease²⁷ offer further support for the connection between improved adherence and lower healthcare costs.

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."²⁸ Thus, the CBO concluded that although improved medication adherence may increase costs in the Medicare Part D program in the short term, these costs are offset by significantly decreased medical costs. Again, these overall healthcare savings occur because patients who take their medications as prescribed avoid expensive hospitalizations and other medical services.

The research is clear: lower out-of-pocket beneficiary prescription drug costs lead to improved medication adherence, which in turn, improves patient health, fosters equity, and reduces overall healthcare costs. ***Thus, CMS' proposed rule should result in multipronged benefits to beneficiaries: lower out-of-pocket prescription drug costs, improved health, and reduced total cost of care.***

Finally, we agree with CMS that the proposed rule could serve to improve the overall beneficiary experience by

²¹ Braithwaite S, et al., *The Role of Medication Adherence in the U.S. Healthcare System*, Avalere Health, June 2013, available at http://www.avalerehealth.net/research/docs/20130612_NACDS_Medication_Adherence.pdf.

²² Choudhry NK, Bykov K, Shrank WH, Toscano M, Rawlins WS, Reisman L, Brennan TA, Franklin JM, *Eliminating medication copayments reduces disparities in cardiovascular care*, *Health Aff (Millwood)*, May 2014, ;33(5):863-70. doi: 10.1377/hlthaff.2013.0654. PMID: 24799585.

²³ Patterson JA, et al., *Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies*, *American Journal of Managed Care*, 2016, available at <https://www.ajmc.com/journals/issue/2016/2016-vol22-n9/cost-benefit-of-appointment-based-medication-synchronization-in-community-pharmacies>.

²⁴ 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, available at <https://www.nber.org/papers/w19948.pdf>.

²⁵ 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*, Aug. 2014, available at <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.1398>.

²⁶ 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.

²⁷ 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 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, Simon-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.

²⁸ Congressional Budget Office, *Offsetting the Effects of Prescription Drug Use on Medicare's Spending for Medical Services*, 2012, available at <https://www.cbo.gov/publication/43741>.

encouraging plans to motivate pharmacies to improve performance through future incentive payments. CMS stated in the proposed rule that:

Part D sponsors and their intermediaries previously asserted in public comments on the 2017 and 2018 rules that network pharmacies lose motivation to improve performance when all performance-based adjustments are required to be reported up-front. Revising the negotiated price definition as proposed would mitigate this concern by allowing sponsors and their intermediaries to motivate network pharmacies to improve their performance with the promise of future incentive payments that would increase pharmacy reimbursement from the level of the lowest possible reimbursement per claim.²⁹

CMS also recognized this in a 2018 proposed rule.³⁰ NACDS would welcome Part D sponsors being more inclined to use incentive payments as a motivational tool for pharmacies to enhance clinically meaningful, quality care for Medicare patients within the Part D program. This should provide pharmacies with new opportunities to make up the difference between the lowest possible reimbursement and optimal reimbursement.

2. NACDS supports the proposal because it could improve market competition and transparency.

Under the CMS proposal, pharmacies would be able to see their lowest possible reimbursement at the point of sale. CMS should finalize this proposal because the transparency would help pharmacies make more consistent and accurate comparisons of the financial impacts of their participation in the various Medicare networks.

The current structure of the Medicare program, with respect to pharmacy price concessions, forces a business environment of perpetual uncertainty. Months after dispensing a medication, pharmacies have indicated that they are unsure of their final reimbursement because pharmacies are unable to ascertain if and to what extent additional price concessions will be recuperated at a future time. Even worse, pharmacies are faced with disparate payment and performance arrangements from plans, resulting in additional, tremendous uncertainty over drug reimbursement. CMS' proposal would be a welcome and long-awaited first step toward improved transparency.

Unlike CMS' proposed treatment of pharmacy price concessions, CMS proposes that all contingent incentive payments (that is, an amount that is paid to the pharmacy instead of a price concession from the pharmacy) be excluded from the negotiated price definition so that the negotiated price is not inflated by any contingency payment and increase beneficiaries' cost share. NACDS supports this proposal as it would serve to keep beneficiaries' costs to a minimum while still providing pharmacies with significant progress toward financial transparency. NACDS appreciates CMS' recognition of the importance of contingent incentive payments for pharmacies by excluding those payments from the negotiated price definition. We urge CMS to consider ways to ensure that plans and PBMs continue performance incentive payments to pharmacies so that contingent incentive payments will continue to serve as a valuable tool for both plans and pharmacies as performance measures become standardized and more useful in the future to improve the experience, quality, and care for beneficiaries. For example, the use of contingent incentive payments within a reimbursement system that relies to a greater extent on standardized pharmacy performance measures (referenced in the attached Exhibit A) could be very helpful in realigning incentives in the Part D program to better serve beneficiaries.

²⁹ 87 Fed. Reg. at 1916.

³⁰ 83 Fed. Reg. 62,178 (November 30, 2018).

Pharmacies having access to greater transparency will help them to better determine which plan networks offer them the most likely and realistic opportunities to meet relevant standardized measures and thus greater opportunities to receive contingent incentive payments. Unfortunately, the current opaque reimbursement model in Part D, with respect to price concessions and incentive payments tied to performance measures, does not allow pharmacies to make clear and fully informed decisions about which networks may offer them opportunities for success in serving Medicare patients.

CMS clarifies that the proposed regulatory changes do not affect reporting requirements for Part D sponsors, nor do they affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point of sale. NACDS understands this to mean that irrespective of the negotiated price reported at the point of sale, plans will still have the ability to contract post-point-of-sale reconciliations with pharmacies. However, pharmacies will have the ability to know, at the point of sale, what their lowest possible reimbursement could be after all relevant and final reconciliation occurs.

CMS recognizes in the proposed rule that the current application of pharmacy price concessions encourages plans to inflate pharmacy DIR fees, harming beneficiaries and pharmacies. Specifically, CMS has stated that “. . . any DIR a sponsor receives that is above the projected amount factored into its plan bids increases revenues and contributes to plan profits, without necessarily being reflected in lower premiums.”³¹ CMS goes on to recognize that “in recent years, DIR amounts that Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts, by an average of 0.6 percent and as much as 3 percent as a share of gross drug costs from 2010 to 2020.”³² Moreover, CMS recognized that plans also have incentives to push beneficiaries toward more expensive medications. All of this puts upward pressure on the Part D program, shifts costs toward beneficiaries, shifts more of the total drug costs into the catastrophic phase, and shifts more overall costs to the government.

Even when plans utilize inflated DIR fees to lower plan premiums, plans would be allowed to capture additional market share through only a technical difference in how plans costs are reported to CMS. This leads to plan bids that are not comparable and premiums that are not valid indicators of relative plan efficacy.³³ We agree with CMS that the proposed rule should help eliminate these currently misaligned plan incentives.

Not only is drug price transparency harmed by the misuse of pharmacy DIR fees, but also pharmacy quality transparency is clouded by the non-standardized and inconsistently applied measures by which DIR fees are assessed. Without a standard set of pharmacy metrics, beneficiaries, pharmacies, and plans are unable to make direct 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.

Recommendation: In addition to transparency, CMS should hold PBMs accountable for continuing performance incentive payments to pharmacies.

³¹ 87 Fed. Reg. at 1913.

³² 87 Fed. Reg. at 1913.

³³ 87 Fed. Reg. at 1915.

3. NACDS supports defining “price concessions” and offers additional language to this definition.

NACDS agrees with CMS that contingent incentive payments to pharmacies should not be reflected in the negotiated price. As CMS notes, including the amount of any contingent incentive payments to pharmacies in the negotiated price could make drug prices appear higher at “high performing” pharmacies that receive incentive payments.³⁴ As a result, including contingent incentive payments in the negotiated price would create incentives for beneficiaries to use lower-performing pharmacies.

Additionally, 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. NACDS also agrees that this definition should be broad enough to account for future types of concessions that may be used in the program. However, 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 be encouraged to leverage ambiguities to reclassify or redefine pharmacy price concessions in a manner that excludes them from negotiated prices, thereby increasing beneficiary drug costs and undermining CMS’ intentions outlined in the proposed rule.

Specifically, CMS is 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, which serves to decrease the costs incurred by the plan.

Recommendation: NACDS supports the intent of the definition and offers the following elements for CMS to consider including in the definition specifically for pharmacy price concessions: any type of fee or other amounts that a Part D sponsor or its intermediary contracting organization retains from payments made to such pharmacies or providers, including but are not limited to transaction fees, network participation fees, and administrative fees.

We also urge that this definition, as well as the negotiated price definition, be applied to instances when a patient is in the coverage gap. We offer more support for this position in section B.2. of this letter.

4. NACDS supports the inclusion of pharmacy administrative services fees in a Part D plan’s bid or in the price concession definition.

In addition to the revised definition, CMS reiterates that “Pharmacy Administrative Services Fees” should be included in a plan’s bid because they offset the sponsor’s or its intermediary’s operating costs under Part D. CMS states that failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit and thus to submit a lower bid than necessary to reflect its revenue requirements.

As CMS works to finalize the proposed rule, we urge CMS to ensure that pharmacy administrative services are properly treated by Part D plans. Pharmacies rarely receive any benefit from these fees they are charged, as the fees are commonly connected to network participation. With this in mind, we agree with CMS that these fees

³⁴ 87 Fed. Reg. at 1916.

must either be accounted for in the plan's Part D bid or included in the definition of price concessions. As CMS recognizes in the proposed rule, plans are currently incentivized not to report these at all, thus under-reporting the true costs of providing the benefit and providing another mechanism to obscure beneficiaries' abilities to make equitable and well-informed plan comparisons.

Recommendation: Since pharmacies rarely receive any benefit from "Pharmacy Administrative Services Fees," most of these fees should be reported in a plan's bid or as a price concession. However, ***we urge CMS to pay close attention to how plans report these fees to ensure that they are not being used to skew competition for beneficiaries.***

In addition, CMS may want to consider applying a "bona fide service fee" test to ensure that if plans do not recognize these fees in their plan bids, then they are included in the negotiated price. CMS could consider applying a "bona fide service fee" test similar to the one found in 42 C.F.R. § 423.501. We urge CMS to ensure that such fees are recognized and properly reported either as a price concession in the negotiated price or reported in the plan bid.

Recommendation: CMS should consider a "bona fide service fee" test to ensure that "Pharmacy Administrative Service Fees" are properly reported either in a plan's bid or as a price concession.

B. CMS should implement regulatory guardrails to successfully effectuate the proposed reform.

CMS' proposed change is a first step to bring about meaningful reform in the Part D program for Medicare patients and the pharmacies that serve them. Yet, this reform could not operate in the way CMS intends if supporting guardrails are not established to prevent Part D plans from being incentivized to leverage these changes to benefit their bottom lines. We offer the following guardrails to help CMS effectuate this reform in alignment with how CMS explains the proposal should work.

Guardrail 1: CMS should evaluate whether reimbursement reflected at the point of sale could impact beneficiaries' access to pharmacies.

CMS notes throughout the proposal that pharmacy DIR has increased significantly, with negative pharmacy price concessions or DIR fees, net of all pharmacy incentive payments, growing more than 107,400 percent between 2010 and 2020.³⁵ While this proposal provides transparency into those DIR fees in the form of up-front discounts, it does not address an underlying issue: regardless of *when* pharmacy price concessions are assessed, these concessions are on an exponential growth path. Most concerning, performance-based pharmacy price concessions, net of all pharmacy incentive payments increased on average nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates.³⁶ We are concerned that the continual downward push on pharmacy reimbursement could lead to negative impacts on beneficiary access to pharmacy services.

It is well established that pharmacy DIR fees are not a monolith and are specific to a pharmacy's contract. However, a price concession category specific to the Part D program are those based on a plan's home-baked performance measures. One theory is that these concessions are on an exponential growth path because there are few restrictions on what plan and PBMs can base these on, which can result in the use of metrics that were

³⁵ *Id.* at 1910.

³⁶ *Id.*

never meant to evaluate a pharmacy's true performance. This opaque and arbitrary barometer serves as a logical opportunity for plans to proliferate profits, with no meaningful ways for a pharmacy to mitigate the impact.

Under today's Part D program, regional and national chain pharmacies have reported that at times, these performance-based price concessions can result in instances where pharmacy reimbursement is below a pharmacy's costs to dispense drugs to Medicare patients. Others have reported that such deep concessions based on so-called performance have made preferred pharmacy networks unsustainable. This structure puts pharmacies in an untenable situation with respect to providing needed care for the patients and communities they serve.

Under the Medicare Part D statute and regulations, "any willing pharmacy" that meets a Part D Plan sponsor's standard terms and conditions must be allowed to participate in a Part D plan's pharmacy network. Over the years, CMS had made clear that this requirements means that Part D network terms are to be "reasonable and relevant."³⁷ In a recent CMS proposed rule, however, it noted that the applicable standard terms and conditions have effectively "circumvented" these any willing pharmacy requirements and inappropriately excluding pharmacies from network participation."³⁸ CMS' final rule following this proposal did not go as far as to set specifics on what would be considered "reasonable and relevant" terms and conditions. Instead, CMS stated the requirement is meant "to minimize barriers to pharmacy network participation" and that terms and conditions must be relevant "in light of the changes and innovations in pharmacy practice and business models."³⁹

With this backdrop, we question whether CMS has considered that the lowest possible reimbursement could result in instances where the terms and conditions of a network would forcibly preclude too many pharmacies from being able to participate.⁴⁰ In the spirit of CMS' final rule cited above, NACDS agrees that Part D's any willing pharmacy statute must not be circumvented to erect barriers to pharmacy network participation. The any willing pharmacy statute is critical to help protect patients' access to pharmacies. In light of the changes in the proposal, and the changing pharmacy business models that may result, we implore CMS to evaluate whether the operation of the finalized proposal could result in instances where pharmacies' terms and conditions are no longer reasonable and relevant, in direct violation of 42 U.S.C. § 1395w-104(b)(1)(A).

Recommendation: CMS should consider whether, in designing their networks, Part D plans and their PBMs have violated the any willing pharmacy mandate in Part D. Accompanying such review, CMS should update 42 C.F.R. § 423.505, the regulations that govern terms and conditions between plans and the government, to ensure that the operation of this proposal, if finalized, would not purposefully hinder participation and competition.

[Guardrail 2: CMS should also apply the negotiated price definition to the coverage gap.](#)

CMS expressly excludes the proposed reform of the negotiated price definition from applying to instances when beneficiaries are in the Part D coverage gap. ***We strongly urge CMS to reconsider this exclusion.*** Our primary concern is that if CMS decides not to require the inclusion of all pharmacy price concessions 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. This could shorten the time it takes for Medicare beneficiaries' Total Out-of-Pocket ("TrOOP") costs to reach the exit point into the catastrophic coverage phase. These higher

³⁷ 42 C.F.R. § 423.505(b)(18).

³⁸ 83 Fed. Reg. 16,440, 16593 (Apr. 16, 2018).

³⁹ *Id.*

⁴⁰ 42 U.S.C. § 1395w-104(b)(1)(A).

beneficiary coverage gap costs can also deter adherence, undermining Medicare’s quality-related goals which can then lead to increased Medicare Trust Fund spending.

Specifically, allowing plans to exclude a portion of pharmacy price concessions would likely result in contracting and operational challenges for CMS, plans, pharmacies, and drug manufacturers. Allowing for the differential treatment of DIR fees 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. The operational and contracting challenges for plans, 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. Additionally, pharmacies will be asked to explain the price at the counter but will not necessarily have access to the answer, thus, driving up the potential for Medicare-related grievances that can be costly to plans and pharmacies, which could create unnecessary barriers to patient access. NACDS strongly supports the inclusion of all pharmacy price concessions in the negotiated price for prescriptions dispensed in the Medicare Part D coverage gap.

Further, NACDS agrees with CMS that the agency has the authority to require plans to include all pharmacy price concessions in negotiated prices during the coverage gap. The statute incorporates 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.⁴¹ 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 paid to the pharmacy is \$8, not \$10. Therefore, under clause (1) of the coverage gap definition of the negotiated price, plans must include all pharmacy price concessions to ensure that the negotiated price reflects pharmacy reimbursement “in total.” 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.”⁴²

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.⁴³

In fact, that is the only way to read clause (2) consistent with clause (1). Clause (1) requires the negotiated price

⁴¹ Compare 42 C.F.R § 423.2305 with 42 C.F.R § 423.100.

⁴² 83 Fed. Reg. at 62,179 (emphasis added).

⁴³ See 79 Fed. Reg. 1918, 1972-74 (Jan. 14, 2014) (emphasis added); see also 79 Fed. Reg. 29844, 29876 (May 23, 2014).

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 sound 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.

Recommendation: CMS should also apply its proposed definition of “negotiated price” to claims in the coverage gap to end plans’ practices of exploiting retroactive DIR fees to the detriment of beneficiaries. Moreover, CMS has the authority to do so.

Guardrail 3: CMS should ensure that the proposed rule can be swiftly operationalized for contract year 2023.

CMS contemplates the proposal should be operationalized by having plans load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems, which interface with contract pharmacies.⁴⁴

We appreciate this explanation, yet we ask CMS to consider issuing guidance or subsequent rulemaking to establish how Part D plans are required to reflect the lowest possible reimbursement at the point of sale. One concern that pharmacies have raised is that it is possible to interpret CMS’ proposed rule in such a way that payers’ claim responses to pharmacies at the point of sale may show the amount to be charged to the patient (based on CMS’ “negotiated price” definition), but not the negotiated price that includes the maximum potential price concessions for each claim. For example, the claim response may indicate to the pharmacy that the patient coinsurance amount is \$10, which is the coinsurance amount for the patient based on the lowest possible reimbursement. Unless the payer also includes the negotiated price in the appropriate field in the claim response, the pharmacy would have no way to determine what their lowest possible reimbursement is on a claim, they just would know what to charge the patient. These potential outcomes would directly undermine one of CMS’ intentions for the proposed rule, which, according to CMS, is to promote transparency so that pharmacies have better information for contract negotiations.⁴⁵ To forestall this potential misinterpretation of the proposal, ***CMS should confirm via guidance or subsequent rulemaking that the payer must transmit in an appropriate field in the claim response the negotiated price so that a pharmacy can see the lowest possible reimbursement for each claim at the point of sale in the claim response, not just the patient cost share based on that lowest possible price.***

Then, CMS should take additional steps to support transparency by requiring plans to provide consistent claim-level detail in the ASC X12 835 electronic remittance file that details reimbursement payments to pharmacies where providing this specific information could be accomplished.

Recommendation: One simple way to do this is to update, via rule, 42 C.F.R. § 423.505, which outlines all terms and conditions of the contract between CMS and Part D plans. CMS could require Part D plans to provide to the pharmacy the lowest possible reimbursement for each claim at the point of sale in the claim response. CMS could also require plans to provide consistent claim-level detail in the electronic remittance advice that accompanies reimbursement payments to pharmacies where doing so could be

⁴⁴ 87 Fed. Reg. at 1845, 1916.

⁴⁵ *Id.* at 1911.

accomplished. Finally, CMS should also require plans to include Group IDs and Network IDs on every claim.

Second, CMS should ensure that payers update their systems in time for the expected implementation date for this proposal: January 1, 2023. The industry has been contemplating CMS' proposal for some time now. In fact, the National Council for Prescription Drug Programs (NCPDP) has reviewed similar approaches in the past and is currently reviewing the proposed rule and how the Telecommunication Standard will effectuate including pharmacy price concessions in the negotiated price.

Recommendation: CMS should require all payers to comply with the rule at least 60 days prior to the implementation of this proposal (January 1, 2023).

Guardrail 4: CMS should support pharmacies' need to ensure cash flow capabilities through standardized, transparent, predictable, and relevant performance measures.

CMS speculates that there is a modest potential indirect effect on pharmacy payment as a result of pharmacies' *independent business decisions*. Specifically, CMS estimates assume "that pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they negotiate with plan sponsors and other third parties to compensate for pricing risk and differences in cash flow" and "...that these business decisions will result in a slight increase in pharmacy payments of 0.1-0.2 percent of Part D gross drug cost."⁴⁶ Importantly, CMS states "the requirement that pharmacy price concessions be passed through to the point-of-sale price only directly impacts the price that is used to determine beneficiary cost-sharing and the information that is populated and reported on the PDE record, but it does not dictate the *amount* that is ultimately paid to the pharmacy or the *timing of payments and adjustments*."⁴⁷

Pharmacies are supportive of this proposal but acknowledge the possible cash flow considerations that may arise from its finalization. For example, NACDS continues to hear concerns expressed from pharmacies that this operational change may result in immediate, but temporary, cash flow issues in the first few months of implementation. We understand this could be because some pharmacies may rely on the present cash flow process. Consequently, it is understandable that some pharmacies may re-structure business agreements in anticipation of the potential cash flow concerns that CMS acknowledges in its preamble.

Another cash flow issue and possible pharmacy response would be for pharmacies to structure agreements that seek out more positive incentive payment adjustments, especially those that a pharmacy may be able to influence (e.g. performance-based). We question, however, whether these types of positive incentive payments based *solely on performance* will occur when, in reality, and by CMS' own admission, it is clear that pharmacies rarely receive these types of payments. Put simply: we question whether there will be payment adjustments at all if there is no incentive for plans to pay any positive performance amounts. And, even if such payments are paid, from a cash flow perspective, we are concerned that a pharmacy could not rely on these adjustments because they will continue to be sporadic and based on opaque, arbitrary, and inconsistent "performance measures." This lack of clarity undermines competition in the Part D program. As described in section C below, NACDS continues to advocate that, to move toward a reimbursement system that relies to a greater extent on meaningful pharmacy performance measures for the benefit of Medicare patients, measures must be standardized.

⁴⁶ *Id.* at 1944.

⁴⁷ *Id.* at 1915.

Recommendation: CMS should immediately implement standardized pharmacy performance measures that are transparent, predictable, and relevant for each participating pharmacy. Doing so could make cash flow more predictable and consistent for pharmacies and improve care for beneficiaries. Such a change better supports competition in the Part D program, increases the intended transparency of the proposed rule, and increases predictability and stability in reimbursement for pharmacies. relevant and attainable for each participating pharmacy. CMS should require Part D plans to provide pharmacies with monthly, member-level reports so that participating pharmacies have transparency and predictability as to what is being measured, what they are measured against, and what will need to be done in order to improve performance and ultimately the quality of patient care. By taking this approach, unnecessary medical spending by the Medicare Trust Fund can be further mitigated.

Guardrail 5: CMS should conduct a thorough analysis on the direct impact such proposal will have on pharmacies and potentially patient access.

Finally, as discussed above, CMS estimates that this proposal could result in a “modest” potential indirect effect on pharmacy payment. CMS assumes that pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they negotiate to compensate for pricing risk and differences in cash flow and that these business decisions will result in a slight increase in pharmacy payments of 0.1 - 0.2 percent of Part D gross drug cost.⁴⁸

While CMS’ estimates sound positive, we question the basis of these assumptions and request CMS provide the numbers or calculations with which they relied upon. We are concerned that these figures will not be an accurate reality for most pharmacies and seek the calculations to better understand and verify CMS’ assumptions.

Further, NACDS is concerned the proposal’s Regulatory Flexibility Act (“RFA”) analysis does not fully contemplate the proposal’s impact on smaller pharmacy businesses.⁴⁹ It is well established that an agency must conduct an RFA analysis or certify that a proposed rule will have a significant impact on a substantial number of small entities.⁵⁰ If the agency does the latter certification, the agency must provide a factual basis, including⁵¹ a description of the number of affected entities and the size of the economic impact on those small businesses, like revenue.

Additionally, CMS should consider the unintended consequences of its 2014 rule, which inadvertently produced the dramatic pharmacy DIR fees seen today by PBMs. Being mindful that it is entirely possible that similar unintended consequences could result from this proposed rulemaking, CMS should carefully monitor novel PBM activities that run counter to CMS’ intent.

Recommendation: CMS should commit to a timeline to publicly provide the assumptions, calculations, and/or models on which it relied to deduce the indirect numbers in the proposal. We ask CMS to conduct a thorough regulatory impact analysis of how this proposal could impact pharmacies pursuant to 5 U.S.C. § 601-612 and to also study and report on PBM industry trends and practices that change noticeably as a result of this proposal that does not have the patient’s best interests in mind.

⁴⁸ *Id.* at 1944.

⁴⁹ 5 U.S.C. § 601-612.

⁵⁰ *Id.*

⁵¹ 70 Fed. Reg. 4194, 4497 (Jan. 28, 2005) (“HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.”).

C. CMS should implement standardized pharmacy measures to effectuate comprehensive pharmacy DIR reform that best serves Medicare patients and improves healthcare quality, equity, and reduce preventable spending.

In this proposal, CMS acknowledges that performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates.⁵² CMS further acknowledged that performance-based incentive payments – payments paid to a pharmacy based on performance – have been extremely unlikely in recent years. NACDS concurs that this has been the experience of pharmacies.

CMS goes on to describe that the proposal changes reporting requirements for Part D sponsors; it does not affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point of sale. To bolster this, CMS states that, “[c]ontracts between sponsors or their PBMs and pharmacies can continue to provide for performance-based payment adjustments. The requirement that pharmacy price concessions be passed through to the point-of-sale price only directly impacts the price that is used to determine beneficiary cost-sharing and the information that is populated and reported on the PDE record, *but it does not dictate the amount that is ultimately paid to the pharmacy or the timing of payments and adjustments.*”⁵³

NACDS highlights that even under the proposed rule, the lack of incentive payments paired with the prevalence of price concessions based on performance would still be significant, outstanding challenges that must be addressed to achieve comprehensive DIR reform and redirect incentives to emphasize better care for beneficiaries. That is, pharmacy price concessions, including those based on performance, included in the negotiated price would remain contingent, variable, and without regard to beneficiary outcomes and care experience. Meaning, performance-based price concessions could continue to be calculated lower and lower, without any regard to performance at all.

Such a structure undermines CMS’ goals to serve Part D beneficiaries and improve healthcare quality, equity and reduce preventable spending. ***Therefore, we ask, at the very least, that the performance metrics used to determine price concessions be standardized so that pharmacies can be assured of performance expectations and opportunities before signing a Part D contract, rather than after-the-fact, as is the current situation.***

Said another way, CMS’ proposal to require disclosure of performance measures to the agency is critically important as a first step in reforming DIR for the benefit of Medicare beneficiaries but is inadequate in effectuating comprehensive DIR reform. We ask that without delaying the implementation of the proposal in FY 2023, CMS implement the clear rules and pharmacy measures needed to produce pharmacy incentives to improve performance based on quality and patient outcomes. Further, these measures need to be within the control of the pharmacy. In order to achieve this goal, measures must be defined, transparent, consistent across plans, and used with time to adjust performance to ensure improvement. Additionally, these measures must be pharmacy-specific, proven, and achievable criteria that consider the drugs dispensed and the disease state(s) being managed. Doing so will help ensure fairness for both Part D plans and pharmacies, while promoting trust that is sorely lacking in the current process, and benefit access to Medicare beneficiaries. Also, importantly, effective pharmacy-level performance measures should first reflect that there should be reimbursement for dispensing,

⁵² 87 Fed. Reg. at 1916.

⁵³ *Id.* at 1915.

separate from performance-based quality measures.

Importantly, CMS is not constrained in defining performance measures and how they should be applied. We strongly encourage CMS to act to standardize performance measures and performance processes to create a system that truly incentivizes performance improvement.

In fact, the development of pharmacy-level quality measures is already underway. Several pharmacy quality measures have been developed, tested, and endorsed by the Pharmacy Quality Alliance (“PQA”) over the last two years for the purpose of evaluating the quality of pharmacies and assessing pharmacist-provided care and pharmacy-based services. To date, PQA has endorsed five pharmacy quality measures, primarily focused on medication adherence.^{54,55} Additional measures are in development, including measures focused on patient health outcomes for some of the most common, costly conditions including high blood pressure and diabetes (A1c), among others.⁵⁶ Beyond the measures recently endorsed for pharmacy-level quality measurement, Exhibit A highlights quality measures ripe for positive pharmacy impact based on measures used in existing CMS programs.

Implementing standardized pharmacy performance metrics would not only help to provide pharmacies with clarity on their performance expectations and opportunities but would also help to redirect and align incentives toward providing better care, equity, and experiences for beneficiaries based on evidence-based, tested quality measures. Beyond this, implementing standardized pharmacy performance metrics would help reduce the total cost of care by aligning incentives for pharmacies, plans, and PBMs to further improve medication adherence, patient health outcomes, and prevent downstream unnecessary spending in addition to undue harm and suffering for patients. As mentioned in section A.1. above, medication adherence is one of the most cited areas where community pharmacies can play a leading 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, especially with respect to medication adherence. However, initiating and implementing a successful medication adherence program will depend on the realignment of the currently perverse Part D program incentives.

Further, while research continues to demonstrate how pharmacy patient care programs improve adherence and reduce costs, no standardized pharmacy quality incentive program nor pharmacy-level measures to improve adherence currently exist within 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. One example of the mismatch of current performance measures with effective patient care is that while many plans assess pharmacy providers on quality measures tied to medication adherence, they often do not account for patients’ comorbid conditions, such as cancer, which may warrant a clinical treatment plan with different adherence goals. Beyond this, some plans may hold a pharmacy accountable for patient adherence to a medication that the pharmacy is not dispensing to the patient, but instead, the patient is receiving from a different pharmacy. Another example of the current dysfunction caused by the lack of standardized pharmacy-level measures is that stores within the same pharmacy chain compete against each other on so-called performance measures given the overlap in their patient population, without respect for the fact that one pharmacy within the chain may dispense a subset of a certain patient’s medications, and another pharmacy location may dispense other

⁵⁴ Pharmacy Quality Alliance, available at <https://www.pqaalliance.org/pqa-endorses-pharmacy-performance-measures-for-medication-adherence-and-specialty-turnaround-time>.

⁵⁵ Pharmacy Quality Alliance, available at <https://www.pqaalliance.org/pqa-endorses-pharmacy-performance-measures>.

⁵⁶ Pharmacy Quality Alliance, available at <https://www.pqaalliance.org/pharmacy-measures>.

medications for that patient. This ineffective system diverts energy that could be better focused on enhancing the quality of care and health outcomes for beneficiaries.

To reiterate, a standard set of measures across plans would fairly apply consistent, evidence-based performance metrics to pharmacy care programs, ensuring that a pharmacy can implement medication adherence programs and other patient-centered health efforts that consistently improve medication adherence, improve health, promote equity, and reduce overall Medicare costs.⁵⁷

As CMS is rightly seeking to create transparency in a newly defined negotiated price, similarly, it should establish transparency and standardization of the measures and methodology used to fairly assess pharmacy quality performance. As such, ***CMS should support the development and implementation of a set of standard pharmacy performance metrics to align quality standards that reflect evidence-based strategies to best improve beneficiary health and reduce overall Medicare costs.*** In the development and implementation of standardized pharmacy quality measures, CMS should seek to ensure certainty and transparency. Further, standardization would allow pharmacies to be more proactive with applying clinical interventions to the right patient, at the right time and in the right way so as to ultimately reduce Medicare Trust Fund spending on hospitalizations, tests, labs, and medical benefit care.

1. To improve the experience, quality, care, and foster equity for beneficiaries, CMS should implement standardized measures to regulate the application of price concessions and incentive payments.

Since the price concessions at issue are presumably based on pharmacy performance, and those price concessions and the performance measures on which they are based are largely unregulated, we believe that any effort to reform the treatment of pharmacy price concessions cannot succeed without the concomitant regulation of related performance measures. Although including pharmacy price concessions in the negotiated price would help reduce beneficiary costs, continuing to allow performance measures to be unregulated and unstandardized perpetuates a situation in which each plan may impose its own measures that have little or no bearing on other plans' measures and such measures may not be relevant for pharmacies. Thus, plans may continue to apply measures in ways that work only to their financial benefit without having any real impact on the beneficiary care and experience.

Under CMS' proposal, beneficiaries would see lower out-of-pocket costs at the point of sale but that could come at the cost of unwittingly choosing a lower quality plan without them ever realizing that they could achieve the same cost-savings with a higher-quality plan. Stated more plainly, we fear that plans will continue to extract greater and greater price concessions from pharmacies and that these price concessions will continue to have little to no impact on true performance or quality for beneficiaries. Since quality and performance are bedrocks of the Medicare Part D benefit, we believe that CMS should not continue to ignore the need for standardized pharmacy performance measures that help align incentives to promote better care for beneficiaries.

Recommendation: In tandem with this proposal, CMS should implement standardized pharmacy performance measures for contract year 2023 to help improve the experience, care, quality, and equity for beneficiaries and affirm that quality and performance are bedrocks of the Medicare Part D benefit. However, should CMS believe that this timeline is not feasible for the implementation of standardized quality

⁵⁷ Further, CMS could study what risk adjustments should be applied based on the socioeconomics and socio-demographics of Medicare beneficiaries.

measures, we emphasize the importance of implementing the proposal in 2023 to address the dire and urgent need for transparency as an important first step in DIR reform and implementing risk-adjusted standardized and transparent measures as soon as possible thereafter.

2. CMS should ensure that standardized pharmacy quality measures are tied to Part D plans' Star Ratings and used within a broader pharmacy quality incentive program to effectively align incentives for Part D plans and pharmacies toward better quality, equity, and reductions in preventable spending for beneficiaries.

NACDS appreciates CMS' finalizing the requirement for Part D plans to report their pharmacy measures to the agency beginning this year. We look forward to the increased transparency that should result from CMS' publishing these reported measures. However, ***we urge CMS to go further to advance quality for beneficiaries and implement a program of standardized pharmacy measures that aligns incentives for pharmacies. In tandem, to align incentives for plans, we recommend that implementation of pharmacy measures be tied to plans' Star Ratings.***

Absent relevant, aligned, standardized performance measures and corresponding incentives aimed at driving better health outcomes and reducing the total costs of care, substantial system dysfunction and unnecessary spending will continue to occur. Failure to implement a pharmacy quality incentive program with standard metrics could unintentionally magnify the existing conflict between drug cost containment and the goal of improving health outcomes, especially given that standalone Part D plans are not held accountable for downstream spending in other parts of Medicare. Without a pharmacy quality incentive program and a tie into Star Ratings, 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 and connecting pharmacy measures with Star Ratings to affirm that quality and value are essential pillars of the Part D program.

Importantly, a pharmacy quality incentive program would strongly encourage plans and pharmacies to collaborate and better engage beneficiaries enrolled in Part D plans in accessible, convenient healthcare settings. Likewise, Medicare beneficiaries would have the opportunity to be more engaged with their trusted pharmacists to improve their health and wellbeing. The clinical expertise of pharmacists paired with their accessibility, including in vulnerable communities, creates tremendous opportunity to improve quality of care and outcomes for beneficiaries and promote equity.

Community pharmacies have flourished and evolved into patient-centered healthcare destinations with pharmacist provision of clinical care such as immunizations, screenings, health and wellness care, treatment for minor illnesses, transitions of care programs, medication optimization and adherence, and chronic care management programs, among many others. Further, a growing number of pharmacy programs have been designed and implemented to provide patients convenient access to affordable, high-quality preventive care, including screening, brief intervention, and referral to treatment (SBIRT) for misuse and abuse of opioids, and HIV prevention like PrEP (Pre-Exposure Prophylaxis) and PEP (Post-Exposure Prophylaxis), in addition to mental and behavioral health screening and support. Exhibit C highlights several research evaluations of pharmacy-based programs within these high-priority clinical areas.

The value and impact of pharmacies in caring for their patients and communities has been underscored during the COVID-19 pandemic. Since the beginning of the pandemic, pharmacies have risen to bolster the Administration's national response with a critical lens on equity. Specifically, pharmacies remained open and available for

patient care while providing key access to COVID-19 testing, COVID-19 and routine vaccinations, COVID-19 therapeutics, and the distribution of free N-95 masks. Fully leveraging the existing retail pharmacy network—which 90 percent of Americans live within 5 miles—has efficiently, equitably, and cost-effectively strengthened important access to critical care for Americans, especially those in underserved urban or rural areas, or that may otherwise face healthcare disparities and inequities.⁵⁸ More specifically, the following highlight some essential efforts pharmacies have led during the Public Health Emergency:

- Pharmacies have administered more than 229 million COVID-19 vaccinations to date⁵⁹
- Today, 2 of every 3 COVID-19 vaccine doses are provided at a pharmacy⁶⁰
- More than 40% of those vaccinated at pharmacies were from racial and ethnic minority groups⁶¹
- About a third of children ages 5 to 11 who received a COVID-19 vaccination did so at a pharmacy⁶²
- Half of pharmacy COVID-19 vaccination sites are located in areas with high social vulnerability⁶³
- Pharmacies have provided more than 11,000 mobile COVID-19 vaccination clinics across the country⁶⁴
- Pharmacies provide more than 20,000 COVID-19 testing sites nationwide
- Pharmacies provide access to COVID-19 antivirals at thousands of locations nationwide
- 70% of pharmacy testing sites are in areas with moderate to severe social vulnerability⁶⁵

Despite strong evidence, the value of pharmacy care has been underutilized by Medicare to improve outcomes and reduce downstream spending. Establishing a pharmacy quality incentive program with standardized measures will better leverage pharmacies to serve beneficiaries. Further, establishing a pharmacy quality incentive program that rewards quality, value, and improved health outcomes will motivate participating entities to reduce the 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 rule, with the expectation that a full program could commence in 2023 in tandem with the finalization of this proposed rule.

Just as CMS has taken the lead on developing a standard quality program for physicians (e.g., 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. A standardized pharmacy performance incentive program would represent innovation aimed at yielding better quality, outcomes, savings, and improvement activities through the advancement of pharmacy care and care coordination.⁶⁶ Exhibit B outlines examples of synergistic alignment between a pharmacy quality incentive program and existing CMS value-based care programs.

As mentioned above, the proposed rule could serve to improve the overall beneficiary experience and care by encouraging plans to motivate pharmacies to improve performance based on future incentive payments. If finalized, the proposal would allow sponsors and their intermediaries to motivate network pharmacies to improve their performance with the promise of future incentive payments that would increase pharmacy

⁵⁸ NACDS, Health Equity, available at <https://www.nacds.org/pdfs/HealthEquity.pdf>.

⁵⁹ CDC, Federal Retail Pharmacy Program, available at <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>.

⁶⁰ White House, available at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actions-to-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/>.

⁶¹ GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, available at <https://www.gao.gov/assets/gao-22-105079.pdf>.

⁶² Biden Administration, COVID-19 Vaccine for Children 6 Months – 4 Years Old Preliminary Considerations for Pediatric Planning, Feb. 2022, available at <https://www.aha.org/system/files/media/file/2022/02/covid-19-vaccine-for-children-6-months-4-years-old-preliminary-considerations-for-pediatric-planning.pdf>.

⁶³ GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, available at <https://www.gao.gov/assets/gao-22-105079.pdf>.

⁶⁴ *Id.*

⁶⁵ White House, FACT SHEET: Biden Administration Announces Historic \$10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities, available at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/>.

⁶⁶ Mechanic RE, et al., Medical Group Responses to Global Payment: Early Lessons From the Alternative Quality Contract in Massachusetts, Health Affairs, 2011, available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0264>; Larson BK, et al., Insights from Transformations Under Way at Four Brookings-Dartmouth Accountable Care Organization Pilot Sites, Health Affairs, 2012, available at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.1219>.

reimbursement from the level of the lowest possible reimbursement per claim.⁶⁷ NACDS would welcome Part D sponsors' being more inclined to use incentive payments as a motivational tool for pharmacies. However, to help ensure plans' interest in adopting and implementing a workable motivational performance program for pharmacies, the implementation of standardized pharmacy performance measures should be tied to plans' Star Ratings. Doing so would provide plans with their own motivations for ensuring that the standardized pharmacy performance measures are implemented and utilized to the fullest extent.

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 need to ensure that high-performing pharmacies are no longer disadvantaged by perverse plan incentives that can unintentionally drive beneficiaries from high-performing to lower-performing pharmacies. A pharmacy quality incentive program is an integral component of pharmacy DIR fee reform because it would provide the right program incentives to advance quality and value of pharmacy care for beneficiaries enrolled in Part D plans.

In sum, CMS should set forth standardized pharmacy quality measures and performance standards, within a pharmacy quality incentive program, which are tied to plans' Star Ratings and that serve as the basis for pharmacy 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, as outlined above. This effort would further demonstrate the quality services provided by pharmacists and could dovetail into other federal quality programs such as the Medicare Shared Savings Program (MSSP) and MIPS.⁶⁸

Recommendation: Standardized pharmacy performance measures must be tied to plans' Star Ratings and implemented within a broader pharmacy quality incentive program because doing so would provide plans and pharmacies with their own motivations for ensuring that the standardized pharmacy performance measures are implemented and effectively utilized to the fullest extent to promote better care for Medicare patients. Without aligned incentives for implementation, the development of standardized pharmacy quality measures will fall short in effectuating meaningful improvements in care for beneficiaries.

3. CMS has the legal authority to promulgate and implement pharmacy performance measures.

CMS has authority under the Medicare statute and regulations to develop a standard set of pharmacy performance measures. This authority aligns with ongoing CMS efforts to ensure high-quality care for Medicare beneficiaries and protect the Medicare Trust Fund.

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.⁶⁹ This language provides CMS authority to establish additional measures beyond those specifically listed in the statute.

Even more specific authority related to pharmacy measures is provided in the statutory and regulatory

⁶⁷ 87 Fed. Reg. 1842, 1916.

⁶⁸ See Exhibits attached.

⁶⁹ 42 U.S.C. § 1395w-111(g)(5)(b) (emphasis added).

requirements for Medication Therapy Management Programs (“MTMPs”) and quality assurance programs.⁷⁰ 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:

[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 the industry to identify new standards for quality and performance that could eventually become plan requirements.*⁷¹

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 the industry to develop measures that can be used to evaluate programs and establish relevant standards.⁷²

Given the experience garnered from many years of administering the Part D program, CMS now has the knowledge to reform the program through the adoption of standardized pharmacy performance measures.

CMS has additional authority to establish standardized pharmacy measures under its Star Ratings system for Medicare Advantage and Part D plans. CMS originally established a Star Ratings system as part of its broad statutory requirements to disseminate information to beneficiaries to help them make informed plan choices.⁷³ Congress then expanded this system to include bonus payments and other benefits for high-performing Medicare Advantage plans. Under the Star Ratings 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.”⁷⁴ Consequently, measures can be broadly established to help educate consumers about issues related to their Part D benefit, including pharmacy quality and performance.

In particular, CMS has adopted Star Ratings measures that are already directly tied to pharmacy performance. Measures related to medication adherence, diabetes treatment, and relevant under 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 Ratings.⁷⁵ CMS has also clarified that it has the authority to adopt new Star Ratings Measures, amend existing measures, or entirely remove measures through its rulemaking process.

⁷⁰ See 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.125(d).

⁷¹ 70 Fed. Reg. 4194, 4277 (Jan. 28, 2005) (emphasis added).

⁷² *Id.* at 4280 (emphasis added).

⁷³ 42 U.S.C. §§ 1395w-21(d) & 22(e); 42 U.S.C. § 1395w-101(d).

⁷⁴ 83 Fed. Reg. 16,440, 16,520 (Apr. 16, 2018).

⁷⁵ CMS, Medicare Star Ratings, available at <https://www.medicare.gov/find-a-plan/staticpages/rating/planrating->. As an example, the Star measure entitled, “Members Who Had a Pharmacist (or Other Health Professional) Help them Understand and Manage Their Medications.”

Furthermore, CMS has noted that it can make technical or more minor changes through its Annual Call Letter.⁷⁶ Overall, CMS can use its Star Ratings system to adopt standardized pharmacy performance 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.

Recommendation: CMS should promulgate and implement standardized pharmacy performance measures pursuant to its legal authority.

D. CMS should finalize the proposed rule because CMS has the requisite legal authority to promulgate and finalize this proposal.

1. The proposal does not violate 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.”⁷⁷ 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.”⁷⁸ NACDS specifically rejects arguments from plans and their PBMs that any government regulation in the Part D space is, by its mere existence, a violation of the non-interference clause.

As CMS has noted in previous rulemaking, “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”⁷⁹ CMS has simply proposed to implement statutory provisions regarding access to negotiated prices. In fact, as discussed at length in the prior section, the Social Security Act authorizes CMS to promulgate rules for “negotiated prices” and “quality programs.”⁸⁰

It would be nonsensical to argue that the non-interference clause prohibits CMS from interpreting and enforcing these and other provisions of the 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.”⁸¹

CMS has not proposed to mandate particular reimbursement amounts or particular price indices. Plans and

⁷⁶ 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/PrescriptionDrugCov-GenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf>.

⁷⁷ 42 U.S.C. § 1395w-111(i).

⁷⁸ 79 Fed. Reg. 29,877, 29874. (May 23, 2014).

⁷⁹ *Id.* quoting 42 U.S.C. § 1395w-102.

⁸⁰ See, e.g., 42 U.S.C. §§ 1395w102, 1395w-104.

⁸¹ 79 Fed. Reg. at 29,875.

pharmacies would be free to negotiate particular reimbursement rates and price concessions associated with purchasing drugs. Requiring plans to comply with the statute by including pharmacy price concessions in negotiated prices, 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 has noted, the noninterference clause imposes a “duty to act” on CMS “to promote competition in the private market for part D drugs.”⁸² CMS has thoroughly documented the considerable anticompetitive effects of not including pharmacy price concessions in negotiated prices.⁸³ In sum, the proposal does not interfere with the competition; it promotes competition.

2. The proposal is consistent with the proper reading of the Part D statute.

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 . . .”.⁸⁴ The repeated use of “shall” in the statute demonstrates that the law mandates the 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.⁸⁵ 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.”⁸⁶ 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.

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

⁸² 79 Fed. Reg. at 29,874.

⁸³ See, e.g., 82 Fed. Reg. at 56,421 (lack of transparency and differential plan treatment of pharmacy price concessions harms competition among plans); 83 Fed. Reg. at 62,176 (expressing concerns about the impact of current plan practices on competition among plans and pharmacies); 79 Fed. Reg. at 29,877 (“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.”).

⁸⁴ Social Security Act § 1860D–2(d), codified at 42 U.S.C. § 1395w–102(d).

⁸⁵ 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.”).

⁸⁶ 83 Fed. Reg. 62,152, 62,174 (Nov. 30, 2018).

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.”⁸⁷ However, CMS clarified that this rule allowed plans to exclude from negotiated prices only manufacturer rebates and other “non-pharmacy” price concessions.⁸⁸ 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.⁸⁹ 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.”⁹⁰ 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.”⁹¹

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 upfront on a per-drug-claim basis.”⁹² 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 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.⁹³ CMS also explained that it did not intend to allow plans to exclude pharmacy price concessions from negotiated prices.⁹⁴ 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.”⁹⁵ 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. This statutory interpretation promotes competition and “align[s] beneficiary and taxpayer interests in minimizing costs.”⁹⁶

As a result, CMS proposed to revise clause (2) of the rule’s definition of negotiated prices to clarify that

⁸⁷ 70 Fed. Reg. 4194 (Jan. 28, 2005).

⁸⁸ See 79 Fed. Reg. 1918, 1972-74 (Jan. 14, 2014) (emphasis added); see also 79 Fed. Reg. 29844, 29876 (May 23, 2014).

⁸⁹ See 73 Fed. Reg. 28555, 28563 (May 16, 2008) (describing how plans’ refusal to include price concessions in negotiated prices harms beneficiaries and taxpayers).

⁹⁰ 74 Fed. Reg. 1494, 1543 (Jan. 12, 2009).

⁹¹ *Id.* at 1506 (emphasis added); see also 73 Fed. Reg. 28,556, 28,564 (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).

⁹² 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, Apr. 1, 2013, available at www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2014.pdf.

⁹³ 79 Fed. Reg. 29,844, 29,877 (May 23, 2014).

⁹⁴ 79 Fed. Reg. 1918, 1872-74 (Jan. 14, 2014).

⁹⁵ *Id.* at 1973 (emphasis added).

⁹⁶ *Id.*

negotiated prices “[a]re inclusive of all price concessions and any other fees charged to network pharmacies.”⁹⁷ 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.⁹⁸ 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.”⁹⁹

Since it adopted the 2014 rule, CMS has continued to interpret the statute as authorizing the agency to mandate the 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.”¹⁰⁰ CMS reiterates this exact same interpretation of the statute in the current proposed rule.¹⁰¹ 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. Conclusion

Thank you for the opportunity to provide our comments on the proposed rule. We reemphasize our support for the pharmacy price concession proposal, which will better align marketplace competition with the interests of Medicare patients and lead to lower total healthcare costs. Furthermore, we urge CMS to seek to understand the steps that plans and PBMs may take in response to the finalized rule to ensure smooth implementation that aligns with CMS’ intent and supports stakeholders in complying with new requirements. We look forward to our continued work with the agency on comprehensive pharmacy DIR reform. For questions or further discussion, please contact NACDS’ Christie Boutte, Senior Vice President, Reimbursement, Innovation & Advocacy, at cboutte@nacds.org or 703-837-4211.

Sincerely,



Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS’ over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 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.

⁹⁷ *Id.* at 2062.

⁹⁸ 79 Fed. Reg. at 29,962.

⁹⁹ The PBMs that manage Medicare drug benefits have 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).

¹⁰⁰ 82 Fed. Reg. at 56,427.

¹⁰¹ See also 83 Fed. Reg. 16,440, 16,616 (Apr. 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.”).

Exhibits

EXHIBIT A: Metrics that Can Be Influenced by Pharmacy Care

The following Table provides an overview of existing, relevant quality measures, illustrating potential opportunities for measuring pharmacy quality in alignment with established CMS clinical priorities. The use of more clinically advanced pharmacy measures promotes value and encourages program innovation.

Quality Metrics in CMS Programs Suited for Pharmacist Influence (Examples)		
Measure Topic	Measure Examples	CMS Programs
Chronic Disease Outcomes		
Chronic Disease Assessment and Management	Blood pressure control A1c control Depression remission Osteoarthritis function assessment	Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS) Medicaid Medicare Shared Savings Program Million Hearts Medicare Part C Star Rating
Patient Experience	CAHPS: Health Promotion and Education CAHPS: Health Status/Functional Status CAHPS: Getting Timely Care, Appointments and Information	Medicare Shared Savings Program
Medication Adherence and Optimization		
Medication Adherence, Persistence, or Optimization	High-risk medications in the elderly Adherence to optimal medications for diabetes, cholesterol, blood pressure, COPD, asthma, schizophrenia, heart failure Concurrent use of benzodiazepines and opioids Improvement in management of oral medication Statin therapy in cardiovascular disease Statin therapy in diabetes	Medicaid, Merit-Based Incentive Payment System (MIPS) Program Medicaid Qualified Health Plan (QHP) Quality Rating System (QRS) Home Health Quality Reporting Home Health Value-Based Purchasing Medicare Part D Star Rating Medicare Shared Savings Program Million Hearts
Transitions of Care		
Reducing Preventable Re-admissions	30 Day All Cause Readmissions	Hospital Compare Merit-Based Incentive Payment System (MIPS) Program Medicare Part C Star Rating Medicaid Qualified Health Plan (QHP) Quality Rating System (QRS) Hospital Readmission Reduction Program
Medication Review/Reconciliation	Medication Reconciliation Post-Discharge	Medicare Part C Star Rating Merit-Based Incentive Payment System (MIPS) Program Physician Compare
Preventive Care and Screening		
Immunization Assessment and Delivery	Childhood Immunization Status Immunizations for Adolescents Pneumococcal Vaccination Status for Older Adults Preventive Care and Screening: Influenza Immunization Zoster (Shingles) Vaccination	Medicare Part C Star Rating Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS) Medicaid Home Health Value-Based Purchasing Hospital Inpatient Quality Reporting Inpatient Psychiatric Facility Quality Reporting

Antibiotic Stewardship	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS)
Screenings and Interventions	BMI, weight, and nutrition assessment Suicide risk assessment Screening and intervention for alcohol use and/or tobacco use DEXA scans Functional status and cognitive assessments Spirometry HIV screening Falls risk assessment/screening Blood pressure and/or diabetes screening	Medicare Part C Star Rating Medicaid Merit-Based Incentive Payment System (MIPS) Program Medicare Shared Savings Program Hospital Compare Inpatient Psychiatric Facility Quality Reporting End-Stage Renal Disease Quality Incentive Program

EXHIBIT B: Establishment of a Pharmacy Quality Incentive Program Synergistically Aligns with Other Federal Quality Programs

NACDS' 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 advance and 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.

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.

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.¹⁰² Similarly, many APM quality metrics are dependent upon improvements affected by optimized medication use as well. These include metrics regarding controlling high 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, dietitians, 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

¹⁰² Pharmacy Today, available at [https://www.pharmacytoday.org/article/S1042-0991\(18\)30783-7/pdf](https://www.pharmacytoday.org/article/S1042-0991(18)30783-7/pdf).

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 the 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.

Exhibit C: The Proven Value of Community Pharmacy Care – Literature Examples Across High-Priority Clinical Areas

The Proven Clinical & Economic Value of Community Pharmacy Care	
Clinical Value/Result of Pharmacist Intervention	Source
Chronic Disease Outcomes	
Pharmacist-provided medication therapy management for medically underserved patients in FQHCs resulted in A1c goal achievement in 52.84% of patients and hypertension control was reported in 65.21%. Pharmacists identified and resolved more than 1400 medication-related problems and addressed multiple adverse drug event issues.	Rodis JL, et al. Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers. <i>Journal of Primary Care & Community Health</i> . 2017. https://www.ncbi.nlm.nih.gov/pub-med/28381095 **Also under Social Determinants of Health & Health Disparities section**
Among black male barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in larger blood-pressure reduction when coupled with medication management in barbershops by pharmacists. The mean reductions in systolic and diastolic blood pressure were 21.6 and 14.9 mmHg greater, respectively, in participants assigned to the pharmacist-led intervention than in those assigned to the active control. In the intervention group, the rate of cohort retention was 95%, there were few adverse events, and self-rated health and patient engagement increased.	Victor RG, et al. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barber-shops. <i>The New England Journal of Medicine</i> . April 2018. https://www.nejm.org/doi/full/10.1056/NEJMoa1717250 **Also under Social Determinants of Health & Health Disparities section**
Patients' A1c measurements as part of the pharmacist program were significantly reduced. Researchers observed a 16% decrease in all-diagnosis costs. Another study, by the same author, found that more than 50% of patients showed a decrease in A1c at each follow-up visit, and more than 50% saw improvement in lipid levels at each measurement. Additionally, total direct mean costs decreased by \$1,200 to \$1,872 per patient per year compared with baseline.	Cranor CW, Christensen DB. The Asheville Project: Short-term outcomes of a community pharmacy diabetes care program. Apr 2003. https://www.sciencedirect.com/science/article/pii/S108658021530005X?via%3Dihub Cranor CW, Bunting BA, et al; "The Asheville Project: Long- Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program;" <i>Journal of the American Pharmacists Association</i> ; 2003. https://www.sciencedirect.com/science/article/pii/S1086580215300073?via%3Dihub
Patients in the pharmacy program had a lower risk for discontinuing therapy and in a cohort of 1,000 patients, the intervention resulted in a reduction of 7 nonfatal strokes, 2 fatal strokes, 16 nonfatal heart attacks, 7 fatal heart attacks, and 16 revascularizations over patients' lifetimes. The intervention also produced considerable net cost savings.	Vegter S, et al.; "Improving Adherence to Lipid-Lowering Therapy in a Community Pharmacy Intervention Program: A Cost-Effectiveness Analysis;" <i>Journal of Managed Care & Specialty Pharmacy</i> ; Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.7.722 ; Last Accessed June 13, 2018.
The results for 6-month systolic BP reading showed significantly decreased rates for the pharmacist group versus the control group (-11.8mmHg vs - 6.2mmHg) and slightly smaller, but observable changes of diastolic BP in the intervention group versus the control group (-8.4 vs -6.2mmHg). Percentage of patients achieving good refill adherence was larger for the intervention group compared to the control group (59.7% vs 36.1%).	Shireman TI, et al.; "Cost-effectiveness of Wisconsin TEAM model for improving adherence and hypertension control in black patients;" <i>Journal of the American Pharmacists Association</i> ; March 2016. https://www.ncbi.nlm.nih.gov/pub-med/27184784
A review by the Department of Veterans Affairs of over 60 research studies found that patients receiving chronic care management from a pharmacist had a higher likelihood of meeting blood pressure, cholesterol, and blood glucose goals , compared to those receiving usual care	Greer N, Bolduc J, Geurkink E et al. (April 26 2016). Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care . <i>Ann Intern Med</i> . Epub ahead of print.
The pharmacy intervention group had statistically significantly higher improvements in the individual areas of A1c, blood pressure, and statin goal attainment. In this study, 40% of patients in the pharmacist intervention group achieved all 3 clinical goals after intervention , compared with only 12% of patients in the usual care group.	Prudencio J, Cutler T, Roberts S, Marin S, Wilson M. The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home . <i>JMCP</i> . 2018;24(5):423-429.

Pharmacy care programs for elderly patients led to increases in medication adherence, medication persistence, and clinically meaningful reductions in blood pressure. After 6 months of intervention, medication adherence increased from a baseline of 61.2% to 96.9% and was associated with significant improvements in systolic BP (133.2 to 129.9) and LDL-C levels (91.7 to 86.8).	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; Available at https://jamanetwork.com/journals/jama/fullarticle/204402 .
This 2010 systematic review of pharmacist interventions concluded that such programs improve therapeutic and safety outcomes, and the results of various meta-analyses conducted for hemoglobin A1c, cholesterol levels, and blood pressure demonstrate the significant benefits of pharmacist care— favoring pharmacists' direct patient care impact over comparative services	Chisholm-Burns AM, et al. US Pharmacists' Effect as Team Members on Patient Care: Systematic Review and Meta-Analyses. Medical Care: October 2010 - Volume 48 - Issue 10 - p 923-933 https://journals.lww.com/lww-medical-care/Fulltext/2010/10000/US_Pharmacists_Effect_as_Team_Members_on_Patient.10.aspx
A study examining pharmacist-led diabetes education, including individual consultations, point of care testing, and care coordination with other providers, led to significant reductions in HbA1C, cholesterol, and blood pressure levels .	Guide to Community Preventive Services. (April 2019). Cardiovascular Disease: Tailored Pharmacy-based Interventions to Improve Medication Adherence. https://www.thecommunityguide.org/findings/cardiovascular-disease-tailored-pharmacy-based-interventions-improve-medication-adherence
This systematic review evaluated the role of community pharmacists in the provision of screening with and without subsequent management of undiagnosed COPD and asthma. The literature review identified that community pharmacists can play an effective role in screening people with poorly controlled asthma and undiagnosed COPD along with delivering management interventions .	Fathima, M et al. (October 2013). The role of community pharmacists in screening and subsequent management of chronic respiratory diseases: a systematic review. Pharmacy Practice, 11(4), 228-245. https://www.ncbi.nlm.nih.gov/pub-med/24367463
Improved Medication Adherence	
Patients receiving the pharmacist adherence intervention increased between baseline and the end of the study (86.0% vs 96.5%) whereas the control group did not have a significant change (86.5% vs 85.4%). The odds of adherence to antihypertensive drug therapy in the pharmacist group was three times higher than the control group.	Fikri-Benbrahim N, et al.: Impact of a community pharmacists' hypertension-care service on medication adherence."; <i>The AFenPA study. Research in Social and Administrative Pharmacy</i> . Available at https://www.ncbi.nlm.nih.gov/pub-med/23391845 . Last Accessed June 13, 2018.
A review of 22 studies showed that community pharmacist-led interventions improve patients' adherence and contribute to improved blood pressure control, cholesterol management, chronic obstructive pulmonary disease, and asthma control .	Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review . International Journal of Pharmacy Practice. 2018; 26(5).
This project evaluated the impact of medication adherence on five chronic medication classes. The study 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 intervention 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 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.	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 .
Pharmacists provided counseling for adherence to diabetes medications and recommendations for other medications often used in tandem with diabetes medications aimed at reducing the risk of cardiovascular disease (ACE-inhibitors or ARBS and/or statins). The return on investment of the initiative was estimated at 3:1.	Brennan TA, et al.; "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients.;" Health Affairs; Available at https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2011.0931?url_ver=Z39.88-2003&rft_id=ori%3Arid%3Across-ref.org&rft_dat=cr_pub%3Dpubmed ;
Patients who received the outpatient pharmacy clinical service program were more likely to be adherent with their diabetes medications (53.5% compared to 37.4%). This group	Spence MM, et al.: "Evaluation of an Outpatient Pharmacy Clinical Services Program on Adherence and Clinical Outcomes Among Patients

was also more likely to continue taking their medication, less likely to have an emergency department visit, and the return on investment for this program was estimated at 5.79:1.	with Diabetes and/or Coronary Artery Disease;" Journal of Managed Care & Specialty Pharmacy; Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.10.1036 ; Last Accessed June 13, 2018.
Pharmacist-led Medication Monitoring and Optimization results: For osteoporosis, therapy discontinuation after 1 year was 16.1% in the pharmacist group, compared with 31.7% in the control group, and was found to be cost-effective in 52,000 patients yearly, initiating osteoporotic therapy with incremental cost-effectiveness. For dyslipidemia, the therapy discontinuation rate was 13.6% in the pharmacist cohort and 25.9% in the control group. The cost-effective aspect was favorable for the primary prevention population and significant for the secondary prevention population (lower costs and more health gains).	Van Boven JF, 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; Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.8.786 . Last Accessed June 13, 2018.
A comprehensive medication management program, led by pharmacists, targeted at high-risk individuals, resulted in a 33% reduction in readmission rate, 31.5% reduction in costs, and an average of 12:1 ROI overall.	https://www.chcs.org/media/Slides-CMMC-National-webinar-3.1.19.pdf
In 2012, a Medicaid managed care plan established a collaborative MTM program for nearly 1,000,000 Ohio Medicaid beneficiaries. By the end of 2013, pharmacists at 1,500 pharmacies had provided over 100,000 MTM interventions, 40% of which were associated with medication adherence. In a program evaluation, the managed care plan reported a 4.4:1 return on investment for total health care expenditures.	Ben Urlick, Patrick Brown, and Jon C. Easter. Achieving Better Quality and Lower Costs in Medicaid Through Enhanced Pharmacy Services North Carolina Medical Journal May-June 2017 78:188-189; doi:10.18043/ncm.78.3.188
Patients receiving the pharmacist adherence intervention increased between baseline and the end of the study (86.0% vs 96.5%) whereas the control group did not have a significant change (86.5% vs 85.4%). The odds of adherence to antihypertensive drug therapy in the pharmacist group was three times higher than the control group.	Fikri-Benbrahim N, et al.; "Impact of a community pharmacists' hypertension-care service on medication adherence."; <i>The AFenPA study. Research in Social and Administrative Pharmacy</i> . Available at https://www.ncbi.nlm.nih.gov/pub-med/23391845 . Last Accessed June 13, 2018.
A study assessing pharmacy-based medication synchronization programs for Medicaid FFS beneficiaries with certain conditions (e.g., hypertension, hyperlipidemia, and diabetes) found improved adherence to cardiovascular medications, cardiovascular clinical outcomes, and significantly lower rates of hospitalization and emergency department visits , compared to a control group.	Krumme A. Glynn, R., Schneeweiss, S. et al. (2018). Medication Synchronization Programs Improve Adherence to Cardiovascular Medications and Health Care Use. <i>Health Affairs</i> 37(1)125-133.
Another relevant example includes a program designed to leverage the clinical expertise of pharmacists for Medicare and Medicaid beneficiaries, which led to improved medication adherence among patients in the pharmacist intervention group by 46% compared to the control group , who received usual care from their doctors and nurses.	Ameer H, Jain SH. How Pharmacists Can Help Ensure That Patients Take Their Medicines. <i>Harvard Business Review</i> . Jan 2019. https://hbr.org/2019/01/how-pharmacists-can-help-ensure-that-patients-take-their-medicines
This retrospective chart review included 728 medication therapy management encounters by pharmacists in a family medicine clinic. Patients were an average of 53.6 years old and took 11.9 medications to treat 5.7 medical conditions. A total of 3057 drug therapy problems were identified in the 728 encounters , of which 1303 were resolved the same day as the visit. This resulted in an average of 4.2 drug therapy problems identified and 2.0 resolved per visit per patient. The most common category identified in this study was the need for additional drug therapy (41.6%).	MacDonald D, Chang H, et al. Drug Therapy Problem Identification and Resolution by Clinical Pharmacists in a Family Medicine Residency Clinic. 2018. https://pubs.lib.umn.edu/in-dex.php/innovations/article/view/971
In this retrospective review of 408 comprehensive medication management visits with a pharmacist, an average of 2.5 drug therapy problems were found per patient visit following hospital discharge. The most common problems were "needs additional therapy" and "dose too low."	Westberg SM, Derr SK, et al. Drug Therapy Problems Identified by Pharmacists Through Comprehensive Medication Management Following Hospital Discharge. <i>Journal of Pharmacy Technology</i> . June 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5998417/
This retrospective chart review included patients seen by a geriatric pharmacist during a one-year period. During this time, a total of 3100 drug therapy problems were identified during 3309 patient-pharmacist encounters for 452 patients (mean age, 81.4 years). Pharmacists provided 4921 interventions , often more than 1 intervention per drug therapy problem, for 275 different medications with an estimated annual financial savings between \$268,690 and \$270,591.	Campbell AM, Corbo JM, et al. Pharmacist-Led Drug Therapy Problem Management in an Interprofessional Geriatric Care Continuum: A subset of the PIVOTS Group. <i>American Health and Drug Benefits</i> . December 2018. http://www.ahdonline.com/issues/2018/december-2018-vol-11-no-9/2678-pharmacist-led-drug-therapy-problem-management-in-an-interprofessional-geriatric-care-continuum-a-subset-of-the-pivots-group

Another pharmacy-led chronic care management program includes a \$12 million CMMI grant to the University of Southern California and AltaMed, aimed to optimize patient health, reduce avoidable hospitalizations and emergency visits by integrating pharmacists into safety-net clinics in Southern California. This collaborative program resulted in reduced rates of uncontrolled blood sugar by nearly a quarter (23%), improvements in elevated LDL with 14% more patients controlled, and improvements in blood pressure with 9% more patients controlled at 6 months in the intervention group (collaborative care model with pharmacists as leads) versus the control group (primary care physicians only). The program resulted in a 33% reduction in readmissions per patient per year primarily attributed to medications estimated at 6 months. Through this project, pharmacists identified 67,169 medication-related problems in 5,775 patients. The top actions made by pharmacists to resolve these problems included: 14,981 dose change/drug interval, 5,554 medications added, 4,230 tests ordered, 3,847 medications discontinued, and 2,665 medication substituted. Further, 100% of program physicians either “strongly agreed” or “agreed” that having pharmacists in their clinics improves their patients’ care, and that pharmacists are knowledgeable. And, 92% of patients rated the program very highly, rating scores of 9 or 10 out of 10.¹⁰³	Chen SW, Hochman M, Olayiwola JN, Rubin A. Integration of Pharmacy Teams into Primary Care. The Center for Excellence in Primary Care and the Center for Care Innovations May 2015. https://www.careinnovations.org/wp-content/uploads/2017/10/USC.CEPC_pharm_webinar_FinalIV.pdf Chen SW. Comprehensive Medication Management (CMM) for Hypertension Patients: Driving Value and Sustainability. University of Southern California. http://betheresandiego.org/storage/files/cmm-for-htn-usc-steven-chen-condensed-slide-deck.pdf
Through a brief pharmacist-to-provider intervention, a significant gap closure in statin therapy was seen in patients with diabetes. The number of statins prescribed was statistically significant between the intervention group (n = 221) versus the control group (n = 199) with 46 statins versus 17 statins, respectively (P <0.001).	Pharmacist-to-prescriber intervention to close therapeutic gaps for statin use in patients with diabetes: A randomized controlled trial. Journal of the American Pharmacists Association Volume 57, Issue 3, Supplement, May–June 2017, Pages S236–S242.e1. https://www.sciencedirect.com/science/article/pii/S1544319117301553?via%3Dihub
A clinical pharmacist and pharmacy resident evaluated the clinical appropriateness and cost of statin therapy, provided recommendations to physicians, facilitated statin prescribing, and provided patient education. After implementation, 375 (82.6%) patients were on statins (P < .0001), compared to 343 before. Recommendations were well-received (90.2% accepted) and no significant adverse effects were reported. Pharmacist implementation of a collaborative, patient-centered initiative increased statin prescribing in diabetic patients, most of which were black and had hypertension, in an internal medicine resident clinic.	Vincent R, Kim J, Ahmed T, Patel V. Pharmacist Statin Prescribing Initiative in Diabetic Patients at an Internal Medicine Resident Clinic. J Pharm Pract. 2019 Jan 29;897190018824820. https://www.ncbi.nlm.nih.gov/pub-med/30696337
Transitions of Care	
Patients who received medication therapy management services from the pharmacist experienced significantly fewer readmissions than patients who received usual care. Approximately 20% of patients who received usual care were re-admitted within 30 days compared to 6.9% of the patients who received pharmacist care.	Luder HR, et al.; “TransitionRx: Impact of Community Pharmacy Postdischarge Medication Therapy Management on Hospital Readmission Rate.”; <i>Journal of the American Pharmacists Association</i>; June 2015. https://www.sciencedirect.com/science/article/pii/S1544319115300558
A budget impact analysis of a pharmacist-provided transition of care program predicts a potential cost savings of \$25 million to a managed Medicaid plan over a period of 2 years, corresponding to over \$4 per member per month.	Ni W, Colayco D, Hashimoto J, et al. Budget impact analysis of a pharmacist-provided transition of care program. J Manag Care Spec Pharm. 2018;24(2):90–96.
A meta-analysis of 32 articles found that, compared to usual care, pharmacy-supported transitions of care programs resulted in a significant 32% reduction in the odds of readmission	Rodrigues, C.R., Harrington, A.R., Murdock, N., et al. Effect of pharmacy-supported transition-of-care interventions on 30-day readmissions: a systematic review and meta-analysis. Ann Pharmacother. 2017; 51: 866–889
A community pharmacy-based transitions of care program demonstrated that patients’ risk of readmission can be decreased by 28% and 31.9% at 30 and 180 days, respectively, when pharmacists are added to usual care. In this program, pharmacist	Ni W., Colayco D., Hashimoto J., Komoto K., Gowda C., Wearda B., McCombs J. Impact of a pharmacy-based transitional care program on hospital readmissions. Am. J. Manag. Care. 2017;23:170–176.

¹⁰³ Chen SW, Hochman M, Olayiwola JN, Rubin A. Integration of Pharmacy Teams into Primary Care. The Center for Excellence in Primary Care and the Center for Care Innovations May 2015. https://www.careinnovations.org/wp-content/uploads/2017/10/USC.CEPC_pharm_webinar_FinalIV.pdf

Chen SW. Comprehensive Medication Management (CMM) for Hypertension Patients: Driving Value and Sustainability. University of Southern California. <http://betheresandiego.org/storage/files/cmm-for-htn-usc-steven-chen-condensed-slide-deck.pdf> ;

interventions focused on patient education, resolving medication-related problems, and facilitating access to post-discharge appointments and medications	
Preventive Care and Screening	
The cost-effectiveness of a pharmacist-directed smoking cessation program that achieved abstinence of at least 1 year in 25% of patients was studied. Depending on the smoker's age at the time of cessation, the incremental discounted cost-effectiveness was \$720- 1,418/life-year saved.	Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. Journal of the American Pharmacists Association. August 2018. https://www.japha.org/article/S1544-3191(18)30231-0/pdf
Pharmacy-based immunization services increased the likelihood of immunization for influenza and pneumococcal diseases, resulting in millions of additional immunizations in the United States. Five years after national implementation of pharmacist-administered immunizations, it is estimated that 6.2 million additional influenza immunizations and 3.5 million additional pneumococcal immunizations are attributable to pharmacy-delivered immunization each year.	Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. Journal of the American Pharmacists Association. August 2018. https://www.japha.org/article/S1544-3191(18)30231-0/pdf **Also under Preventive Care and Screening section**
3,726 patients were screened for depression by pharmacists during the study period. A total of 67 (1.8%) patients screened positive on the PHQ-2. Of the patients who completed the PHQ-9, approximately 25% met the criteria for consideration of diagnosis and were referred to their physician. Five patients presented with suicidal thoughts and were referred for urgent treatment. Approximately 60% of patients with a positive PHQ-9 had initiated or modified treatment at the time of follow-up. Using the PHQ, pharmacists were able to quickly identify undiagnosed patients with symptoms of depression.	Rosser S, Frede S, et al. Development, Implementation, and Evaluation of Pharmacist-Conducted Screening Program for Depression. Journal of the American Pharmacists Association. Feb 2013. https://www.sciencedirect.com/science/article/pii/S1544319115302831?via%3Dihub **Also under Mental and Behavioral Health section**
Community pharmacists used a rapid antigen detection test for strep throat and provided medication for positive results through the research project. The cost associated with providing the treatment was compared to 5 physician-provided treatment strategies for strep throat. Pharmacist treatment of strep throat was the most cost-effective.	Klepser D, Bisanz SE, Klepser ME. Cost-effectiveness of pharmacist-provided treatment of adult pharyngitis. The American Journal of Managed Care. April 2012. https://euro-pepmc.org/abstract/med/22554040
This umbrella review included 13 research syntheses, finding that the provision of preventive services at community pharmacies is shown to be effective at increasing immunization rates, supporting smoking cessation, managing hormonal contraceptive therapies, and identifying patients at high risk for certain diseases. Community pharmacies offer an ideal venue for the provision of preventive services due to their convenient location and extended hours of operation.	San-Juan-Rodriguez A, Newman TV, Hernandez I, et al. Impact of community pharmacist-provided preventive services on clinical, utilization, and economic outcomes: An umbrella review. Preventive Medicine. 2018. https://www.ncbi.nlm.nih.gov/pub-med/30145351
Pharmacist-initiated HCV screening in community pharmacy assists with identifying patients at risk for HCV infection and provide patients with linkage to care.	Isho N, et al.; "Pharmacist-initiated hepatitis C virus screening in a community pharmacy to increase awareness and link to care at the medical center."; <i>Journal of the American Pharmacists Association</i> ; March 2017. https://www.japha.org/article/S1544-3191(17)30136-X/pdf
In Michigan, a pharmacist-provided HIV testing model, which incorporated rapid HIV testing, counseling, and linkage to confirmatory HIV testing services, was developed and implemented. Approximately 42% of the participants stated it was their first HIV test, many of whom reported high-risk behaviors in the prior 6 months. This project demonstrated the acceptability and feasibility of pharmacist-provided rapid HIV testing and increase access to care within the community.	Darin KM, et al.; "Pharmacist-provided rapid HIV testing in two community pharmacies;" <i>Journal of the American Pharmacists Association</i> ; Feb 2015. https://www.japha.org/article/S1544-3191(15)30015-7/pdf
A literature review showed that community pharmacies conducted and analyzed point-of-care tests had satisfactory analytical quality. This review further supports that community pharmacies are well-positioned to deliver a wide range of point-of-care tests and will allow for patients to have increased access to various screenings.	Buss V.H., Naunton M. Analytical quality and effectiveness of point of care testing in community pharmacies: A systematic literature review . Res. Soc. Adm. Pharm. 2019;15:483–495. doi: 10.1016/j.sapharm.2018.07.013.
Pharmacist-provided Annual Medicare Wellness Visits are comparable to those provided by physicians and offer an additional access point for valuable services for Medicare beneficiaries.	Sewell, Mary Jean. Et. al. Comparison of Pharmacist and Physician Managed Annual Medicare Wellness Services. J Manag Care Spec Pharm. 2016;22(12):1412-16, available at: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2016.22.12.1412

This systematic search determined significant heterogeneity for all included outcomes, however, determined that pharmacies are feasible sites for screening for diabetes and cardiovascular disease risk.	Willis A, Rivers P, Gray LJ, Davies M, Khunti K. The effectiveness of screening for diabetes and cardiovascular disease risk factors in a community pharmacy setting. <i>PLoS One</i>. 2014;9(4):e91157. Published 2014 Apr 1. doi:10.1371/journal.pone.0091157 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3972156/
This retrospective analysis studied community pharmacies providing flu and group A streptococcus (GAS) testing. Participating pharmacies reported 661 visits for adult (age 18 and over) patients tested for influenza and for GAS pharyngitis. For the GAS patients, 91 (16.9%) tested positive. For the Influenza patients, 22.9% tested positive and 64 (77.1%) tested negative. Access to care was improved as patients presented to the visit outside normal clinic hours for 38% of the pharmacy visits, and 53.7% did not have a primary care provider.	Klepser D, et al. (2018). Utilization of influenza and streptococcal pharyngitis point-of-care testing in the community pharmacy practice setting. <i>Research in Social Administrative Pharmacy</i>. https://www.ncbi.nlm.nih.gov/pubmed/28479019
Between September 2015 and February 2016, 1298 individuals consented to HCV community-based antibody testing. Two patients withdrew consent after testing. In all, 8% (103/1296) were HCV antibody-positive; of them, 91 (88%) were contacted by an HCV management specialist. During the 21- to 28-day follow-up, 56 individuals (62%; 56/91) were reached by an HCV management specialist, and 29 (52%; 29/56) confirmed that an HCV RNA test was ordered. The authors conclude: supportive results of point-of-care HCV screening in retail pharmacies for at-risk individuals in the United States.	Kugelmas M, Pedicone LD, Lio I, Simon S, Pietrandoni G. Hepatitis C Point-of-Care Screening in Retail Pharmacies in the United States. <i>Gastroenterol Hepatol (N Y)</i>. 2017;13(2):98–104. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5402690/
Pharmacists provided 606 TB tests administered to 578 patients; 70.9% women, median age 31 years (4–93 years). Employment and school were the main reasons for obtaining a TB test. A total of 578 of 623 (92.8%) patients followed up to have their TSTs read. A total of 18 positive tests (3.1% positivity rate) were identified and appropriate referrals were made. The authors conclude that pharmacist-performed TB testing had a valuable public health benefit. TB testing follow-up rates at community pharmacies in New Mexico were high, most likely due to convenient hours, accessible locations, and no required appointments.	B Jakeman, et al. Evaluation of a pharmacist-performed tuberculosis testing initiative in New Mexico. <i>Journal of the American Pharmacists Association</i>. Volume 55, Issue 3, May–June 2015, Pages 307–312. https://www.sciencedirect.com/science/article/pii/S1544319115300650?via%3Dihub
This pilot project established HIV testing in several community pharmacies and retail clinics to offer rapid, point-of-care HIV testing. It demonstrated the willingness and ability of staff at community pharmacies and retail clinics to provide confidential HIV testing to patients. Expanding this model to additional sites and evaluating its feasibility and effectiveness may serve unmet needs in urban and rural settings.	Weidle, P, Lecher, S, Botts, L, et al. (2014). HIV testing in community pharmacies and retail clinics: A model to expand access to screening for HIV infection. <i>Journal of the American Pharmacist Association</i>, 54(5), 486–492. https://www.ncbi.nlm.nih.gov/pubmed/25216878
Mental and Behavioral Health	
Community pharmacists have the capacity to identify patients at risk for misuse of opioid medications. Of the 164 patients who completed the survey, 14.3% screened positive for prescription opioid misuse risk, 7.3% for illicit drug use, 21.4% for hazardous alcohol use, 25.8% for depression, and 17.1% for post-traumatic stress disorder (PTSD).	Cochran G, Rubinstein J, Bacci JL, Ylioja T, Tarter R. Screening Community Pharmacy Patients for Risk of Prescription Opioid Misuse. <i>J Addict Med</i>. 2015 Sep-Oct;9(5):411-6. https://www.ncbi.nlm.nih.gov/pubmed/26291546
3,726 patients were screened for depression by pharmacists during the study period. A total of 67 (1.8%) patients screened positive on the PHQ-2. Of the patients who completed the PHQ-9, approximately 25% met the criteria for consideration of diagnosis and were referred to their physician. Five patients presented with suicidal thoughts and were referred for urgent treatment. Approximately 60% of patients with a positive PHQ-9 had initiated or modified treatment at the time of follow-up. Using the PHQ, pharmacists were able to quickly identify undiagnosed patients with symptoms of depression.	Rosser S, Frede S, et al. Development, Implementation, and Evaluation of Pharmacist-Conducted Screening Program for Depression. <i>Journal of the American Pharmacists Association</i>. Feb 2013. https://www.sciencedirect.com/science/article/pii/S1544319115302831?via%3Dihub **Also under Preventive Care and Screening section**
In Rhode Island, a grant from the National Institute on Drug Abuse is being used to allow patients to receive addiction care at a community pharmacy. Through this program, patients receive their initial prescription from a physician and, when stable, a pharmacist will take over their care, including conducting toxicology swabs to determine adherence and providing motivational counseling. Participants report increased convenience and comfort with receiving addiction care at their local pharmacy.	Freyer F. In Rhode Island, Some Get Addiction Care at the Pharmacy. <i>Boston Globe</i>. March 2019. https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVILRX1W9X3WdeOP/story.html

In this pharmacist-physician collaborative care model, pharmacists conducted intake assessments and follow-up appointments with patients taking buprenorphine in order to further expand access to treatment . This program demonstrated 100% 6-month retention rates and 73% 12-month retention rates with an estimated cost savings of \$22,000 . Data from this pilot was then used to develop a permanent program utilizing this model.	DiPaula BA, Menachery E. Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients. J Am Pharm Assoc (2003). 2015 Mar-Apr;55(2):187-92. https://www.ncbi.nlm.nih.gov/pub-med/25749264
Twenty-six percent of individuals (n = 107) receiving opioid prescriptions were identified as at some risk of misuse and 30% at risk of an accidental overdose . Participating pharmacists preferred the value of having an objective measurement of the potential of opioid misuse , to relying only on professional judgment. They also reported the value of the toolkit elements in enhancing conversations with patients.	Strand MA, Eukel H, Burck S. Moving opioid misuse prevention upstream: A pilot study of community pharmacists screening for opioid misuse risk. Res Social Adm Pharm. 2019 Aug;15(8):1032-1036. https://www.ncbi.nlm.nih.gov/pub-med/30031696
This study found large and statistically significant decreases for almost every measure of substance use in patients who received SBIRT method screening services, including decreases in alcohol use, heavy drinking, and illicit drug use. Greater intervention intensity was also associated with a larger decrease in substance use.	Aldridge A, Linford R, Bray J. Substance use outcomes of patients served by a large US implementation of Screening, Brief Intervention and Referral to Treatment (SBIRT). Addiction. 2017 Feb;112 Suppl 2:43-53. https://www.ncbi.nlm.nih.gov/pub-med/28074561
An Australian study examined the impact of community pharmacists performing screenings and risk assessments for depression and found that pharmacists were able to provide screening and risk assessment services and make referrals as needed – which could facilitate early intervention and reduce the overall burden of disease associated with depression	O'Reilly CL, Wong E, Chen TF. A feasibility study of community pharmacists performing depression screening services. Res Social Adm Pharm. 2015 May-Jun;11(3):364-81.. https://www.ncbi.nlm.nih.gov/pub-med/25438728
Immunizations	
Pharmacy-based immunization services increased the likelihood of immunization for influenza and pneumococcal diseases, resulting in millions of additional immunizations in the United States. Five years after national implementation of pharmacist-administered immunizations, it is estimated that 6.2 million additional influenza immunizations and 3.5 million additional pneumococcal immunizations are attributable to pharmacy-delivered immunization each year.	Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. Journal of the American Pharmacists Association. August 2018. https://www.japha.org/article/S1544-3191(18)30231-0/pdf **Also under Preventive Care and Screening section**
A 2019 study found that a community pharmacy vaccination program demonstrated an increase of immunization rates for influenza, herpes zoster, and pertussis vaccination rates by 37%, 12%, and 74%, respectively .	NK Wehbi, JR Wani, DG Klepser, J Murry, AS Khan. Impact of a Technology Platform to Increase Rates of Adult Immunization in Pharmacies. Vaccine. Volume 37, Issue 1, 3 January 2019, Pages 56-60. https://www.ncbi.nlm.nih.gov/pub-med/30471954
A 2018 study that modeled the clinical and economic impacts of using pharmacies to administer influenza vaccinations estimated that including pharmacies in addition to other locations for vaccination (e.g. clinics, physician offices, urgent care centers) could prevent up to 16.5 million symptomatic influenza cases and 145,278 deaths at an estimated cost savings of \$4.1 to \$11.5 billion .	Bartsch SM et al. Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. Vaccine. November 2018. https://www.ncbi.nlm.nih.gov/pub-med/30340884
In a CDC-funded, adult immunization initiative, more than 300 pharmacies across four states explored and developed approaches aimed at incentivizing community pharmacies and other stakeholders to improve rates for influenza, pneumococcal, pertussis, and herpes zoster vaccine. This effort resulted in 304,405 immunizations administered and significant improvements in routinely recommended adult vaccination rates with the most consistent increases across all sites seen for influenza (20-45%) and pertussis (13-74%) vaccines.	NACDS. (2018). CDC Project – Immunization Rates and VBM.
Policy changes permitting pharmacist immunization resulted in influenza immunization administration rates rising from 32.2% in 2003 to 40.3% in 2013.	Drozdz EM, Miller L, Johnsrud M. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States. Clinical Therapeutics. 2017

	Aug;39(8):1563-1580.e17. https://www.ncbi.nlm.nih.gov/pub-med/28781217
A 2016 review of 36 different studies found that pharmacist involvement in the immunization process, whether as educators, facilitators, or administrators, always resulted in an increase in immunization coverage .	Iseñor JE, Edwards NT, Alia TA, Slayter KL, MacDougall DM, McNeil SA, Bowles SK. Impact of pharmacists as immunizers on vaccination rates: A systematic review and meta-analysis. Vaccine. 2016 Nov 11;34(47):5708-5723. https://www.ncbi.nlm.nih.gov/pub-med/27765379
A large proportion of adults being vaccinated receive their vaccines during the evening, weekend, and holiday hours at the pharmacy when traditional vaccine providers are likely unavailable. Of the nearly 6.3 million vaccinations administered during the study period, 30.5% were given during off-clinic hours. Younger, working-aged, healthy adults, in particular, received a variety of immunizations during off-clinic hours. With the low rates of adult and adolescent vaccination in the United States, community pharmacies are creating new opportunities for vaccination that expand access and convenience.	Goad JA, Taitel MS, Fensterheim LE, Cannon AE. Vaccinations administered during off-clinic hours at a national community pharmacy: implications for increasing patient access and convenience. Annals of Family Medicine. 2013 Sep-Oct;11(5):429-36. https://www.ncbi.nlm.nih.gov/pub-med/24019274
Social Determinants of Health & Health Disparities	
This example of pharmacists' ability to improve chronic care reached rural, underserved patients, and included a collaboration between A&B Pharmacy and Emporia Medical Associates, yielding significant patient outcomes. Through this program, pharmacists provided chronic care management (CCM) services for Emporia Medical Associates' Medicare patients. Pharmacists supported patients by providing medication reconciliation/synchronization services, educating them on how to self-monitor blood glucose and blood pressure, and answering questions about chronic disease management during monthly CCM appointments. Pharmacists also worked collaboratively with the physician to develop an appropriate care plan. The program resulted in an 8% increase in medication reconciliation , an 11% increase in the use of tobacco cessation services , and a 6% increase in the number of patients receiving chronic care management through the provision of pharmacist-led services. All participating patients also reported improvements in health outcomes related to healthy eating and exercise.	A Team-based Care Approach to Reach Rural, Underserved Virginia Patients. WWCDPC. 2018. https://chronicdis-ease.host/WWCDPC/admin/dompdf/SuccessStories.php?id=712 Health Quality Innovators. A Partnership in Chronic Care Management. http://qin.hqi.solutions/wp-content/uploads/2018/05/CCM-poster-with-3-video-QR-link.pdf
This study describes the result of a pharmacist-driven, type 2 diabetes targeted, collaborative practice within an urban, underserved federally qualified health center. Pharmacists, within a primary care team, managed patients with chronic illnesses utilizing a collaborative practice agreement. Pharmacists had a significant impact on improving the health outcomes of patients with Type 2 diabetes , with significant improvements in patient attainment of A1c <9%, ACE inhibitor/angiotensin receptor blocker and statin use, and tobacco cessation at follow-up.	Ray S, Lokken J, Whyte C, Baumann A, Olandi M. The impact of a pharmacist-driven, collaborative practice on diabetes management in an Urban underserved population: a mixed method assessment. Journal of Interprofessional Care. 2020 Jan-Feb;34(1):27-35. https://www.ncbi.nlm.nih.gov/pub-med/31381470
Pharmacist-provided MTM can improve chronic disease intermediate outcomes for medically underserved patients in FQHCs. This pilot study displayed improvement in diabetes and hypertension clinical markers associated with pharmacist provision of MTM. A1c goal achievement occurred in 52.84% of patients and hypertension control was reported in 65.21%. Pharmacists identified and resolved more than 1400 medication-related problems and addressed multiple adverse drug event issues.	Rodis JL, et al. (2017). Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers. Journal of Primary Care & Community Health. https://www.ncbi.nlm.nih.gov/pub-med/28381095 **Also under Chronic Disease Outcomes section**
This survey analyzes Oregon pharmacy practices in the provision of hormonal contraception (HC) and evaluates if pharmacists' motivation to prescribe HC changed after 6 and 12 months of experience. The survey results demonstrated that pharmacist prescribing of HC continues to grow with almost 50% of pharmacists billing insurance for the visit. Visits take <30 minutes and the top 3 motivators continue to be enhanced access to care , reducing unintended pregnancy, and expanding pharmacists' scope of practice.	Rodriguez MI et al. Pharmacists' experience with prescribing hormonal contraception in Oregon. Journal of the American Pharmacists Association. December 2018. https://www.ncbi.nlm.nih.gov/pub-med/30190201
Among black male barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in larger blood-pressure reduction when coupled with	Victor RG, et al. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black

medication management in barbershops by specialty-trained pharmacists. The mean reductions in systolic and diastolic blood pressure were 21.6 and 14.9 mmHg greater, respectively, in participants assigned to the pharmacist-led intervention than in those assigned to the active control. In the intervention group, the rate of cohort retention was 95%, there were few adverse events, and self-rated health and patient engagement increased.	Barbershops. The New England Journal of Medicine. April 2018. https://www.nejm.org/doi/full/10.1056/NEJMoa1717250 **Also under Chronic Disease Outcomes section**
This article highlights three health systems – Yale-New Haven Health, Ascension, and the University of Illinois Hospital and Health Sciences System – that are utilizing pharmacists to provide healthcare services to underserved patients.	Wild D. ASHP Intersections. June 2018. https://www.ashpintersections.org/2018/06/underserved-patients-rely-on-pharmacists-to-fill-care-gap/