NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-4201-P
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Submitted via http://www.regulations.gov

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications; CMS-4201-P

Dear Administrator Brooks-LaSure:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on CMS' proposed technical changes to the Medicare Program, Medicare Advantage, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program as well as the implementation of provisions from important federal legislation. Retail pharmacies are critical healthcare access destinations for patients and population health. A poll of adults conducted March 4-6, 2022, by Morning Consult and commissioned by NACDS found that retail pharmacies received the highest ratings for ease of access among the destinations tested. Of note, 79 percent of those surveyed also support pharmacists helping patients prevent chronic diseases. Many of our comments focus on legacy issues under CMS's jurisdiction that may be exacerbated under the proposed rule and hinder timely patient access, pharmacy sustainability, and pharmacy's innovative vision to empower patients' total health and wellness.

I. Pharmacy Direct and Indirect Remuneration (DIR) Fees and Standardized Pharmacy Measures

A. CMS Should Continue to Reform Pharmacy Direct and Indirect Remuneration (DIR) Fees

On April 29, 2022, CMS issued the final Medicare Part D rule entitled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" ("2022 Final Rule") affecting Direct and Indirect Remuneration (DIR) fee transparency, among other provisions.[1] Of note, the CMS 2022 Final Rule adopts a revised definition of "negotiated price" for a

[1] 87 Fed. Reg. 27704 (May 9, 2022)

covered Part D drug that would include all pharmacy price concessions at the point of sale, effective January 2024.[2] In our comments in response to the 2022 rule, NACDS indicated our support for this CMS proposal for a revised definition of "negotiated price" because of our belief that the proposal would 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. We further believe this reform would promote better medication adherence, mitigation of health disparities, and in turn, better health outcomes. Moreover, we believe the proposal was a step in the right direction to meaningfully reform pharmacy DIR because it offers the possibility of transparency for pharmacies operating in the program. Although we appreciate CMS taking this first step toward comprehensive DIR fee reform, much work remains to be done.

Unfortunately, the 2022 rule did not eliminate pharmacy DIR clawbacks that plan sponsors and PBMs impose on pharmacies, nor did the rule eliminate sponsors' and PBMs' incentives to continue to do so. Pharmacy DIR was intended as a payment or fee adjustment after the point-of-sale, with the amount calculated according to pharmacy performance metrics, but instead, PBMs have exploited DIR to create a loophole in the Medicare regulation allowing them now to dictate pharmacies' reimbursement based on factors unknown or opaque to pharmacies. In the Part D bidding process, sponsors and PBMs may continue to underestimate DIR fees and then over-collect from pharmacies, with the potential for great financial benefit to the plan sponsors and PBMs. While the 2022 rule allows for the potential of increased transparency for pharmacies operating in the Part D program, there is no actual requirement for any transparency. CMS left unaddressed the issue of how a sponsor or PBM would communicate to pharmacies the lowest possible reimbursement at the point-of-sale. In addition, in the preamble to the final 2022 rule, CMS indicated that it had received comments that it should establish safeguards to guarantee that pharmacies participating in Medicare Part D receive a reasonable rate of reimbursement, such as assurance that the negotiated price at a minimum cover the pharmacy's costs of purchasing and dispensing covered items and providing covered services.[3] CMS indicated that it would consider these suggestions for future rulemaking. We are disappointed that CMS has not addressed pharmacies' ability to receive a reasonable rate of reimbursement in this proposed rule. This is especially troubling as CMS also continues to fail to act, yet again in this proposed rule, to address the longstanding and continuously growing problem of pharmacy DIR clawbacks.

CMS is aware that 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 (which is approx. $9.5 billion); 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") and with lack of clinical benefit to Medicare beneficiaries. Moreover, according to a study commissioned by the PBMs' own trade association, the Pharmaceutical Care Management Association (PCMA), recognizes that retail community pharmacies, and particularly chain pharmacies, are in trouble[4]. While PCMA does not suggest why chains are closing pharmacies, in a recent Supreme Court filing, PCMA agreed it is "undisputed" that "reimbursements below cost are approximately 10% of prescriptions filled."[5]

[2] *Id.*
[3] *Id.* at 27845.
[4] *See* https://www.pcmanet.org/the-independent-pharmacy-marketplace-is-stable/
[5] *Rutledge v. Pharmaceutical Care Management Association*, 18-540, 1 App. 341

Finally, the 2022 rule did not address concerns about the performance metrics used to determine pharmacy price concessions. Such performance metrics should be standardized and transparent to promote improvements in quality, outcomes, and value in the Part D program and so that pharmacies may be assured of performance expectations and opportunities before signing a Part D contract, rather than after-the-fact, as is the current situation.

B. Standardized Pharmacy Performance Measures

1. <u>Standardized Pharmacy Performance Measures are Integral to Comprehensive DIR Fee Reform</u>

We continue to strongly urge CMS to implement standardized pharmacy performance measures as part of comprehensive DIR reform. These measures should include patient-centered, clinically-meaningful metrics developed through a neutral third-party facilitator, with experience creating and testing potential pharmacy performance measures based on industry consensus to better align with broader CMS goals on healthcare equity, access, quality, and value.[6] Appropriate implementation of standardized pharmacy performance measures would help reduce preventable spending by incentivizing pharmacies to help achieve better health for Medicare beneficiaries in harmonization with others across the healthcare system. Aligned engagement of pharmacies to improve healthcare quality not only drives needed innovations for beneficiaries but also supports CMS' strategic pillars. Importantly, CMS' inaction on this matter to date continues to foster a system in which pharmacy price concessions, including those based on performance, remain contingent, variable, and without regard to beneficiary outcomes and care experience. In other words, arbitrary performance-based price concessions continue to be extracted from pharmacies and may continue to be calculated lower and lower, without any regard to performance at all nor meaningful measures. This structure undermines CMS' goals to best serve the needs of Part D beneficiaries. As CMS looks to measure what matters to patients, the inclusion of pharmacies is essential given their accessibility, trust, and clinical expertise. A great deal of literature and research supports the ability of pharmacists to impact the majority of CMS quality measures implemented across programs today. (See Appendix A)

In addition, CMS should ensure that standardized pharmacy performance measures are tied to a plan's Star Ratings to effectively align incentives. Absent the implementation of relevant, aligned, standardized pharmacy 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, especially considering that standalone Part D plans are not held accountable for downstream spending in other parts of Medicare. A pharmacy quality incentive program would strongly encourage plans and pharmacies to collaborate and better engage beneficiaries in accessible, convenient healthcare settings. Likewise, Medicare beneficiaries would have greater opportunities to be more engaged with their trusted pharmacists to improve their overall health and well-being. The clinical expertise of pharmacists and their accessibility create tremendous opportunities to improve quality of care and outcomes for beneficiaries, yet have been vastly untapped by CMS to date. To achieve improved outcomes for beneficiaries, new solutions, and reimbursement models are critically needed. While CMS has engaged so many others across the healthcare system to address quality and outcomes, the most visited and accessible – community

[6] https://www.govinfo.gov/content/pkg/FR-2021-01-19/pdf/2021-00538.pdf

pharmacies – have been overlooked. Now more than ever, in the aftermath of the COVID pandemic where pharmacies achieved unimaginable access for the nation to receive needed pandemic services, standardized pharmacy performance measures are critical to the transformation and evolution of our healthcare system to integrate evidence-based and innovative solutions. Consider, the nation's pharmacies administered 300 million COVID vaccines, more than 42 million tests, dispensed nearly 7 million antiviral courses, and were the top provider of OTC COVID tests in CMS' demonstration program. Using conservative estimates, pandemic interventions by pharmacists and pharmacy personnel averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.[7]

In sum, CMS should implement standardized pharmacy performance measures, within a pharmacy quality incentive program, that are tied to plans' Star Ratings and serve as the basis for pharmacy incentive payments. Such measures should be based on pharmacy-specific, proven, and achievable criteria, as well as take into account the medications dispensed and the disease state being managed. Measures should be clinically meaningful and patient-centered in alignment with other quality measures used across CMS programs where relevant.

2. <u>CMS has the Legal Authority to Implement Pharmacy Performance Measures</u>

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' 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.[8] 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 requirements for Medication Therapy Management Programs ("MTMPs") and quality assurance programs.[9] 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 MTMPs 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

[7] Grabenstein JD. Essential services: Quantifying the contributions of America's pharmacists in COVID-19 clinical interventions. J Am Pharm Assoc (2003). 2022 Nov-Dec;62(6):1929-1945.e1. doi: 10.1016/j.japh.2022.08.010. Epub 2022 Aug 18. PMID: 36202712; PMCID: PMC9387064.
[8] 42 U.S.C. § 1395w–111(g)(5)(b) (emphasis added).
[9] *See* 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.125(d).

> 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.*[10]

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 the 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.[11]

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.[12] 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."[13] 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.[14] 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. Furthermore, CMS has noted that it can make technical or more minor changes through its Annual Call Letter.[15] 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 drugs and Medicare Advantage plans.

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[10] 70 Fed. Reg. 4194, 4277 (Jan. 28, 2005) (emphasis added).
[11] *Id.* at 4280 (emphasis added).
[12] 42 U.S.C. §§ 1395w-21(d) & 22(e); 42 U.S.C. §1395w-101(d).
[13] 83 Fed. Reg. 16,440, 16,520 (Apr. 16, 2018).
[14] 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."
[15] *See, e.g.*, CMS, Letter to Medicare Advantage Organizations, Prescription Drug Plans Sponsors and Other Interested Parties Re: Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond (Nov. 12, 2015), *available at* https://www.cms.gov/Medicare/Prescription-Drug- Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf.

C. CMS Should Evaluate whether Reimbursement Reflected at the Point of Sale Could Impact Beneficiaries' Access to Pharmacies

In the 2022 proposed rule, CMS acknowledged that pharmacy DIR continues to increase 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.[16] DIR has 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.[17] As the 2022 rule is being implemented, we wish to raise, once again, our concern with CMS that the continual downward push on pharmacy reimbursement could lead to negative impacts on beneficiary access to pharmacy services.

Under today's Part D program, all types of pharmacies have reported that at times, DIR fees can result in instances where pharmacy reimbursement is below a pharmacy's costs to acquire and dispense drugs to Medicare patients. Others have reported that such deep concessions have made preferred pharmacy networks unsustainable. This structure puts pharmacies in an untenable situation for 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 requirement means that Part D network terms are to be "reasonable and relevant."[18] In a recent CMS final rule, however, it noted that the applicable standard terms and conditions have effectively "circumvented" these any willing pharmacy requirements and are inappropriately excluding pharmacies from network participation.[19] CMS 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."[20]

With this backdrop, we question whether CMS has considered that the lowest possible reimbursement provision of the 2022 rule could result in instances where the terms and conditions of a network may forcibly preclude too many pharmacies from being able to participate.[21] In the spirit of CMS' final rule cited above, we agree 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 2022 final rule, and the changing pharmacy business models that may result, we again 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).

[16] 87 Fed. Reg. 1842, 1916 (Jan. 12, 2022).
[17] *Id*. at 1910.
[18] 42 C.F.R. § 423.505(b)(18).
[19] 83 Fed. Reg. 16,440 (Apr. 16, 2018).
[20] *Id.*
[21] 42 U.S.C. § 1395w-104(b)(1)(A).

II. E-Prescribing and Real-Time Benefit Standard

NACDS Supports Modernizing the Rules to Incorporate Updated E-Prescribing and Real-Time Benefit Standards

Chain pharmacy has long supported policies that promote the widespread adoption and use of electronic prescribing. As CMS acknowledged in recent rulemaking, the use of this technology has numerous benefits that include: "improved workflow efficiencies; deterring and detecting prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes; enhanced patient safety through patient identity checks, safety alerts, medication menus, electronic history files, and medication recommendations that lower the risk of errors and potentially harmful interactions; and providing more timely and accurate data than paper prescriptions by avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions… [and] may reduce the burden on prescribers who need to coordinate and manage paper prescriptions among staff, patients, facilities, other care sites, and pharmacies."[22]

Since CMS initially established standards for electronic prescribing for Part D in 2005, the rate of use among healthcare providers has grown substantially. According to the most recent data, 2.12 billion prescriptions were issued electronically in the United States in the last year alone (accounting for 94% of all prescriptions.)[23] With nearly every prescription issued in electronic form, electronic prescribing has become an integral tool in the delivery of patient care. As such, we commend CMS and its partners at ONC for acting to adopt updated electronic prescribing standards that will further support and enhance healthcare provider use of electronic prescribing.

A. Adoption of Updated NCPDP SCRIPT Standard, Version 2023011 (Instead of Version 2022011)

In the proposed rule, CMS outlined the agency's plans for adopting the NCPDP SCRIPT Standard, Version 2022011, and for codifying certain transactions for which the use of the standard is mandatory. Additionally, CMS indicated that in making this change, the agency would cross reference to ONC rules under 45 CFR 170.205(b), wherein ONC proposes to adopt NCPDP SCRIPT standard version 2022011, to support alignment between ONC and CMS for their respective programs going forward.

NACDS agrees that there is a need to sunset the NCPDP SCRIPT Standard Version 2017071 and move to an updated version. Notably, NCPDP recently published the updated NCPDP SCRIPT Standard Version 2023011, which compared to the older Version 2022011 that CMS has proposed for adoption in this rulemaking, includes various enhancements to the standards including new messages and features to improve patient safety and efficiency throughout the health care system. Accordingly, **NACDS urges CMS and ONC to adopt Version 2023011 now - instead of in the future – as it will assist in future migrations and enable participants to immediately use these new enhancements.** However, with respect to the specific transactions from the NCPDP SCRIPT Standard that CMS has proposed to designate as mandatory transactions, **we request that CMS not revise paragraph § 423.160(b)(4)(ii) to indicate the exclusive use of**

[22] 87 Fed. Reg. 46241 (July 29, 2022).
[23] The Surescripts *2021 National Progress Report* is available here: https://surescripts.com/docs/default-source/national-progress-reports/2021-national-progress-report.pdf

NCPDP SCRIPT Standard Version 2017071 for medication history transactions because these types of transactions are not new, and there are already solutions for these types of transactions in use among trading partners that may not comply with the NCPDP Standard.

CMS is also seeking comment on whether the proposed date of January 1, 2025, to retire NCPDP SCRIPT standard version 201071 provides a sufficient transition period for the industry and other interested stakeholders or if delaying this date to January 1, 2026, or later offers advantages or disadvantages. CMS should delay the retirement of the NCPDP SCRIPT standard version 201071 until 2026, as moving to the new standard will pose a significant burden to some pharmacies and the 2025 date would not provide a sufficient transition period for them. In addition, NACDS asks that CMS not retire this standard on January 1, as a great number of pharmacy benefit plan changes occur at the beginning of each year. Moreover, many organizations implement software code freezes before January 1. A January 1 date for retirement would impose unnecessary burdens at a transitional and already extraordinarily busy time of year.

B. NCPDP Real-Time Prescription Benefit (RTPB) Standard

CMS is proposing to require the NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 12 for adoption at 45 CFR 170.205(c) as the standard for prescriber real-time benefit tools (RTBTs) and to incorporate this standard by reference in 45 CFR 170.299. Part D sponsors' RTBT would have to comply with 45 CFR 170.205(c) as of January 1, 2025.

Rather than adopt Version 12 of the NCPDP RTPB Standard, we believe that CMS should adopt Version 13. Version 12 of the Standard was published in October 2021; since that time, there have been enhancements added that are needed by the industry incorporated into Version 13.

III. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

NACDS Supports Making Permanent the LI NET Program

NACDS supports CMS' proposal to make the LI NET demonstration program permanent as directed by the Consolidated Appropriations Act of 2021. To help ensure that eligible beneficiaries do not experience gaps in coverage, we appreciate CMS' proposal to align the sunsetting of the demonstration with the start of the LI NET program. However, we have concerns about CMS' proposal to sunset the demonstration program on December 31, 2023, and to start the permanent LI NET program on January 1, 2024. The start of the year is a busy time for pharmacies as many patients often will have new insurance coverage with the start of the new year and may not be aware of the details of how their coverage works. Pharmacy personnel often must spend extra time with patients in the first few weeks of each year helping them navigate their new benefits. Pharmacy personnel often must triage and help patients research their coverage as glitches can occur as patients switch from one type of coverage to another. To help ensure a smooth transition from demonstration to permanent, we ask that CMS begin the permanent program before sunsetting the demonstration program in case glitches arise in the transition. This way, eligible beneficiaries could still rely on the demonstration program until any glitches with the permanent program are resolved. To achieve this protection for beneficiaries, we believe CMS should still begin the permanent program on January 1, 2024,

but we ask the demonstration program be scheduled to continue until at least the second quarter of 2024 or until all potential unforeseen glitches are worked out, whichever is later. This would help ensure uninterrupted coverage for eligible beneficiaries during the very busy first quarter of the year.

To help provide beneficiaries with the broadest options of available pharmacies, NACDS supports CMS' proposal to require the LI NET sponsor to permit all pharmacies that CMS determines to be in good standing to participate in the program, regardless of whether the pharmacy is in-network or out-of-network pharmacy for the LI NET sponsor. The purpose of the LI NET program is to provide immediate coverage to eligible beneficiaries. Sponsors set up their pharmacy networks for purposes that are irrelevant to the aim of the LI NET program. Whether a pharmacy is in-network or not should not prevent a beneficiary from receiving their medication through LI NET. Similarly and for the same reasons, we support CMS' proposal to require the LI NET sponsor to adjudicate claims from out-of-network pharmacies according to the LI NET sponsor's standard reimbursement for their network pharmacies.

NACDS supports CMS' proposal to retain in the permanent program the following features and aspects of the demonstration program:

- To prevent gaps in coverage, granting immediate access to covered Part D drugs at the point-of-sale for individuals whose eligibility cannot be confirmed at the point-of-sale.
- To help provide the greatest likelihood that a beneficiaries' medication would be covered under the program, codifying the requirement that the permanent program provides access to all Part D drugs under an open formulary.
- To help ensure the broadest possible nationwide coverage for eligible beneficiaries, requiring that the LI NET sponsor has a national presence, with an established contracted pharmacy network in all geographic areas in which LIS is available. For the same reasons, we support CMS' proposal to consider pharmacy access among the selection criteria that CMS will use in appointing an LI NET sponsor.
- To help ensure the smooth and seamless operation of the program, requiring that the LI NET sponsor have the technical capability and infrastructure to provide immediate, current, and retroactive coverage for enrollees and the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible enrollees.
- To help ensure that patients, stakeholders, and pharmacies have awareness of the details of the program, requiring the LI NET sponsor to implement outreach programs in consultation with CMS.
- To help provide the best possible service to enrollees in meeting their immediate healthcare needs without delay, requiring the LI NET sponsor to establish and manage a toll-free customer service telephone line and fax line that can be accessed by pharmacies and beneficiaries, or others acting on their behalf, to handle program inquiries, providing status of eligibility or claims, and accepting documentation for evidence of eligibility. However, to help prevent delays in care, we urge CMS to require the sponsor to maintain the telephone and fax lines 24 hours a day, 7 days a week, and every day of the year. In addition, CMS should set customer service standards that include limits on average hold times and disconnect rates, and availability of interpreters.

IV. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act

CMS Should Not Replace the "Reasonable Diligence Standard" with the "Knowingly" Standard

CMS proposes to revise its current overpayment rule, at 42 C.F.R. Sec. 401.305(a)(2), to eliminate the reasonable diligence provision, which expressly allows for the identification of an overpayment after one has, or should have, exercised "reasonable diligence" to make that determination and calculation. Under this provision, the payment recipient is allowed a period of time (6 months) to exercise its reasonable diligence, upon credible information of a potential overpayment, before the 60-day repayment clock starts running. CMS proposes substituting instead the False Claims Act definition of "knowingly."

Adopting this substitution, CMS unwisely would abolish the useful, and often necessary, six-month investigation period. This compliance tool has proven to be beneficial in helping providers identify potential CMS program overpayments. While providers, such as pharmacies, are interested in identifying and rectifying any overpayments, claims reviews to quantify an overpayment are very burdensome, consuming considerable time and resources. Thus, shrinking the six-month plus 60-day period down to just 60 days to investigate and report an overpayment to CMS means that providers have to assume an even greater burden to investigate thoroughly potential overpayment situations. The reality of such an unreasonable burden is reinforced by the fact that it can take the government up to two years, thereafter, to resolve that same self-disclosure. The proposed compressed timeline, therefore, would increase the already heavy administrative burden on pharmacies and other providers and, unfairly, may increase the risk of liability under the FCA. For these reasons, we strongly recommend that CMS not make the proposed changes to its overpayment rule and maintain the current "reasonable diligence" language.

V. Validity of DEA Registration Numbers for Controlled Substances

NACDS Supports CMS' Proposal Not to Require Sponsors to Reject All Claims for which They Cannot Validate the DEA Number

CMS proposes that a Part D sponsor must confirm the prescriber's DEA registration number on a prescription drug claim for a controlled substance, and if the DEA registration number is not on the claim, then the sponsor must cross-reference the prescriber's Type 1 NPI on the claim to any associated individual prescriber DEA number. CMS further proposes that if the DEA registration number is not valid or active or the DEA registration number does not have an associated Schedule that is consistent with the drug for which the claim was submitted, then the Part D sponsor must reject the claim and provide the pharmacy with the electronic reason code when rejecting the claim. Further, if the pharmacy confirms the validity of the DEA registration number via electronic override code, or the sponsor is not able to cross-reference the Type 1 NPI to a prescriber DEA registration number, the sponsor must process the claim under the applicable benefit rule.

NACDS supports CMS' provisions as proposed, but urges CMS not to require sponsors to reject all claims for controlled substances for which they cannot validate the DEA registration number and Schedule. Although we appreciate CMS' policy intent to support frontline pharmacists' efforts to comply with state and federal requirements with respect to controlled substances, requiring sponsors to reject all claims for controlled substances for which sponsors cannot validate the DEA registration number and Schedule could lead to situations in which perfectly valid prescription claims would be rejected and thus would likely negatively impact beneficiary access. First, pharmacies routinely validate the prescriber's DEA registration number and

Schedule. Consequently, there likely are situations where the pharmacy may have access to DEA registration number information that is more current and accurate than that of the Part D sponsor. Second, as DEA recognizes in the preamble to the proposed rule, some prescribers, such as hospital residents, prescribe controlled substances under an organizational health care provider's DEA registration number and do not have an individual DEA registration number. Consequently, rejections caused by situations in which there is not an individual prescriber DEA registration number associated with the Type 1 NPI would likely lead to unnecessary interference of beneficiary access to needed medications.

VI. Shortages of Formulary Drug Products During a Plan Year

NACDS Supports Eliminating Coverage Restrictions During Shortages

CMS is proposing that enrollees affected by a drug or biological shortage be able to obtain coverage of a therapeutically equivalent drug or interchangeable biological product without meeting formulary exception requirements for at least the duration of the shortage. NACDS supports CMS' proposal and agrees with CMS that the proposal should help minimize unnecessary changes in therapy resulting from temporary shortages of multiple-source drugs and biological products.

VII. Part D Proposed Automatic Shipment Requirements

Proposed Refund Requirements Should Apply Only After Patient Notification; The Pharmacy Should Be Able to Rely on the Enrollee, Prescriber, or Enrollee's Representative for Opt-Out

Under the proposed rule, pharmacies would have to provide a refund for any shipped prescriptions that an enrollee reports as unneeded or unwanted. Considering that the rule would provide patients with the ability to opt-in on a drug-by-drug basis and would receive from the pharmacy multiple reminders of shipping, we believe the proposed refund requirements should apply for shipments made after patient notification is made. There are numerous reasons why a patient may notify the pharmacy that they do not need or want the medication (e.g., lack of adherence, change in dose/drug, the patient decides to stop taking a drug, etc.). If the patient fails to report this to the pharmacy before the prescription being filled and shipped, despite the checks and balances provided via the patient notification, the financial impact being shouldered by the pharmacy through a refund seems inappropriate. Once patient notification is made, only then should the responsibility and financial burden be on the pharmacy.

In addition, pharmacies would have to discontinue the auto-ship service if it receives a request from the enrollee, enrollee's prescriber, or authorized representative to opt-out or if the pharmacy received notification that the enrollee has entered into a skilled nursing facility or elected hospice coverage. We believe that CMS should require the pharmacy to discontinue the auto-ship service if it receives a request from the enrollee, enrollee's prescriber, or authorized representative to opt-out, but not with regard to notifications in which the enrollee has entered into a skilled nursing facility or elected hospice, as it may not be clear how these types of notifications regarding skilled nursing facilities and hospice are provided to the pharmacy. The pharmacy should be able to rely on the enrollee, enrollee's prescriber, or authorized representative to communicate the opt-out to the pharmacy.

VIII. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

NACDS Supports Advancing Health Equity in Quality Measures

NACDS supports CMS' efforts to advance health equity by both incentivizing needed improvements in care for vulnerable populations and taking steps to avoid unfairly penalizing those caring for underserved patients who face disproportionate barriers to better health. In particular, NACDS supports risk-adjustment for quality measures. However, because many plans leverage the expertise of community pharmacies and pharmacists to promote medication adherence, but are not required to implement a standard set of pharmacy performance measures, there is concern that even if risk-adjustment is made to medication adherence measures in Part D, these changes may not be duly made by plans in their evaluation of pharmacies. This dilemma emphasizes the importance of the development and appropriate implementation of standardized pharmacy performance metrics as outlined in Section I of these comments above.

IX. Part D Medication Therapy Management (MTM) Program

NACDS Supports MTM Eligibility Expansions in Part D

NACDS strongly supports CMS' proposed changes to expand the eligible population for the Part D Medication Therapy Management (MTM) program. Chronic diseases are the leading causes of death and disability and contribute to 90% of the nation's $4.1 trillion in healthcare spend.[24] The prevalence of chronic diseases continues to rise. Of all non-dual-eligible Medicare beneficiaries in 2017, 66 percent were living with two or more chronic conditions.[25] Worsening and exacerbation of chronic conditions can be prevented through effective management and control, often medication therapy in conjunction with lifestyle changes is recommended by clinical guidelines for the management and control of many chronic conditions. Because appropriate medication use is a cornerstone of the management and control of chronic diseases, MTM is a critical resource for eligible Part D beneficiaries. As CMS identifies in the proposed rule, only 4.5 million or 9 percent of beneficiaries are currently eligible, limiting beneficiaries who may benefit from MTM from accessing it.

NACDS strongly supports CMS' proposals that would increase eligibility to an estimated 11.4 million or 23 percent of beneficiaries. NACDS supports the proposed 9 core chronic diseases and the addition of HIV/AIDS and cancer as beneficiaries impacted by these conditions may be likely to benefit from MTM services given the importance of medication adherence in their treatment plan, the potential for adverse effects that need to be managed appropriately, drug interactions, medication regimen complexity, and other factors that lend well to the expertise of community pharmacies and pharmacists who are often collaborating with health plans to engage patients in MTM programs. The inclusion of HIV/AIDS and cancer in the core chronic diseases in MTM eligibility also aligns well with some pharmacies' specialty pharmacy offerings and clinical services. NACDS also supports lowering the maximum number of Part D drugs a sponsor may require from 8 to 5 and requiring sponsors to include all Part D maintenance drugs. NACDS also supports the revision of the cost threshold methodology to align with the annual cost of 5 generic Part D drugs. The average daily cost for a drug would be based on PDE data, multiplied by 365 to determine the annual cost, and be based

[24] https://www.cdc.gov/chronicdisease/about/costs/index.htm
[25] https://www.commonwealthfund.org/publications/issue-briefs/2021/mar/managing-medicare-beneficiaries-chronic-conditions-covid#6

on the ingredient cost, dispensing fees, sales tax, and vaccine administration fees, if applicable, and would include both the plan paid amounts and enrollee cost sharing.

NACDS also supports amending regulation to require that the CMR be performed either in person or via synchronous telehealth to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth. NACDS strongly supports the ongoing ability for the CMR to be performed in person or using the telephone, video conferencing, or another real-time method. Telephonic CMR is an important option to maintain patient access given that many patients, especially seniors, may benefit from a telephonic access option.

X. Medicare Advantage (MA) and Part D Marketing

NACDS Requests Clarity on MA and Part D Listing Marketing Requirements

NACDS supports strengthening Medicare beneficiaries' protections against inaccurate and misleading marketing information from plan sponsors. Under the proposed marketing requirements, there are several proposed prohibitions around marketing such as requiring Third Party Marketing Organizations (TPMOs) to list all the names of the MA organization or Part D sponsors (or the marketing names) that they sell in the applicable service area and that the names of those same sponsors that offer the benefits being advertised be clearly identified. The proposed rule concludes that MA organizations and Part D sponsors are prohibited from marketing any products or plans, benefits, or costs unless the names (as listed in the HPMS of the entities offering the referenced products or plans) are identified in the marketing material. We understand CMS' intention to help beneficiaries make more informed decisions, but we ask that CMS clarify whether all names of the MA organizations, Part D sponsors, or TPMOs representing the plan sponsors need to be listed on non-plan specific messaging issued by first-tier, downstream and related entities (FDR) that generally addresses the services or advantages offered by such FDR (e.g., low copays, $0 vaccine, ability to use OTC cards). We think this could potentially be a distraction and lead to further confusion for many beneficiaries and recommend that there be a distinction or further clarification when a listing of the plan sponsors may be more appropriate depending on the modality of the advertisement (e.g., in-store sign vs. commercial) or propose another channel beneficiaries could receive (or entities can provide) the list of names if it's not detailed on, for example, a store's sign that will still help beneficiaries maintain control of their information.

Secondly, we ask CMS to clear up the distinction between marketing versus communication by an FDR. For example, pharmacy signage or messaging is a communication tool designed to inform and educate beneficiaries of non-plan specific information such as updates from the Inflation Reduction Act regarding no cost sharing for adult vaccines covered under Medicare Part D or regulatory changes enabling access to over-the-counter hearing aids for millions of Americans without a medical exam or prescription. This form of messaging is not intended to advertise, mislead, or market to beneficiaries on behalf of plan sponsors but to help ensure beneficiaries are unequivocally informed as to their options so they can make the best health care decision moving forward regardless of their plan sponsor. We also believe community pharmacies are in a unique position to be a reliable source of information for beneficiaries to improve population health; therefore, we believe this type and form of communication intended for information purposes would be excused from many of the proposed marketing requirements, including the listing of all the names of the MA organization or Part D sponsors (or the marketing names) in the marketing material or on products and

should be further clarified in the rule. We applaud CMS's efforts to establish guardrails around misleading marketing to preserve information integrity for beneficiaries and appreciate the opportunity to share our perspective on the proposed marketing requirements.

XI. Updating Translation Standards for Required Materials and Content

NACDS Requests Clarity on Translation Standard Requirements

NACDS supports updating the translation standards for beneficiaries who have limited English proficiency or auxiliary aids or service needs. Under the proposed rule, CMS requires MA organizations, Part D sponsors, cost plans, and special needs plans (SNPs) to provide materials to enrollees on a standing basis in any non-English language that is the primary language of at least 5 percent of individuals in a plan's service area and in any accessible format using auxiliary aids and services as requested or learned from the enrollee's preference. We understand the onus of this requirement lies with the MA organizations, Part D sponsors, and SNPs and that the expected implementation of the standing request would reduce future costs to MA organizations, cost plans, and Part D sponsors by only having to send one set of information in the correct language and form. This requirement does not apply to TPMOs or any first-tier, downstream and related entities (FDR). NACDS has heard complaints from members about confusion in the industry regarding who is responsible for bearing the cost and impact of providing materials that adhere to CMS' translation standards.

We see this proposed rule as an opportunity to recommend that CMS please clarify that both existing and proposed translation standard requirements do not apply to TPMOs or FDR unless otherwise agreed upon between the MA organization and the TPMO or FDR, or the Part D sponsors and the TPMO or FDR. We believe this clarification will help resolve any lingering misunderstandings on the matter and achieve the end goal of helping beneficiaries get the information they need and understand.

XII. Changes to an Approved Formulary

NACDS Applauds the Immediate Substitution of Interchangeable Biological Products

As we saw during the COVID-19 pandemic, helping assure that pharmacists can make medications quickly and efficiently available, especially during drug shortages, can lead to improved outcomes for patients and overall population health. Doing so also empowers pharmacists to champion for reasonable and fair reimbursement for any drug and biological product substitution. The proposed rule would allow Part D sponsors to immediately substitute a new interchangeable biological product, a new unbranded biological product, and a new generic for their corresponding reference product, brand biological product, and brand product respectively. In addition, the proposed rule would streamline notice requirements for faster implementation of formulary changes. These provisions of the proposed rule would serve as a glide path for optimized patient care delivery services and increased patient access for Part D eligible individuals at the pharmacy counter.

NACDS supports the immediate substitution of interchangeable biological products. The emergence of interchangeable biosimilars such as Semglee (insulin glargine-yfgn) opens the doors for additional

healthcare savings and most critically, improves access to affordable medications for patients. NACDS will continue its decades-long work to support policies such as this proposed rule that enhance pharmacies' ability to provide these medications to patients and relieve burdens on the national healthcare system.

XIII. Expanding Low-Income Subsidies under Part D

NACDS Supports the IRA Implementation of the Expanded Eligibility LIS Program

It is well understood that beneficiaries with chronic diseases or other health conditions and low-income status are particularly sensitive to the cost of medications. This rule would further support the statute's intent to expand eligibility under the low-income subsidy (LIS) program up to 150% of the federal poverty level and allow beneficiaries who currently qualify for partial subsidy to receive full subsidy beginning on or after January 1, 2024.

As CMS works to finalize this provision, we respectfully request that CMS assesses the potential disproportionate impact of this proposed rule and the 2022 final rule on pharmacy reimbursements due to the current climate of skyrocketing DIR fees and overall, below-cost reimbursements to pharmacies by PBMs and establish clear guardrails to protect pharmacy reimbursement for covered Part D drugs and patient care delivery services. NACDS supports expanding access for vulnerable patient populations that benefit from the LIS program. However, we fear that CMS' aim could be frustrated by not considering the unintended consequences of not addressing the need to protect pharmacy reimbursement.

XIV. Part D Global and Targeted Reopening

CMS Should Ensure Pharmacy Protections During Extended Reopenings

As stated in the January 2005 Part D final rule, the Secretary has the authority to inspect and audit any books and records of a Part D sponsor or MA organization regarding costs. If such a mistake or issue exists, then the Secretary would need to reopen final determinations made on payments so the payment issue can be rectified. Pharmacies have experienced on a multitude of occasions predatory practices involving plan sponsors and PBMs leveraging DIR fees to over-collect from pharmacies and challenge patient access and pharmacies' viability as health and wellness pillars in the community. The 2022 final rule did not eliminate pharmacy DIR clawbacks that plans sponsors and PBMs impose on pharmacies, nor did the rule eliminate sponsors' and PBMs' incentives to continue to do so. In light of this, we are concerned that extending the timeframe for performing a reopening for good cause from within 4 years to within 6 years (to align with the 6-year overpayment look-back period) without any guardrails or protections in place for community pharmacies could lead to instances in which plan sponsors, MA-PDs, and PDPs take advantage of this process to further clawback payments from pharmacies (since there are no rules or restrictions around this act) if they are negatively impacted by CMS's overpayment findings. NACDS supports codifying the definitions of "global reopening" and "targeted reopening," as it's consistent with CMS's current guidance, and we understand the need to standardize these processes; however, we request that CMS consider establishing protections for pharmacies and patients against Part D sponsors or MA organizations recouping overpayments from pharmacies that sponsors are responsible for during the proposed 6-year timeframe of Part D global and targeted reopenings.

XV. Special Enrollment Period

NACDS Supports Timely Patient Access to Prescription Drugs and Resolving Pharmacy Reimbursement Vulnerabilities

NACDS supports timely patient access to prescription drug coverage (MA plan, MA-PD, or PDP plan) under the proposed special enrollment period (SEP) where beneficiaries can use a Medicare exceptional condition SEP to enroll in Medicare Part A and/or B. Under the proposed rule, this would allow vulnerable beneficiaries access to prescription drug coverage to become effective the first of the month following the month the plan sponsor receives the enrollment request.

Although we support CMS' policy intent with this proposal, with increased prescription coverage for beneficiaries, this will likely exacerbate current reimbursement challenges at the pharmacy counter—where pharmacies are being paid below costs for many of the prescriptions they purchase and dispense. Without addressing these fundamental and dire pharmacy reimbursement challenges (e.g., DIR fees, fair and adequate cost-based reimbursement) we, as an organization, have been highlighting for over the past decade and are at a tipping point, then this proposed rule along with others (e.g., LIS program) intended to increase patient access could facilitate undue strain and setbacks on an already tested and hypersensitive healthcare system, especially the pharmacy sector. We must address these vulnerabilities in pharmacy reimbursement and continue to invest in a strong and sustainable pharmacy infrastructure for Americans, including our Medicare beneficiaries.

Conclusion

NACDS thanks CMS for the opportunity to comment on technical changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications. For questions or further discussion, please contact NACDS' Christie Boutte, Senior Vice President, Reimbursement, Innovation and 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

Appendix A: Examples of Evidence: Value of Pharmacist-Provided Care

The following chart presents a chart that reviews research and other materials and summarizes key findings related to the impact of pharmacy care. Evidence is organized into the following categories:

- Preventive care
- Preventive Screenings
- Chronic Disease Management
- Medication Adherence and Optimization
- Mental and Behavioral Health
- Social Determinants of Health & Health Disparities

Examples of Evidence: Value of Pharmacist-Provided Care	
Result of Pharmacist Intervention	**Source**
Preventive Care	
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/pubmed/30145351
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
Pharmacists have demonstrated their value in the community setting by providing high-quality and accessible care but are faced with barriers. This article discussed ways to optimize access to care in communities and implementation strategies to further improve population health outcomes while minimizing downstream healthcare costs.	Newman TV, Hernandez I, Keyser D, et al. Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations. J Manag Care Spec Pharm. 2019. https://www.jmcp.org/doi/10.18553/jmcp.2019.25.9.995
This article emphasizes **the need for collaboration between practices, patients, and payers to improve healthcare outcomes and reduce costs** by moving toward value-based payment models.	Armistead LT, Ferreri SP. Improving Value Through Community Pharmacy Partnerships. Population Health Management. 2018. https://www.liebertpub.com/doi/abs/10.1089/pop.2018.0040?journalCode=pop
Evidence suggests **pharmacists can prescribe to the same standards as other providers of care**, including the ability to better adhere to dosing guidelines when prescribing by protocol.	Poh EW, McArthur A, et al. Effects of pharmacist prescribing on patient outcomes in the hospital setting. JBI Database of Systematic Reviews and Implementation Reports. September 2018. https://journals.lww.com/jbisrir/Abstract/2018/09000/Effects_of_pharmacist_prescribing_on_patient.9.aspx
As hospitals and other care sites continue to close, especially in underserved areas, it is necessary for patients to have alternative locations to receive coordinated, high-quality care including chronic care management, and preventive care. Community pharmacies are well-positioned to serve as care sites to support the rest of the care continuum.	Heath S. How Pharmacists Can Drive Patient Engagement, Value-Based Care. March 2019. https://patientengagementhit.com/news/how-pharmacists-can-drive-_p atient-engagement-value-based-care
Preventive Screenings	

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. PLoS One. April 2014 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3972156/
A literature review showed that community pharmacies that 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 patients to have increased access to various screenings.	Buss V.H., Naunton M. (May 2019). 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. https://www.ncbi.nlm.nih.gov/pubmed/30057328
The Centers for Disease Control and Prevention's (CDC's) Community Preventive Services Task Force (CPSTF) recognized the importance of pharmacy-based prevention by issuing a **strong recommendation for a pharmacy-based adherence intervention for cardiovascular disease prevention**, with its guidance based on its comprehensive literature review of 48 cases.	CDC. (2016). Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. https://www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdfhttps://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf
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. Research in Social Administrative Pharmacy. h ttps://www.ncbi.nlm.nih.gov/pubmed/2 8 479019
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. (March 2017). "Pharmacist-initiated hepatitis C virus screening in a community pharmacy to increase awareness and link to care at the medical center."; *Journal of the American Pharmacists Association*. https://www.japha.org/article/S1544-3191(17)30136-X/pdf
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. *Gastroenterol Hepatol (N Y)*. 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 of 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. Journal of the American Pharmacists Association. Volume 55, Issue 3, May–June 2015, Pages 307-312. https://www.sciencedirect.com/science/article/pii/S1544319115300650?via%3Dihub
In Michigan, a pharmacist-provided HIV testing model, which incorporated rapid HIV testing, counseling, and linkage to confirmatory HIV testing demonstrated the acceptability and feasibility of pharmacist-provided rapid HIV testing and increased access to care. Approximately **42% of the participants stated it was their first HIV test, many of whom reported high-risk behaviors in prior 6 months.**	Darin KM, et al. (February 2015). "Pharmacist-provided rapid HIV testing in two community pharmacies;" *Journal of the American Pharmacists Association*. https://www.japha.org/article/S1544-3191(15)30015-7/pdf

A partnership between the Virginia Department of Public Health and community **pharmacies provided HIV tests to more than 3,600 individuals over 2 years.** Approximately half of these patients had never been tested for HIV before, and those who tested positive were linked to appropriate care with the assistance of a pharmacist.	Collin B, et al. The "No Wrong Door" Approach to HIV Testing: Results From a Statewide Retail Pharmacy–Based HIV Testing Program in Virginia, 2014-2016. 2018. Public Health Rep. https://journals.sagepub.com/doi/full/10.1177/0033354918801026
Pharmacies are increasingly providing a wide range of point-of-care tests including COVID-19, flu, strep throat, A1c screening, and more. Importantly, pharmacies throughout the country have also **partnered with local health departments to develop HIV and hepatitis C pharmacy-based screening programs that include linkage to care** if a test is positive.	Hoth A, Shafer C, et al. Iowa TelePrEP: A Public-Health-Partnered Telehealth Model for HIV Pre-Exposure Prophylaxis (PrEP) Delivery in a Rural State. Sexually Transmitted Diseases. May 2019. https://www.ncbi.nlm.nih.gov/pubmed/31157732 Dong BJ, et al. Pharmacists performing hepatitis C antibody point-of-care screening in a community pharmacy: A pilot project. Journal of the American Pharmacists Association. Volume 57, Issue 4, July–August 2017, Pages 510-515. https://www.sciencedirect.com/science/article/pii/S1544319117306660?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. Journal of the American Pharmacist Association, 54(5), 486-492. https://www.ncbi.nlm.nih.gov/pubmed/25216878
To help combat challenges in HIV PrEP and PEP access to care, more and more states are looking to pharmacists to help fill care gaps. For example, states including New Mexico, Iowa, and Washington, have piloted studies that show **pharmacist-run, or pharmacist-involved, PrEP clinics are an effective way to increase uptake of the medication**, which can then lead to decreased HIV transmission.	Ryan K, Lewis J, Sanchez D, et al. The Next Step in PrEP: Evaluating Outcomes of a Pharmacist-Run HIV Pre-Exposure Prophylaxis (PrEP) Clinic. ID Week 2018 Poster Abstract Session. Oct 2018. https://idsa.confex.com/idsa/2018/webprogram/Paper72194.html Tung EL, Thomas A, Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. Sex Health. Nov 2018. https://www.ncbi.nlm.nih.gov/pubmed/30401342
Chronic Disease Management	
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-medicalcare/Fulltext/2010/10000/US_Pharmacists__Effect_as_Team_Members_on_Patient.10.aspx
Notable agencies within the healthcare system, such as the Department of Veterans Affairs, Department of Defense, Public Health Service, CDC, and the U.S. Surgeon General **recognize the value of pharmacists in improving quality and healthcare outcomes through services such as transitions of care and chronic disease management**, for example. By providing these important services in a convenient, easily accessible location, patients in underserved areas can benefit from expanded access to care and improved health outcomes.	A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. CDC. August 2012. https://www.cdc.gov/dhdsp/programs/spha/docs/pharmacist_guide.pdf Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011. https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

	Surgeon General supports USPHS report on pharmacists as providers. APhA. January 2012. https://www.pharmacist.com/CEOBlog/surgeon-general-supports-usphs-report-pharmacists-providers?is_sso_called=1
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
A review of 22 studies showed that community pharmacist-led interventions **improve patients' adherence** and contribute to **improved blood pressure control, cholesterol management, and chronic obstructive pulmonary disease and asthma control.**	Milosavljevic A, Aspden T, Harrison J. (June 2018). Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. International Journal of Pharmacy Practice. 26(5). https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462
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. (May 2018). The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home. JMCP. 2018;24(5):423-429. https://www.ncbi.nlm.nih.gov/pubmed/29694290
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. (January 2018). Medication Synchronization Programs Improve Adherence to Cardiovascular Medications and Health Care Use. Health Affairs 37(1)125-133. https://www.ncbi.nlm.nih.gov/pubmed/29309231
The results for 6-month **systolic blood pressure** 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 blood pressure 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. (March 2016). "Cost-effectiveness of Wisconsin TEAM model for improving adherence and hypertension control in black patients;" *Journal of the American Pharmacists Association*. https://www.ncbi.nlm.nih.gov/pubmed/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 2016). Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care. Ann Intern Med. Epub ahead of print.
CDC, CMS, and other public health leaders have noted the **robust ability for pharmacists to play an important role in smoking cessation**.	Centers for Disease Control and Prevention, Pharmacists: Help Your Patients Quit Smoking, April 22, 2019. https://www.cdc.gov/tobacco/campaign/tips/partners/health/pharmacist/index.html Department of Health and Human Services, Centers for Medicare & Medicaid Services; CMCS Informational Bulletin, State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf

	Tobacco Control Network, Access to Tobacco Cessation Medication Through Pharmacists, Feb 8, 2017, *available at* http://www.astho.org/Prevention/Tobacco/Tobacco-Cessation-Via-Pharmacists/
Pharmacy care program 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 baseline of 61.2% to 96.9%** and associated with significant **improvements in systolic blood pressure** (133.2 to 129.9) and **LDL-C levels** (91.7 to 86.8).	Lee JK, et al. (December 2006). "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 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 of 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/pubmed/24367463
Several states authorize pharmacies to play an elevated role in initiation of prescription and over the counter products to support patients in smoking cessation. In fact, Colorado, Idaho, Indiana, and New Mexico **authorize pharmacists to initiate all medications approved by the U.S. Food and Drug Administration for smoking cessation**.	Adams AJ, Hudmon KS. Pharmacist prescriptive authority for smoking cessation medications in the United States. J Am Pharm Assoc (2003). 2018. doi: 10.1016/j.japh.2017.12.015.
Medication Adherence and Optimization	
A recent analysis completed by Community Health Group showed Comprehensive Medication Reviews reduced medical expenses by $4000 per patient per year.	https://outcomesmtm.com/wp-content/uploads/2022/06/Case_Study_Part2_CHG_Value_Analysis.pdf
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 (Aug. 2014), available at https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.1398
Patients receiving the pharmacist **adherence intervention for antihypertensives** 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. (December 2013). Impact of a community pharmacists' hypertension-care service on medication adherence."; *The AFenPA study. Research in Social and Administrative Pharmacy*. Available at https://www.ncbi.nlm.nih.gov/pubmed/23391845. Last Accessed June 13, 2018.
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. Harvard Business Review. 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	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/index.php/innovations/article/view/971

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%).	
In this retrospective review of 408 comprehensive medication management visits with a pharmacist, and 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. Journal of Pharmacy Technology. 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. American Health and Drug Benefits. December 2018. http://www.ahdbonline.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 problem 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.	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_FinalV.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 intervention group (n = 221) versus 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 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/pubmed/30696337
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	Cochran G, Rubinstein J, Bacci JL, Ylioja T, Tarter R. Screening Community Pharmacy Patients for Risk of Prescription Opioid Misuse. J Addict Med.

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).	2015 Sep-Oct;9(5):411-6. https://www.ncbi.nlm.nih.gov/pubmed/26291546
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. Boston Globe. March 2019. https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVlLRXX1W9X3WdeOP/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/pubmed/25749264
During the study period, 3,726 patients were screened for depression by pharmacists. 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**. The author concluded that a screening program for depression can be successfully developed and implemented in the community pharmacy setting. Using the PHQ, **pharmacists were able to quickly identify undiagnosed patients with symptoms of depression**. The majority of patients with a positive screening had initiated or modified treatment at the time of follow-up.	Rosser S, Frede S, Conrad WF, Heaton PC. Development, implementation, and evaluation of a pharmacist-conducted screening program for depression. J Am Pharm Assoc. 2013 Jan-Feb;53(1):22-9. doi: 10.1331/JAPhA.2013.11176. https://www.ncbi.nlm.nih.gov/pubmed/23636152
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 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/pubmed/30031696
Pharmacists are increasingly being trained in mental health first aid. Research to date has demonstrated effectiveness and positive public perceptions.	Witry MJ, Fadare O, Pudlo A. Pharmacy professionals' preparedness to use Mental Health First Aid (MHFA) behaviors. Pharm Pract (Granada). 2020 Oct-Dec;18(4):2102. doi: 10.18549/PharmPract.2020.4.2102. Epub 2020 Nov 14. PMID: 33294061; PMCID: PMC7699831. Mospan CM, Gilletee C, Mckee J, et al. Community Pharmacists as Partners in Reducing Suicide Risk. The Journal of the American Board of Family Medicine. Nov 2019. DOI: 10.3122/jabfm.2019.06.190021 Dollar KJ, Ruisinger JF, Graham EE, Prohaska ES, Melton BL. Public awareness of Mental Health First Aid and perception of community pharmacists as Mental Health First Aid providers. J Am Pharm Assoc. March 2020. doi: 10.1016/j.japh.2020.01.017.
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 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/pubmed/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/pubmed/25438728
Immunizations	
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/pubmed/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/pubmed/30340884
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, it is estimated that **6.2 million additional influenza immunizations and 3.5 million additional pneumococcal immunizations** are attributable to pharmacy-delivered immunization services 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.ncbi.nlm.nih.gov/pubmed/30076098
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.	Drozd 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/pubmed/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**.	Isenor 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/pubmed/27765379
A large proportion of adults being vaccinated receive their vaccines during 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/pubmed/24019274
Social Determinants of Health & Health Disparities	
Leveraging community pharmacists to complete a SDOH screening resulted in an average $1500 decrease in medical spending.	https://www.pqaalliance.org/sdoh-resource-guide

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 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 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://chronicdisease.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, Oldani 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/pubmed/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/pubmed/28381095
Socioeconomic challenges might influence education about interventions and lifestyle decisions, access to support activities, access to nutrition/health and wellness services, and access to screenings and services which would emphasize the need for well-positioned care. Community pharmacists are located where many patients facing socioeconomic challenges live and work, offering accessible preventive care opportunities.	Tucker M, Barclay L. What's the Effect of Diabetes Prevention Services? Medscape. July 2019. https://www.medscape.org/viewarticle/915077
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 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.	Victor RG, et al. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops. The New England Journal of Medicine. April 2018. https://www.nejm.org/doi/full/10.1056/NEJMoa1717250