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DIR Fee Reform Will Have Repercussions in 2024, But Pharmacists Can Prepare

Erin Hunter

The Centers for Medicare and Medicaid Services (CMS) is revising its Medicare Part D plan to now require that plan sponsors include all pharmacy direct and indirect remuneration (DIR) fees (also called price concessions) at point-of-sale (POS); in other words, CMS plans to remove retroactive DIR fees, which are often billed more than 6 months after a purchase.¹

The new rule goes into effect on January 1, 2024, but pharmacists should brace themselves for high DIR fees and low POS reimbursement during the transition period—the first half of 2024—according to expert Crystal Lennartz, vice president and general manager, Health Mart Atlas & Atlas Specialty, who updated independent pharmacists of these imminent changes during a session at McKesson ideaShare 2023 in Las Vegas, Nevada.²

“It’s anticipated that how [plan sponsors] are going to handle data is that any[thing] from the midpoint to the full DIR is going to be built into those POS rates come 2024,” Lennartz said during the session.

DIR is a regulatory loophole that allows a patient with a Medicare Part D plan to earn back money from a drug purchase via a pharmacy benefit manager (PBM).³

“The PBM receives additional compensation after the POS that serves to change the final cost of the drug for the payer,” True North Political Solutions said in a statement.

DIR includes discounts, chargebacks, rebates, upfront payments, grants, or other price concessions. These “clawbacks,” which consist of a percentage of the total cost of a

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prescription, are supposed to reduce the cost of a prescription set by Medicare.

In theory, payers can take back money from every purchase made at POS based on the pharmacy's performance, as assessed by a PBM.¹ PBMs posit that DIR fees incentivize good performance—better performance would mean lower DIR fees—but performance is an inconsistent measure for how much the pharmacist improved patient outcomes.⁴

Further, some PBMs have taken advantage of this system, critics say. They evaluate DIR fees after scoring the pharmacy for performance in a way that does not affect their scores.⁴

DIR fees end up hurting pharmacies because pharmacists, who now owe money back to the patient, are billed long after the patient made a purchase. In effect, the pharmacy ends up losing lots of money when processing these Medicare Part D claims.

The update should be considered a win for patients with CMS Medicare or Medicaid who, under current regulation, also pay an inflated price for a prescription drug. This is because DIR fees are often calculated into POS cost, inflating the price.¹ In 2024, patients will have lower co-pays up front because they will not need to be reimbursed for DIR fees after a purchase.

Pharmacists will also benefit from increased drug cost transparency, Lennartz explained. Under the new rule, pharmacists can negotiate the price of a drug with a patient upfront, and the DIR fees will now be reflected in this negotiation.²

However, the updated guidelines are likely will impact 2024 cash-flows, particularly during the first 5 months of 2024, Lennartz said. During early 2024, pharmacists will have to pay their 2023 DIR payments. Simultaneously, CMS will pay pharmacists less money for drugs, she added.

The reason there will be a low POS reimbursement is because starting 2024, the DIR fee will no longer inflate the cost of drugs at POS. Although this is good news in the long-term, pharmacists may make less money while paying

more in retroactive fees.

“What [pharmacists] need to do to prepare is to really understand your pharmacy-specific cash flow implications, and how you might want to set aside or free up cash flow to mind this gap,” Lennartz said.

Lennartz noted specifically that CVS Caremark and Prime Therapeutics will be collecting large dollar amounts. Come January 2024, Caremark will collect DIR fees from May through August 2023 and in March 2024, Caremark will start collecting fees from claim activity from September to December 2023, Lennartz said. They will collect these trimester 3 claims until May 2024.

Prime will collect DIR fees based on Q3 claims activity in January 2024 and will collect fees from Q4 in April 2024 only, Lennartz said. She suggests setting aside funds to meet 2023 DIR obligations between June and December 2023. If a pharmacist does not want to or is unable to set aside these funds, a pharmacist can alternatively start a business high interest savings account.

Programs such as Health Mart Atlas's voluntary DIR Assist were created to help pharmacists set aside funds via Central Pay Funds, and Pinpoint Community Solutions can help pharmacists lower inventory costs, Lennartz said.

“I strongly encourage pharmacists to take the step to protect your pharmacy against these cash flow challenges that are coming,” she concluded.

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Inflation Reduction Act, EOM, PBM Reform Remain Hot Topics on Capitol Hill

Alana Hippensteale

The message from Capitol Hill with the Inflation Reduction Act (IRA) is that they've got their pound of flesh from the pharma industry in their pursuit of

negotiating drug pricing, explained Nick Ferreyros, managing director of policy, advocacy, and communications at the Community Oncology Alliance, during a panel discussion

at the 2023 Advanced Topics for Oncology Pharmacy Professionals (ATOPP) Summit in New Orleans, Louisiana. Ferreyros explained further that, depending on how the implementation of the IRA goes, Congress is likely going to shift their attention to other topics they'd like to have an impact on, such as pharmacy benefit managers (PBMs).

"I don't know about y'all, but one of the things that keeps me up at night, as someone who has many years ahead of him getting into the cancer era, is the impact this will have on new drug development," Ferreyros said during the panel. "Because the impact is going to [be in] the long-term in investment in drug development and discovery."

Panelist Lalan Wilfong, MD, a medical oncologist/hematologist with Texas Oncology, PA and physician liaison for value-based care for McKesson Specialty Health, noted that this is a challenging topic because there are mixed responses to the IRA among the public, as well as within industry and pharmacy. Because cancer predominantly affects the elderly (age 65 and older) than other demographics, the high price of oral drugs result in significant financial toxicity and even bankruptcy.

"A lot of our seniors can't afford these drugs," Wilfong said. "I just had a patient in the past couple of weeks who told me they weren't going to take a therapy because they didn't want to spend the money. We all know the shenanigans that PBMs are doing that are cutting into patient assistance programs, but to seniors, [the IRA] capping out-of-pocket costs at \$2000 is a pretty big deal, and they're feeling pretty good about that."

Additionally, Wilfong noted that employers are also responding positively to the changes enacted by the IRA.

"Employers are fed up with drug prices," Wilfong said. "Employers are saying, 'We like this. We want the drug prices to be lower.' So, I think this is a challenge because most of the people in the United States outside of our industry think this is a huge win."

However, Ferreyros noted that the IRA will have a significant impact on Medicare Part B add-on payments when negotiations actually begin in 2028. Although the negotiation phase will start in October 2023—at which point manufacturers will need to start disclosing details about pricing to the government to begin the process—the negotiation process won't officially start until 5 years following this disclosure requirement.

Additionally, Wilfong explained that another hot topic on the Hill will continue to be the Enhancing Oncology Model (EOM). The Oncology Care Model (OCM) was the government's alternative payment model for oncology from

2016 through 2021. It ran for 6 years, with approximately 180 practices in the model at the start and 120 at the end—some dropped out and others consolidated. According to Wilfong, there are a lot of reasons why those numbers changed over the years, but it was a fairly successful model overall, at least in the eyes of oncology stakeholders.

"Prior to the [OCM], we had a very loose coalition of how we managed our patients [with cancer], but post-OCM, it was much more formalized. And when I say 'how we manage our cancer patients,' it was whether you did patient education, prior to the OCM, that was kind of at the discretion of the physician and their team," Wilfong said. "Post-OCM, we have a very formal way of talking to patients about their cancer diagnosis and their treatment options, reporting to the Institute of Medicine the care management plan and the different components of that around the patients' diagnosis, their biomarkers, their prognosis, what treatment is expected, the side effects—so things like that."

According to Wilfong, the OCM gave oncology professionals a much more prescriptive way of thinking about their patient population, pushing oncology professionals to consider their patients more holistically. Wilfong explained that with the advent of the OCM, he needed to start thinking differently about how his patients were doing while they were outside of his office and not just while they're sitting in his office in front of him.

"You had to start thinking about that a lot more, and how you help meet your patients where they need to improve their outcomes. It really was a radical shift," Wilfong said. "It was one of those things where, if you wanted to be a good physician, and that was important to you, then now you're required to do those things."

Wilfong explained that a consensus across the oncology community was that post-OCM, there was a greater focus on patients more holistically than pre-OCM. However, the CMS found that the OCM was not a successful model because it didn't really improve quality of care and save costs in a general sense.

The EOM, which started July 1, is different from the OCM in that the latter was a broad model—it incorporated every patient with cancer that was on any sort of therapy for cancer. On the other hand, the EOM now only focuses on the 7 most common cancers—breast cancer, lung cancer, small intestine/colorectal cancer, lymphoma, chronic leukemia, multiple myeloma, and prostate cancer—in the 65 years of age and older population.

However, according to Wilfong, only 44 practices have signed up to participate in the EOM, which is significantly

smaller than the number who had signed up for the OCM.

“The reasons why are multiple, but the big one is that it’s a risk model from the get-go, meaning that as a practice participating in EOM, we are at risk for total cost of care. If we spend more than our target price, which is 2% less than benchmark, we have to pay back Medicare, and nobody likes to give the government more money,” Wilfong said. “There are some nuances to the model that make it more challenging to perform well, depending on practice dynamics and practice culture. The amount of care management money that we’re getting is much less in the model, and there’s some extra requirements around helping people with social determinants of health [SDOH] and electronic patient reported outcomes. So, it is a much more challenging model.”

For those practices with a culture focused on value-based care, the EOM may more easily fit into the objectives and strategies of that practice, according to Wilfong. Regardless, he noted that it will be interesting to see what happens with the EOM due to the challenges it presents for oncology practices.

Additionally, Ferreyros noted that most of the 44 practices participating in the EOM are larger multisite practices. This trend suggests that in order to participate in the EOM with a greater potential for success, a significant investment and team are necessary, which perhaps only larger practices are able to handle.

Wilfong responded, noting that in his experience with the OCM at his practice, the significant investment in technology alone for documentation purposes was challenging for practices.

“I’ve spent a year working with our team in adjusting our EMR to be able to just document SDOH,” Wilfong said. “There’s a lot that goes into participation in these models.”

For those practices that did participate in the OCM, they’ve now done a lot of the work required to then reinvest in the EOM, according to Wilfong. However, of the 44, there were a couple that weren’t participating in the OCM that joined the EOM.

“But I haven’t seen the list yet and haven’t actually done the comparison to see who of the 44 were in OCM versus not,” Wilfong said.

However, with only 44 practices participating in the EOM, Wilfong postulated that CMS will likely not be able to hit the mark of the statistical significance required to obtain sufficient statistical data to demonstrate a meaningful impact from the model.

“I think if you look at some of the other models, [CMS] had that had smaller participation, they had to change the model and encourage more participation, and then ultimately

had to close the model,” Wilfong said.

Moving to the discussion of PBMs, Ferreyros asked Jonathan E. Levitt, Esq, to introduce himself.

“So, my name is John. I sue PBMs,” Levitt said.

As the room erupted in laughter and applause, he moved onto explain that he’s been suing PBMs for the past 2 or 3 years and developed a subspecialty in direct and indirect remuneration (DIR) fees. “I’m going to guess in this room, collectively you’ve paid probably \$300, maybe \$400 million in [direct and indirect remuneration (DIR)] fees.”

Specifically, PBMs do not make clear to practices the metrics by which they are judging their performance in areas such as adherence, according to Levitt.

“Do you know how PBMs are judging you on your adherence? The answer is no, no one does, because the contracts don’t tell you,” he said. “We file these arbitrations, and we find out. When the PBM says, ‘We’re not going to give you data, we’re not going to tell you how we judge adherence,’ which is ridiculous, and an arbitrator says, ‘Okay, you have to give these data to the law firm.’ The first time we discovered how a PBM was actually judging adherence, we just couldn’t believe it. And you won’t believe it either. [However,] I’ve been told by this PBM that it’s not public information, and if I disclose it, they will sue me; they said it’s their secret sauce.”

Levitt explained further that DIR fees are only in the Medicare Part D program, and PBMs only charge DIR fees on Medicare Part D claims. One PBM makes their reimbursement rate contingent on performance, which is based on medication adherence.

“So the worse your score, the higher your DIR fee,” Levitt said.

Additionally, these scores do not necessarily take into account a patient’s need to discontinue a medication based on the presentation of toxicity while on the treatment. For such cases, the rate can simply show a low score for adherence rather than acknowledging the need for discontinuation.

“I’m here to tell you that under Medicare, there’s a federal law that applies to this, it’s called the Any Willing Provider law, and it’s very, very simple—it’s much more simple than cancer care. It says the terms and conditions in the Medicare part D program have to be reasonable and relevant,” Levitt said.

Levitt explained that when suing PBMs, their goal is to assess whether a fee is reasonable and relevant, as required by federal law.

“And PBMs, they say, ‘That law doesn’t apply to us.’ I can

tell you, in my job, I get to look at contracts between these big prescription drug plans and CMS, and it says, ‘This law applies.’ It refers to the Any Willing Provider law,” Levitt said. “You all have rights here, in this room, and you’re all overpaying on DIR fees, and you have the right to challenge

it. We’ve had a lot of success in these cases. We’ve collected \$100 million for oncology hospitals and oncology practices.”

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Legal Battles Intensify: Pharmaceutical Manufacturers’ Lawsuits Targeting Compounding Pharmacies

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Pharmacy compounding is a fundamental component of pharmacy practice and is essential to the provision of health care. However, for years, pharmaceutical manufacturers have been filing lawsuits against compounding pharmacies, accusing the pharmacies of infringing on their patents.

This rise in legal actions is driven by the growing prevalence of compounding practices over the years, despite the heightened regulatory oversight imposed on 503A compounding at the federal level through the Drug Quality & Security Act (DQSA),¹ and at the state level through state boards of pharmacy.

Recent legal actions have specifically targeted pharmacy compounders that fall into the realm of intellectual property. While 503B outsourcing facilities have not been immune from lawsuits by manufacturers, the focus of this article is on 503A compounding pharmacies.

Lawsuits often have claims based on state deceptive and unfair trade practices acts, patent infringement, Lanham Act violations for false statements in product advertisements, and trademark infringement or dilution. Most recently, cases have emerged accusing compounders of selling unapproved new drugs or generic versions in violation of state Food Drug & Cosmetic (FDC) Acts.² These allegations highlight the evolving legal landscape surrounding compounding pharmacies and the challenges they face in navigating regulatory compliance and intellectual property issues.

WHAT DOES FEDERAL LAW AND STATE LAW ALLOW?

Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounded drugs are not FDA-approved and do not undergo premarket

review for safety, efficacy, or quality.

Sections 503A and 503B of the FDC Act set conditions under which compounded drug products are exempt from certain federal requirements, such as pre-market drug approval.³ In some cases, compounds serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product or where the drug is not available either due to shortages, product discontinuation, or other supply chain issues. According to FDA guidance, compounders are exempt from needing FDA approval for their drugs unless what they are compounding is “essentially a copy.”⁴

One of the restrictions of section 503A prohibits compounding products that are essentially copies of commercially available drugs. However, when a drug appears on the FDA’s drug shortages list, some restrictions may be lifted—in particular, restrictions on compounding drugs that are essentially copies of approved drugs.

One reason is that the FDA does not consider a drug to be commercially available when it appears on the FDA’s drug shortages list. If a drug is in shortage, “copies” can be compounded under section 503A provided that the compounding is not done “regularly or in inordinate amounts.” All other conditions of section 503A must still be met, including compounding based on a valid prescription for an identified individual patient.

Each state has its own set of Board of Pharmacy rules that apply to 503A compounding pharmacies, resulting in a patchwork of regulations across the 50 states. These pharmacies must be licensed by the state boards, adhere to all pharmacy rules, and compound according to USP <797> (sterile products) and USP <795>. Additionally, they may only compound patient-specific prescriptions and some limited anticipatory compounding prior to receipt of prescriptions.

BASIS OF CLAIMS OF PATENT INFRINGEMENT

The fundamental aim of pharmaceutical patents is to find a balance between providing incentives for innovation and the costs imposed on the public, such as higher prices and lack of competition.⁵ Patents can claim the chemical compound, i.e., active pharmaceutical ingredient (API), a particular formulation, a method of synthesis or use of the product. Patents grant exclusive rights to manufacture, use, sell, and import the patented product. Additionally, for innovative products, the FDA grants marketing exclusivities upon obtaining regulatory approval.

A patent confers no right to exclude products or processes that do not actually infringe. Claims for patent infringement can only prevail when a 503A is compounding a drug that is “essentially a copy” of a commercially available drug.

Claims of patent infringement for drugs on shortage and hence, not commercially available, will not prevail. FDA guidance on compounding drugs on the FDA shortage list makes no distinction for a patented drug.

If Congress intended to prohibit the compounding of drugs that are covered by a patent, but in shortage, the FDA guidance would have stated that. However, such a prohibition on compounding drugs on patent would not be in accordance with the purpose of permitting compounding of drugs in short supply, which is to ensure patients can continue to access needed and often essential medications despite supply chain issues or disruptions.

Only compounding pharmacies and not their suppliers (i.e., API manufacturers) are exempt from patent infringement. In some of the lawsuits, brand manufacturers claim that generic versions of their products are unapproved new drugs. Since the API is patent-protected, they argue the compounders could not be obtaining API from an FDA-approved manufacturer.

Despite this, API manufacturers are rarely named as defendants in the most recent lawsuits. Generally, lawsuits tend to be filed against the generic drug companies. This may be because patent damages are either calculated as lost profits or reasonable royalty as a percent of infringing sales.

BASIS OF CLAIMS OF TRADEMARK INFRINGEMENT OR DILUTION

Any discussion of trademarks, trademark infringement, and unfair competition must begin with the Lanham Act, which defies the term “trademark” and prevents free riding on a trademark owner’s goodwill and reputation.⁶ Recent cases involving both 503B facilities and 503A compounding

pharmacies have invoked the Lanham Act in different ways.

In some recent 503B cases, the Lanham Act analysis has worked in favor of the 503B facilities in which the plaintiffs were unable to show that the compounder, “made any false description or representation of fact.”⁷ However, many of the recent cases against 503A compounding pharmacies pertaining to compounding of semaglutide involve allegations of trademark infringement,⁸ use of false designation of origin and unfair competition,⁹ and false and misleading advertising and promotion.¹⁰ Trademarks protect the identification of pharmaceutical products.

The allegations state that compounding pharmacies are “passing off” their unapproved compounded drugs purporting to contain semaglutide as Ozempic or Wegovy, or in some cases, promoting their products as these brand products.¹¹ The allegations are that the compounders are using the brand drug’s name on their advertising and promotion on their website and that when viewed by patients seeking to obtain the brand drug, there is a prominent and misleading use of the trademark. It is further alleged that this leads to consumer confusion in which they think they are purchasing the brand product.

In trademark infringement cases, although there is no way to determine how a court will decide a particular case, even where the use of a trademark is without permission, consent, or authorization, the plaintiffs must prove a likelihood of confusion. Additionally, there are some exceptions to the use of another’s trademark in advertisements.

One of those fair use exceptions is in comparative advertising in which advertisements must be truthful and non-deceptive, and the use of a third party’s trademark must be only for comparison purposes or descriptive and not false or misleading. Additionally, the purpose cannot be merely to associate the compound product with the brand product. Each fair use assessment is highly fact-sensitive, and it is advisable to consult with trademark counsel for review of any comparative advertising.

Unlike trademark infringement, trademark dilution is not based on likelihood of confusion, but rather whether the unauthorized use of the plaintiff’s trademark tarnishes or blurs the trademark.¹² Did the use of the plaintiff’s trademark impair the distinctive qualities of the mark? Tarnishment involves an unauthorized use of a mark that links it to low quality products, an assertion common in such cases because of the lack of safety and efficacy, as well as drug approval for compounded products. The burden of proof lies with the plaintiff with both infringement and dilution cases.

CONCLUSION

Pharmaceutical manufacturers are increasing asserting unfair competition and arguing that compounding pharmacies are acting beyond their authorized purpose when they mimic commercially available drugs. However, courts generally find the FDA's guidance on 503A to be persuasive authority. Claims for trademark infringement and dilution are fact specific. Because 503A pharmacies know that litigation is extremely costly, the threat of it often acts as an effective deterrent to 503A pharmacies compounding, thereby achieving the manufacturers' intended goal.

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What is 340B? Exploring Pharmacist Contributions, its Important Role in Hospitals

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It is indisputable that hospitals are indispensable providers of health care services under current complex circumstances and challenges facing our constantly evolving health care environment.¹ Despite its importance, the 340B program needs to receive more attention despite its essential role in supporting hospitals' financial stability.¹

The 340B initiative was established in 1992 to ensure medication manufacturers offer more affordable drugs to covered entities.^{1,2} Hospitals meeting specific criteria, such as catering to uninsured or underinsured populations, can qualify for lower-priced medications under this federally mandated initiative.²

Providing much needed medications at affordable prices is a crucial part of hospital operations because it enables them to manage limited resources efficiently and provide equitable access to necessary treatments, particularly for underserved communities who have difficulties affording treatments otherwise without undue economic hardship placed on them.^{1,3}

Considering these benefits, we must acknowledge just how important initiatives such as the 340B program are, especially when considering patients depending on prompt access to adequate medical care containing life-saving medication prescriptions, among other essentials.³ There is an increasingly vocal public push that recognizes how

escalating drug prices have resulted in higher outpatient care demands.⁴

It is gratifying to see Medicaid expansion plus consolidation efforts for various health care industries leading more hospitals to receive qualified status from involvement with this exceptional national benefit scheme empowering beneficiaries struggling amid challenging times because drug costs continue rising.⁴ At the same time, incomes stagnate further still over time, and their plight elsewhere from affordability issues burden caregivers struggling to support multiple dependents amid health challenges thwarting retaining well-being suffer most setbacks.⁵

By utilizing innovative approaches that promote affordable treatments, health care providers can improve patient outcomes and decrease readmissions.⁵ For instance, providing post-hospitalization delivery services for medications is one of many ways that pharmacists have leveraged the 340B initiative to reduce medication non-adherence rates significantly.⁵

Since it was launched in 1992, participant numbers initially started low, with only around 23.5% of hospitals in 2010 participating. Nearly one-third currently collaborates with outpatient pharmacies as beneficiaries can afford better access thanks to these programs altogether regardless of their original backstories.

All should be entitled to a reasonable quality standard

of care without undue financial strain. The results are that underprivileged individuals are pushed toward getting healthy again by supporting populations who have traditionally faced medical deserts or chronic health inequalities, such as limited mobility or lack of safe living environments among other structural inequities.^{4,6}

Proper support and funding for 340B beneficiaries are critical if we are ever to close the accessibility gap and advance equitable distribution solutions. We must also continue to bolster hospital-level outreach initiatives that seek to promote patient well-being from adverse effects that arise from non-adherence because there is such a gap separating people wanting cost-effective medical intervention requirements amid deepening divisions within our society around issues such as drug costs and inadequate insurance coverage models near or below the poverty line altogether.⁶

Providing greater access to medication leads to better patient outcomes; however, much of this access depends on eligibility criteria for programs such as 340B.^{6,7}

Although debates about financial impacts continue in future decision-making regarding these programs, funds must be allocated accordingly.⁷ Current evidence suggests that hospitals have benefited from participating in this scheme to help offset drug price inflation despite concerns about funding criteria.¹

As medical costs increase nationally, the benefits of this program continue coming off as a critical lifeline providing additional revenue and allowing hospitals the resources to facilitate the provision of essential services and quality care without putting excessive strain on their budgets.^{6,7}

On a fundamental level, initiatives such as the 340B program are fundamental in today's health care environment, not only by supplying marginalized demographics with affordable medication, but also increasing outcomes and reducing readmission rates.^{6,7} The success of the 340B program has allowed Medicaid expansion to provide more facilities access to this resource.⁴

Furthermore, as demand grows for affordable medication due to an aging population, pharmacists occupy a vital role in ensuring optimum implementation.⁷ Through participation in the drug pricing program, which furnish prescription drugs at lowered costs for entities committed to serving those in jeopardy, such resources become more accessible.⁷

Studies depict improvement rates for patients who benefit from pharmacist-administered pharmacy delivery services while the hospital admission process continues resulting in reduced readmission rates.^{7,8}

The general outcome of health care, including cost and intensity, has significantly increased according to recent research between 1996-2013.⁷ Programs such as 340B have revealed that it is essential to recognize financial benefits while offering high-quality health care, ensuring that every patient rightfully gains access to these programs and reducing costs on hospitals, empowering them with more resources.⁹

Pharmacists' positive impact on reducing medication expenses cannot be overstated as they leverage their medication management expertise within hospital settings through collaboration with the 340B program.⁹ Through such collaborations come affordable prescriptions available to underserved populations receiving care in these settings, which supports lessening their readmissions in future follow-up visits.²

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