
2020 NACDS RxIMPACT Day on Capitol Hill

Legislative Requests

1. DIR Fee Reform

Ask: NACDS urges members of Congress to express to House and Senate leaders the need to pass necessary DIR reforms this year and cosponsor the *Phair Pricing Act* (H.R. 1034/S. 640).

To co-sponsor H.R. 1034 contact dan.ashworth@mail.house.gov

To co-sponsor S. 640 contact cassie_leonard@kennedy.senate.gov

- Congress has included critical DIR fee reforms in House and Senate drug pricing legislation. Those reforms include reflecting the use of the fees at the point of sale as well as ensuring that they are based on standard pharmacy quality measures. These critical reforms are needed now to bring down the cost of medicines for patients and preserve community pharmacies that provide vital healthcare access.

2. The Pharmacy Reimbursement Crisis

Ask: Please consider taking the time to tour a pharmacy in your state or Congressional district to hear directly from pharmacists about how declining reimbursements are affecting them and the patients they serve.

- There are now approximately 2,000 fewer pharmacies than just two years ago. Retail pharmacies are in crisis, facing unsustainable financial pressures as they are increasingly reimbursed by payers below the cost of buying and dispensing prescription drugs.
- NACDS stands ready to assist with setting up a tour of one of our member pharmacies in your state or Congressional district.

3. Modernize Consumer and Patient Privacy

Ask: NACDS encourages Congress to work to harmonize privacy protections, while maintaining HIPAA protections in a changing modern healthcare environment.

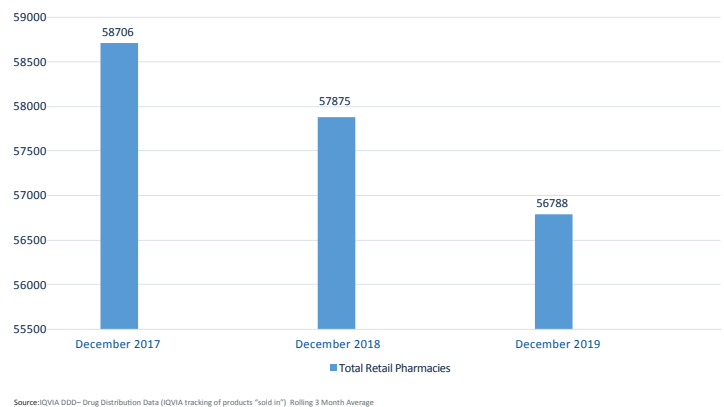
- Congress should implement a comprehensive and uniform Federal standard for patients and providers that preserves privacy and transparency by ensuring patients are clearly informed about how their data is collected and used and maintains the voluntary, mutually beneficial patient-provider relationship, that includes prescription refill reminders, rewards, and loyalty programs.

The Pharmacy Reimbursement Crisis

Retail pharmacies are in crisis, facing unsustainable financial pressures as they are increasingly reimbursed by payers below the cost of buying and dispensing prescription drugs.

- The Pharmacy Closure Epidemic!** Dire financial pressures have caused an alarming number of pharmacies to shut their doors. Payers have increasingly reduced reimbursements; in many cases pharmacies dispense prescriptions below cost. Retroactive fees, known as Direct and Indirect Remuneration (DIR), often occur weeks or months after a transaction closes, when a payer decides to recoup a portion of the pharmacy's reimbursement. These fees have made the economic viability of community pharmacies increasingly difficult, due to the unpredictability of reimbursement and the increased damage to bottom lines. Last year pharmacies paid over \$9 billion in DIR fees. **There are now approximately 2,000 fewer pharmacies than just two years ago¹.**

The number of Retail Pharmacies is 3% lower than 2017 and 2% lower than 2018



- Vital Patient Access is Threatened!** The epidemic of pharmacy closures is reducing access to vital healthcare services, especially in rural areas where options are already limited. Recent polling by Morning Consult confirmed that pharmacies are considered the most accessible part of the healthcare delivery system. However, that accessibility is increasingly threatened as more pharmacies go out of business. A recent study published in the *Journal of the American Medical Association* found that pharmacy closures led to a significant drop in medication adherence for older adults taking cardiovascular medications. **These closures directly impact the health of average Americans.**
- First Steps:** To keep pharmacies in business, serve patients, and protect their access to healthcare, Congress must immediately enact legislation. Important reforms already included in Senate/House drug pricing legislation to reform abusive pharmacy DIR fees, especially the adoption of pharmacy quality measures, are an essential first step to stop the damage being done to important healthcare access. **This is the number one legislative priority of community pharmacy.**
- Long-term Solutions:** In the longer-term, policymakers must act so that pharmacists are reimbursed for the valuable services they can offer to optimize health and reduce the cost of care. The adoption of pharmacy quality performance measures will help establish the foundation for pharmacies to continue to provide vital services and participate in value-based care programs. And the advanced education and training pharmacists receive equips them well to provide services including health tests and screenings, management of chronic conditions and medications, immunizations, and point of care testing (e.g. flu, strep). **Medicare Part B provider status and better integration of pharmacies in value-based care/payment models would allow pharmacists to deliver services that produce better health and provide increased savings.**

¹ Independent data sources have reported that the number of retail pharmacies in the United States dropped by almost 2,000 over the past two years. See IQVIA, DDD – Drug Distribution Data (last visited Feb. 20, 2020) (showing the number of U.S. retail pharmacies dropped from 58,706 in December 2017 to 56,788 in December 2019); National Council for Prescription Drug Programs, dataQ (last visited Feb. 20, 2020) (showing 995 pharmacy profiles closed in 2018 and 695 pharmacy profiles closed in 2019).

DIR Fee Reform: Reducing Costs, Improving Health

Please ask Congressional Leadership to pass legislation containing important DIR fee reforms this year, and co-sponsor H.R. 1034/S. 640, the *Phair Pricing Act*.

Direct and indirect remuneration (DIR) fees are loopholes used by payers to claw back reimbursement paid to pharmacies for prescriptions. DIR fees result in higher costs for patients. This negatively affects “medication adherence” - it dissuades people from taking medications as prescribed. This leads to diminished health, reliance on more costly treatment, and higher overall healthcare costs.

The Centers for Medicare & Medicaid Services (CMS) recognizes that “when pharmacy price concessions are not reflected in the price of a drug at the point of sale, [patients] do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug.” *83 Fed. Reg. 231, 62174 (published Nov. 30, 2018)*

Congress has included DIR fee reform in House/Senate drug pricing legislation. Those reforms include reflecting the use of the fees at the point of sale as well as ensuring they are based on standard pharmacy quality measures. These critical reforms will bring down the cost of medicine for patients and preserve community pharmacies that provide vital healthcare access to millions of Americans.

DIR reform reduces patient cost sharing for medications.

Reforming pharmacy DIR fees will save patients \$7.1 to \$9.2 billion over 10 years.

83 Fed. Reg. 231, 62154 (published Nov. 30, 2018)



DIR reform increases the likelihood that patients take their medications as prescribed.

A review of 160 studies revealed that medication adherence significantly decreases as the medication cost to the patient increases.

Eddy MT, et al. “How patient cost-sharing trends affect adherence and outcomes.” Pharmacy & Therapeutics, January 2012.



DIR reform allows patients to stay healthier, and avoid more costly care.

Disease-specific cost of non-adherence is estimated up to \$44,190 per person, and costs attributed to ‘all causes’ non-adherence is estimated up to \$52,341 per person.

Cutler RL, et al. “Economic impact of medication non-adherence by disease groups: a systematic review.” BMJ Open, January 2018.



DIR reform lowers overall healthcare costs, saving the Federal government money.

If 25% of hypertension patients who were non-adherent became adherent, Medicare could save nearly \$14 billion annually, averting over 100,000 emergency room visits and 7 million inpatient hospital days.

Lloyd JT, et al. “How much does medication nonadherence cost the Medicare Fee-for-Service Program?” Medical Care, January 2019.



A Way to Reduce Out-of-Pocket Drug Costs: What Will You Do?

Steven C. Anderson, IOM, CAE

President and CEO, National Association of Chain Drug Stores

A simple truth is emerging about the complex topic known as pharmacy direct and indirect remuneration (DIR) fees: they are as damaging to patients and to pharmacies as advertised.

DIR Fees: A New Record and a Realization

Adam J. Fein, Ph.D., CEO of Drug Channels Institute, on February 13 announced his analysis that these fees “have grown faster than most people realize” – and reached a record \$9.1 billion in 2019.

Dr. Fein wrote powerfully:

“Our long time readers know that I’ve been skeptical about pharmacy owners’ claims regarding the impact of DIR fees. But it does now appear that these payments have become a significant economic burden. When the facts change, I change my mind. What do you do?”

Those not familiar with DIR fees may appreciate an explanation. Conveniently, the term “DIR fees” coincides nicely with the word “dire,” which pretty much sums them up.

DIR Fees = Dire

More specifically, DIR fees results from a Medicare regulatory loophole. Payers “claw back” reimbursement paid to pharmacies for Medicare prescriptions, claiming that they can do so based on pharmacies’ performance on quality measures. However, these metrics can lack transparency, vary widely, impose unattainable requirements, and relate to topics out of a pharmacy’s control.

Two important results flow from this dire situation: these DIR fees needlessly inflate patients’ out-of-pocket drug costs at the pharmacy counter, and they also are forcing pharmacies of all sizes to fill many prescriptions below-cost – an unfair and unsustainable situation.

The Centers for Medicare & Medicaid Services has estimated that patients would save \$7.1 billion to \$9.2 billion over 10 years in cost sharing if DIR fees were reformed.

Reform also would help to confront the unsustainable situation faced by pharmacies. IQVIA – which specializes in healthcare data – found that about 2,000 pharmacies have closed in the past two years.

Research demonstrates that higher out-of-pocket costs and pharmacy closures both contribute to medication non-adherence, or the failure to take medications as prescribed. This leads to poorer health, increased reliance on more drastic forms of care, and higher healthcare costs.

A study published in January 2019 in *Medical Care* found that if one-quarter of hypertension patients who were non-adherent became adherent, Medicare could save nearly \$14 billion annually – preventing more than 100,000 emergency room visits and 7 million inpatient hospital days.

The American Medical Association’s *JAMA Network Open* in April 2019 published a study that found pharmacy closures led to “an immediate statistically and clinically significant decline in adherence.”

DIR Fee Relief Necessary for Drug-Pricing Reform

The recent journey of DIR fee relief has made the most wild roller coaster look tame. Last year at this time, it looked like there could be a chance for relief through a federal regulatory path. That did not happen and necessity has required pursuit of relief at all levels of government.

Among the opportunities now before us, all eyes are on the bipartisan Senate Finance Committee drug-pricing legislation by Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR). Currently, that legislation includes important provisions that would address the ability of payers to “claw back” pharmacy reimbursement, as well as establish standardized and relevant pharmacy quality measures.

In his State of the Union Address, President Trump urged that bipartisan drug-pricing legislation be passed and sent to his desk for signature.

Time will tell if DIR fee relief can finally become a reality, but – as the realities of DIR fees become more and more apparent – time is not on the side of patients, nor on the side of pharmacies.

Dr. Fein posed a question that should be considered by those who would stand in the way of DIR fee relief, or who would tolerate inaction: *“When the facts change, I change my mind. What do you do?”*

Modernize Consumer and Patient Privacy

HIPAA Works

For more than 20 years, the *Health Insurance Portability and Accountability Act* (HIPAA) has protected individuals' privacy with a strong framework of rules and guidance, backed up by consistent enforcement by the Department of Health and Human Services. This framework has also provided HIPAA-covered entities with established parameters within which to operate.

Times Have Changed

Despite this strong framework, the patient-provider relationship has significantly evolved since HIPAA was implemented. Information sharing utilized to optimize care, coordination, and health outcomes now extends beyond the data covered under HIPAA.

Modernize

With a number of states considering their own consumer data privacy measures, now is the time for Congress to take steps to harmonize privacy protections, while maintaining important HIPAA protections in a rapidly changing modern healthcare environment by considering the following:



Implement a comprehensive and uniform Federal standard for patients and providers to interact that encompasses all health-related data. This standard should conform with current HIPAA guidelines and not disrupt the day-to-day practices of HIPAA-covered entities and their business associates.



Preserve privacy and transparency by ensuring patients are clearly informed about how their data is collected and used.



Maintain the voluntary, mutually beneficial patient-provider relationship, including prescription refill reminders, rewards and loyalty programs. A patient-centric approach that allows innovation and the optimization of healthcare resources should remain at the center of efforts.



CLOSED

After 50 years

In the last two years, 2,000 pharmacies have closed for good.

Visit your local pharmacy to hear first-hand about the reimbursement crisis that threatens patient healthcare access.

NACDS invites the 116th Congress to see the impact decreasing reimbursement is having on pharmacies & patients. In the past decade, we have hosted 700 Congressional tours showcasing how pharmacy increases health outcomes and lower costs. The dire reimbursement climate threatens the very ability of pharmacies to remain viable and offer these vital services.

Your NACDS RxIMPACT Pharmacy Tour will showcase:

- Reimbursement issues that threaten **patient access to health care and pharmacy viability**;
- Ways pharmacies **improve patient care access and provide value-based care**;
- Approaches to reliably **reduce patients out of pocket costs**; and
- Pharmacy commitment to **opioid-abuse prevention, and new policy recommendations**.

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