MDedge Rheumatology

PERSPECTIVES

Unintended consequences of perfectly good programs and policies

Publish date: January 18, 2023

By Madelaine (Mattie) Feldman, MD

IN COLLABORATION WITH CSRO
Coalition of State Rheumatology Organizations

Some of our worst decisions seemed like really good ideas at the time. We wouldn't make them otherwise; but often we fall into the unintended consequence of "the cure being worse than the poison." We have seen this when government is trying to fix a problem, often an emotionally charged problem, without considering the long-term consequences of the "fix." We have seen the unintended consequences of certain health care policies and programs lead to abuse and negative downstream effects on the same population that they were intended to protect.

It has been postulated that unintended consequences fall into a framework that's "based upon level of knowledge and the scope for avoidance." Essentially, that means these consequences fall into one of four categories: knowable and avoidable, knowable and unavoidable, unknowable and avoidable, and unknowable and unavoidable.

What category do the following policies fall into?

Pharmacy benefit managers' safe harbor from the Anti-Kickback Statute

Let's start with the "safe harbor" from the Anti-Kickback Statute (AKS) for payments from drug companies to health insurance companies and pharmacy benefit managers (PBMs). The AKS was created in 1972 and its "main purpose is to protect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions." During the 1990s, a number of safe harbor provisions under the AKS were instituted for certain payments to health insurance companies, PBMs, and other providers. The thinking was that these payments needed a safe harbor because, although they might meet the statutory definition of "kickbacks," they were beneficial because they would reduce the cost of care and, more specifically, the prices of drugs.

RELATED

Use 2022's advocacy successes and frustrations as a catalyst for the new year

While well-intentioned, those safe harbors now protect a system of such perverse incentives that patients are whipsawed back and forth onto drugs that are the most profitable for the PBMs, who create the annual list of insurance covered drugs (i.e., the formulary). It is clear now that protected kickbacks ($$), in the form of rebates and fees paid by pharmaceutical manufacturers to PBMs, determine what drugs will be on the formulary. PBMs then use utilization management tools such as step therapy to force patients to take those drugs first. Consequently, safe harbor protection from the AKS allows manufacturers to buy market share at the expense of patient's health. Because these protected kickbacks are based on a percentage of the list price of the drugs, PBMs profit more from higher priced drugs, which PBMs call the lowest cost medications (for them, that is). These bids from various manufacturers can change over the course of a year, allowing PBMs to change formulary coverage (even mid-year) and nonmedically switch stable patients to the drug that is the most profitable. Much of this happens as a result of the unintended consequence of this particular safe harbor from the AKS. Ironically, the safe harbor has helped to create the very behavior that the law was supposed to prevent and has harmed the patients it was supposed to protect. Health care decisions are being corrupted by the influence of profits allowed by safe harbor from the AKS.

340B drug program lacks oversight

Helping hospitals pay for care of the indigent: What could go wrong with that? The 340B Drug Pricing Program was created in 1992 to help low-income patients have better access to outpatient medications. The program requires drug companies to offer deep discounts to safety-net providers and qualified "disproportionate share hospitals," which have a minimum percentage threshold of Medicare and Medicaid patients. The idea was that these qualified entities would pass these savings through to their low-income patients who needed the medications. Sounds like a great idea!

Apparently, there is a lot of money to be made under the 340B program because what started in 1992 with 90 covered entities had expanded by 2017 to more than 12,000 covered entities. The program became a profit center in part because reimbursement for 340B-acquired drugs far exceeds the acquisition costs. Over the years, in order to increase profits, qualified entities, such as disproportionate share hospitals, added for-profit contracted outpatient pharmacies, significantly increasing the amount of 340B drugs dispensed to commercial patients. From 2010 to 2020, the number of contract pharmacy arrangements increased from 2,000 to over 100,000, massively increasing profits for the qualified hospitals and their for-profit contracted pharmacies, which included a number of Fortune 25 companies.

Unfortunately, there is no oversight of 340B programs, and there are no requirements that the 340B drug profits be used for charitable care. In fact, nearly 10 years ago, two experts stated in Health Affairs that, "our findings support the criticism that the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics." In spite of the immense profits generated at 340B hospitals, an analysis by Avalere Health revealed that "65 percent of 340B hospitals provide less charity care than the national average for all short-term acute care hospitals, including for-profit hospitals."

I have seen this dynamic at work in my own community in south Louisiana. There is a major expanding 340B hospital system that refuses Medicaid patients into its clinics once the hospital has reached its minimum disproportionate share of Medicaid patients. Our community has many young female African American patients with lupus, many of whom are covered by Medicaid. Even though this 340B hospital system has rheumatology fellows, it closes its rheumatology clinic doors to patients with lupus who have Medicaid as soon as it has reached its 11.75% of Medicaid patients. Clearly, this is an abuse of a program instituted specifically to take care of those in need – and here in our community, it creates inequitable access to rheumatologic care for patients with lupus.

The statute that created 340B specifically listed certain nonhospital providers who need – and should continue to receive – access to 340B discounts, such as Federally Qualified Health Centers and others. There are many deserving safety net providers and special disease clinics that are taking care of the truly needy and deserve to get the 340B highly discounted drug pricing. However, many so-called nonprofit hospital systems are spreading into wealthy neighborhoods with contracted pharmacies making large profits without caring for those in need. Five years ago, the U.S. Government Accountability Office stated that more oversight of the 340B program was needed, but that still hasn't happened. The combination of vague statutory language and a lack of oversight has led to unintended consequences of fraud and abuse of the system, with indigent patients not realizing the benefit of the steep discounts, being sued when they can't pay their bills, and even turned away from clinics when the qualified hospital reaches it mandated minimum of Medicaid patients.

Knowable and avoidable?

Should it have been known that these abuses would result from these policies and programs? And if so, could guardrails have been put in place from the start to avoid these abuses? Maybe the answers to these questions are irrelevant: All we can do now is fix what is not working, which will require changes and oversight to ensure that the safe harbor policy and 340B drug discount program are achieving the desired ends. At this point, unfortunately, it is clear that they're not. In fact, it looks like they have enabled "profits over patients" all the way.

As recently stated by Dr. Megan Ranney of Brown University: "In this country, we continually forget that the profit motive is not sufficient for the public's health." Yes, hindsight is 20/20. But now we need to take off our blinders, see what is happening, and act to finally put "patients over profits."

Dr. Feldman is a rheumatologist in private practice with The Rheumatology Group in New Orleans. She is the CSRO's Vice President of Advocacy and Government Affairs and its immediate Past President, as well as past chair of the Alliance for Safe Biologic Medicines and a past member of the American College of Rheumatology insurance subcommittee. You can reach her at rhnews@mdedge.com.