The recently passed Inflation Reduction Act made fundamental changes to federal health and climate policy. The law was unexpected and unusually broad. Barely a week before the Senate passed the bill, there was no sign of pending legislation. Three weeks later, the bill was signed into law.

Some parts of the legislation were expected in any budget deal, including extending the enhanced subsidies for the Affordable Care Act’s marketplaces, first enacted as part of the American Rescue Plan Act of 2021. The enhanced subsidies are now in place through 2025 and may well become permanent.

The changes to Medicare’s purchases of prescription drugs were particularly unexpected and are more controversial. Medicare purchases pharmaceuticals through 2 mechanisms: through Part D for prescribed drugs dispensed through pharmacies, and in Part B for physician-administered drugs. Each of these programs will undergo changes.

For Part D, beneficiary access will be improved in several ways. For the first time, there will be a limit on total spending for prescription drugs, $2000 per year. In addition, cost sharing for Medicare beneficiaries who use insulin will be capped at $35 per month and vaccines covered under Part D will be available without cost sharing. Several million people will benefit from these provisions, and the use of pharmaceuticals will increase accordingly.

The pharmaceutical industry will face several cost-reduction provisions, however. Starting in 2023, pharmaceutical companies will have to pay rebates to Medicare if their Medicare prices increase more rapidly than inflation. This provision applies to almost all Part D drugs, along with single-source and biologic drugs covered under Part B. Such inflation rebates are already in place for Medicaid and thus are familiar to market participants.

Most controversially, the bill requires Medicare to negotiate prices for a small set of drugs. In all, up to 60 drugs will be subject to negotiation, spread over a 4-year period from 2026 through 2029. Negotiations are designed for drugs that are top sellers and have been on the market for many years, but do not have competition. Based on current criteria, the list of drugs subject to negotiation would likely include top Part D sellers such as blood thinners apixaban (Eliquis) and rivaroxaban (Xarelto), and Part B drugs such as the cancer medication pembrolizumab (Keytruda) and the eye disease medication aflibercept (Eylea), which is used to treat age-related macular degeneration, macular edema, and diabetic retinopathy. For drugs that are subject to negotiation, the law establishes a maximum fair price that is roughly 25% below current prices, with the ability for negotiation to take prices even lower. Even without significant bargaining, some price reductions are guaranteed.

Despite the fact that the drug negotiation provision is expected to save only a little more than the inflation provision ($102 billion vs $62 billion over 10 years), much more controversy has attended the negotiation provision than the inflation provision. The Pharmaceutical Research and Manufacturers of America came out strongly opposed to the negotiation provision and has threatened to sue to prevent it from taking effect.

Without precedent of negotiation in Medicare, nobody knows what effect the negotiation provision will have. However, several considerations seem relevant. First, there is likely to be some attempts by pharmaceutical firms to game the system—ie, operating with the rules but finding ways to circumvent their intended effects—to avoid having a drug subject to negotiation. For example,
pharmaceutical companies may be able to sponsor small-scale entry of generics or biosimilars to get around the provision that selects drugs for negotiation on the basis of lack of competition. The fact that the new law does not constrain launch prices is also noteworthy. With the limitation on price inflation enacted as part of the law and the reduction in patient cost sharing in other provisions of the legislation, launch prices may increase. And because people will be better insured, the amount that pharmaceutical companies choose to spend on patient assistance programs is likely to decrease, effectively reducing rebates for a significant share of the population.

When it comes time for the Centers for Medicare & Medicaid Services (CMS) to negotiate with pharmaceutical companies, the outcome of the negotiation may be relatively close to the minimum reduction specified in law because to get a better deal, the CMS would have to be willing to not purchase the medication. Because the drugs being negotiated are high-volume drugs with many users, this threat is not very credible. Knowing this, pharmaceutical companies will not agree to a particularly large discount.

Almost certainly, the best strategy for the CMS and pharmaceutical companies is to make the negotiation about more than just price. It is difficult for negotiations to be harmonious if the bargaining is over a single number, in which a win for one side is inevitably a loss for others. In the case of pharmaceuticals, however, both the CMS and pharmaceutical companies have an interest in ensuring that medications are taken by all patients who need them. Addressing such policies in negotiations could be a way to offset the losses from lower prices. For example, the CMS could push Part D plans to reduce prior authorization requirements on patients who meet clinical criteria, in exchange for more favorable pricing. Similarly, the CMS and pharmaceutical companies could collaborate on patient registries to determine who is appropriate for medications but is not taking them.

Alternately, the CMS and pharmaceutical companies could agree on a tiered pricing structure: a higher price up to some amount of sales and a lower price after that. The lower price would encourage greater use without materially reducing revenues. In the limit, the negotiation could lead to a subscription-type model, such as the one that some states reached with firms supplying hepatitis C medications. States such as Louisiana and Washington paid pharmaceutical companies a fixed amount of money based on what they thought they would spend on hepatitis C drugs at existing prices, but made the payment as a fixed amount.4 Because the overall payment was fixed, any additional use was welcome by states. States thus promoted treatment widely. And because producing additional doses cost pharmaceutical companies relatively little, they were amenable to take in the revenue and treat all comers. A model of this form may not work for all pharmaceuticals—biologic drugs are often expensive to produce, for example—but the idea that additional sales are valuable to both sides could lead to productive negotiations.

Despite the harsh words back and forth, pharmaceutical companies and the CMS have many common interests. If the Inflation Reduction Act can focus attention on these areas of commonality, the law could lead to changes that benefit everyone.
REFERENCES


