



ILLEGAL PRICING INDEX



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The Illegal Pricing Index

By Ken Cuccinelli

Government price controls, wherever and whenever exerted, violate the laws of economics and cause unintended consequences. Price floors cause oversupply and underconsumption, leading to wasted resources. Price ceilings encourage overconsumption and underproduction, leading to shortages. While government routinely ignores these simple truths, imposing all sorts of price controls from minimum wage laws to rent controls, in one critical area of our economy the laws of economics have been, to some extent, respected by the law of the land.

The American healthcare system as a whole is by no means an example of government recognizing and obeying the laws of economics. Despite what many on the political left may claim, the reason healthcare in the United States can be so prohibitively expensive is primarily because the government has perpetually increased its role in it. From subsidizing and providing comprehensive insurance policies that discourage patients and providers from being sensitive to prices, to countless rules, regulations, and taxes that restrict suppliers' ability to enter the market. It is no wonder the cost of healthcare has exploded and now threatens to undermine government finances and the economy as a whole. However, within this morass of unintended consequences of benevolent intentions, what modicum is left of market forces in healthcare has provided Americans with a healthcare system that is still the envy of the world when it comes to innovation and access to new and revolutionary treatments.

Nowhere is this more apparent than in the area of prescription drugs. In most of the rest of the industrialized world, prescription drugs are subject to either outright price controls or de-facto price controls by way of government healthcare monopolies. Yet in the United States, even with massive single-payer programs like Medicare and Medicaid, prescription drug prices are not explicitly regulated. Distortionary policies do exist that drive prices higher, yet drug makers are largely free to set prices that allow them to recoup the massive costs of not just inventing a new drug but also surmounting the regulatory hurdles required to bring that new drug to market. For this reason, the United States leads the world in terms of both pharmaceutical research and development, new drug discoveries, and patient access to new drugs.¹

¹For more see Hedger, Patrick, "Poison Pill: Importing Foreign Drug Price Controls," FreedomWorks Foundation, February 2019: <http://fw-d7-freedomworks-org.s3.amazonaws.com/POISON%20PILL.pdf>

This small area of sanity in our healthcare sector is now under threat, however. A new proposal by the Department of Health and Human Services (HHS), referred to as the International Pricing Index (IPI), would dramatically undermine American leadership in pharmaceutical innovation and risk patient access to life-changing and life-saving treatments. The economic problems with the IPI are significant, but what many have not considered is that the proposal also faces significant legal obstacles, some of which have been erected to prevent exactly this kind of destructive policy. The Department of Health and Human Services (HHS) conducted an analysis that found physician administered drugs in Medicare Part B are almost twice as expensive as comparable ones in other developed economies. HHS began seeking input on a proposal to capture some of the same cost savings. According to the agency, this proposal “would aim to preserve or enhance quality of care for beneficiaries while reducing expenditures for Medicare Part B drugs to more closely reflect international” prices.²

Unfortunately, the proposal that was developed, the IPI model, embodied some of the worst aspects of the command and control policies found overseas, especially in socialist countries and healthcare systems. The IPI proposal would artificially align Medicare Part B expenditures with those overseas for equivalent treatments. Medicare Part B generally covers drugs administered to patients while in the care of their healthcare providers, such as those provided to patients in a hospital. Typically, Medicare payments for Part B drugs are calculated by adding six percent to the average sales price (ASP) of that drug. The ASP is itself based on private market transactions within the United States. Under this proposal, reimbursements would instead be calculated by aggregating sales prices in over a dozen foreign nations, each with some form of outright price controls or de-facto price controls through government healthcare monopolies.

Physicians, hospitals, providers, and suppliers in selected geographic areas would receive drugs from private sector vendors based on the international reference price or IPI. Those outside the trial area would continue operating as normal. The scope of this trial would impact roughly half of the Medicare Part B population.

There are three key legal problems with the IPI proposal.

Perhaps the most pressing legal problem with the IPI is the law under which it has been proposed. The IPI is a product of the Center for Medicare and Medicaid Innovation (CMMI). CMMI is an office within the sub-agency of the Center for Medicare and Medicaid Services (CMS) at HHS. CMMI itself was created by none other than the Patient Protection and Affordable Care Act, better known as Obamacare.

² <https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs>

While Obamacare is sadly still the law of the land, that may not be the case for long. There is a case working its way through the courts called *Texas v. United States*. The crux of the case is simple. In a 2012, the Supreme Court issued its ruling in *National Federation of Independent Business v. Sebelius* and upheld Obamacare's individual mandate (the requirement for individuals to have some form of health insurance or pay a fine) as a tax. However, the recent Tax Cuts and Jobs Act of 2017, while not eliminating the nominal existence of the penalty, reduced the penalty to \$0. While some may argue that it is now simply a tax of zero dollars, the majority opinion in *National Federation of Independent Business v. Sebelius* upheld the individual mandate as a tax because it "yields the essential feature of any tax: it produces at least some revenue for the Government."³ A tax of \$0 clearly does no such thing. The argument of the petitioners in *Texas v. United States* is that because the tax effectively no longer exists, Obamacare as a whole is no longer constitutional given the mandate's interdependence with the other provisions of the law.

The federal government – the defendant in the case – has taken the unusual step of agreeing with the plaintiffs in *Texas v. United States*. On May 1, 2019, the Department of Justice filed a brief with the Fifth Circuit Court regarding a decision by United States District Court for the Northern District of Texas, which struck down Obamacare as unconstitutional based on the \$0 mandate. The Department of Justice brief concludes, "The district court correctly held that the individual mandate is unconstitutional in light of the elimination of its penalty, that the guaranteed-issue and community rating provisions are inseverable from the mandate, and that the remainder of the ACA [Obamacare] is inseverable in turn."⁴

The Department of Justice has laid out a clear and compelling case for Obamacare to be struck down in its entirety. This presents two problems for the IPI proposal. First, should the IPI proposal be finalized prior to *Texas v. United States* being resolved, the latter of which is unlikely to occur before early 2020, the administration will be in a position of arguing that Obamacare is unconstitutional while simultaneously using Obamacare to achieve policy objectives on prescription drug prices. With the IPI proposal facing an inevitable lawsuit, the administration will be before the court with unclean hands in any attempted defense of the IPI.

The second problem is that should Obamacare indeed be completely struck down by the courts, CMMI would no longer exist. If CMMI proceeds ahead with implementing the IPI prior to a decision being reached in *Texas v. United States*, there is a substantial risk of destabilizing the healthcare sector through regulatory uncertainty. The IPI proposal presents a substantial disruption itself, but having to reverse course within a matter of months, as is likely should the IPI proposal be finalized, creates a significant level of regulatory instability which will only exacerbate the crisis of exploding healthcare costs.

³ *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) at 564

⁴ <https://affordablecareactlitigation.files.wordpress.com/2019/05/5c-us-brief.pdf>

The second legal problem for the IPI is its vast size. While Obamacare may ultimately be struck down, for now it is still the law of the land and the law under which CMMI is governed. But, the IPI proposal goes far beyond anything Congress could have ever intended to empower CMMI to do.

The specific part of the statute authorizing CMMI is clear: “The purpose of the [CMMI] is to test innovative payment and service delivery models to reduce program expenditures under the applicable subchapters while preserving or enhancing the quality of care furnished to individuals[.]”⁵

The statute goes on to clarify what a potential test model must do, stating that CMMI “shall select models to be tested from models where [it is] determine[d] that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.”⁶

The proposed IPI would subject 50 percent of Medicare Part B to the IPI.⁷ In addition, HHS Secretary Alex Azar is on record bragging that the impact of the proposed IPI will extend beyond not just the model, but beyond Medicare itself. Secretary Azar stated: “It’s not just patients in areas covered by the model who can benefit, however. As payments within the model are reduced, the average sales price Medicare pays will drop, reducing what patients outside the model pay.”⁸

The impact of the proposed IPI would expand beyond Medicare through its impact on the ASP of drugs covered under the model. As one analysis explains, “The government envisions that to meet the reduced ‘target prices’ that Medicare will pay in the pilot, manufacturers will discount their drugs down to that level. Those discounts will, in turn, reduce drug ASP elsewhere and will consequently reduce the amount that Medicare (and many commercial health plans) reimburse outside of the pilot to providers that continue to buy and bill.”⁹

When one considers the words used by Congress in the statute authorizing CMMI, including “shall,” “test,” and “defined population,” it is hard to imagine that Congress intended for any “test” to alter half of Medicare, let alone spill over into the rest of Medicare and the private healthcare market. Additionally, such an impact reaches far beyond any reasonable definition of a “defined population.” Finally, the use of “shall” in the statute is important as well. Congress did not use suggestive language such as “may” or “should.” “Shall” is not a suggestion, rather it is a word of command in legal language.

In short, CMMI does not have great legal flexibility when it comes to conducting

⁵ 42 USC 1315a (a)(1) (emphasis added).

⁶ 42 USC 1315a (b)(2)(A) (emphasis added).

⁷ <https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html>

⁸ <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-at-brookings-on-drug-pricing.html>

⁹ <https://info.zs.com/activeingredient/trumps-medicare-pricing-policy-could-mean-big-disruptions-to-medical-benefits>

a “test” on a “defined population,” and Congress made this clear in terms that regulators themselves use to impose binding obligations upon the American people. It is not the prerogative of CMMI to either discount or entirely disregard the words chosen by Congress.

Unfortunately, this is not the first time CMMI has taken steps in the direction of expanding beyond its legal boundaries. Fortunately, precedent within the agency is restraining of CMMI when it comes to expansive proposals that go beyond what Congress intended.

In March 2016, CMMI proposed adopting changes to reimbursements under Medicare Part B that were far less aggressive than the proposed IPI. Instead of basing reimbursements on the explicit and implicit price controls imposed by foreign governments, CMMI proposed adopting various tools employed by private sector firms such as hospitals and insurance companies to negotiate pharmaceutical prices. This approach, while more reasonable than essentially adopting the price controls of socialized medical systems abroad, was still seen as far too aggressive for CMMI.

The Obama administration announced in December 2016 that it would not proceed ahead with the model after bipartisan objections were raised, including relating to the scope of the model going beyond the authority of CMMI.¹⁰ The rule was officially withdrawn in October 2017 by the Trump administration.¹¹ Thus, the Trump administration is on record acknowledging the objections to excessive CMMI test models, something which would undoubtedly undercut any legal defense of the proposed IPI model going forward.

The third major legal weakness of the proposed IPI is its straightforward conflict with prior law blocking the federal government from negotiating drug prices. While the 2016 proposed model referenced above was not as aggressive as the IPI model currently under consideration, the two models share a fundamental problem, one that goes beyond even the constraints put on CMMI by Obamacare. What the 2016 model and IPI have in common is the federal government “negotiating” drug prices and using the weight of Medicare to do so. This is something which Congress has very clearly forbidden.

When Congress passed Medicare Part D, providing prescription drug coverage for Medicare participants, it included what is called the “noninterference” clause. This clause explicitly bans the federal government from using Medicare to influence drug prices. The clause states, in part, that HHS “may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors[.]”¹² The statute does not say that such a provision is limited to Medicare Part D, but rather that

¹⁰ <https://www.finance.senate.gov/chairmans-news/finance-republicans-call-for-withdrawal-of-proposed-drug-rule-for-medicare-part-b> and <https://morningconsult.com/2016/11/21/top-dems-urge-administration-not-finalize-medicare-drug-payment-proposal/>

¹¹ <https://www.federalregister.gov/documents/2017/10/04/2017-21420/medicare-program-part-b-drug-payment-model-withdrawal>

¹² 42 USC 1395w-111 (i)

its purpose is “to promote competition under this part[.]” Id. As noted above, sweeping changes to the drug reimbursement models under Medicare Part B would have spill over effects into the price negotiations in the private market. This would appear to be a violation of the noninterference clause.

It may seem imprudent to hamstring the federal government from negotiating for the best drug prices, however, such a restriction is important to have in place. This is because governments hold a monopoly on force. Governments have all the power to tax and regulate the private sector. Given this power, they do not come to the negotiating table with an even hand as would any other private sector actor in a transaction. Governments can threaten and follow through on threats in order to induce transactions that may not have otherwise occurred in the private market. This has the same economic impact as an explicit price control. Prices reduced by force or through the threat of force still result in shortages. This is why Medicare is restricted to basing its reimbursements on the ASP of a drug, or the price reached through private market transactions. On the other hand, the IPI model bases reimbursements on a collection of non-market transactions that occur between foreign governments and drug companies.

If the government is interested in the worthy goal of reducing the price of prescription drugs, it must focus its efforts on ensuring that regulatory and other hurdles or misaligned incentives are not needlessly driving up the ASP of drugs in private market transactions. If private market prices fall, so too will the prices reimbursed by Medicare. This is the only legal way for the federal government to achieve the very noble end of making prescription drugs more affordable without inflicting irreparable damage to critical pharmaceutical investment and innovation that occurs predominantly here in America and not abroad.



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