



# Negotiation Plus

## A Framework for Value-Based Drug Pricing Negotiation

By Topher Spiro, Maura Calsyn, and Thomas Huelskoetter September 26, 2016

Today, pharmaceutical industry executives set the prices that Americans pay for drugs with their own profits in mind, rather than based on how well the drug works. Surveys show that roughly two-thirds of Americans—including majorities of Democrats, Republicans, and Independents—support government action to make prescription drugs more affordable.<sup>1</sup>

This issue brief builds on the Center for American Progress' previous drug pricing proposals<sup>2</sup> and outlines a framework to establish a negotiation process for Medicare and private health care payers. This approach incorporates comparative effectiveness research, or CER, which compares the clinical benefits of two or more treatment alternatives, such as prescription drugs. Backing up these negotiations with the prospect of binding arbitration would empower Medicare and private payers to negotiate drug prices effectively. The Congressional Budget Office has said that Medicare would lack sufficient leverage to negotiate lower prices effectively absent additional policy changes, such as permitting Medicare to establish a formulary, or list of covered drugs.<sup>3</sup> Under this proposal, the existence of the arbitration process would provide the needed leverage for Medicare without the need to develop a formulary.<sup>4</sup>

It is also important to make sure that insurers and other health care payers pass along the savings from these negotiations to consumers. For this reason, drugs with value-based prices will have preferential cost sharing so that patients will be able to afford their medications. And by increasing the prevalence and usage of CER, this framework will also give doctors more information about clinical benefits of the drugs they prescribe, which will help them select the best treatments for their patients.

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### Step 1: CER review determination

Under the new negotiation framework, a drug manufacturer would continue to set the price for a drug after it receives approval from the Food and Drug Administration, or FDA, as is currently the case. During the first three months following FDA approval, the secretary of health and human services could decide to refer the drug for compara-

tive effectiveness research review. In determining whether to do so, she would take into account the drug's current price, prevalence and usage, approved indications, and the number of alternative treatments for each approved use.

The review would be conducted separately by two different certified research organizations, which would be selected automatically from a rotation of qualifying organizations. These organizations would have been previously certified by the secretary; they must be independent, free of any conflicts of interest, and have a transparent methodology that can be reviewed by third parties. They should be nonprofits governed by a board that includes representatives from payers, patients, drug manufacturers, and consumer groups. Moreover, in certifying a CER organization, the secretary should consider groups with different CER methodologies.

Once a drug is selected for review, its manufacturer would be required to submit any existing internal comparative effectiveness data to the certified organizations. These include any data that the manufacturer has sent to foreign regulators as part of the drug approval or pricing processes in other countries. Manufacturers may also use this opportunity to submit any additional data they wish to include.

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## Step 2: Price recommendation report

Nine months after the submission of these data to the certified comparative effectiveness research organizations, the organizations would release a draft price recommendation report. Based on the drug's comparative effectiveness, the report would categorize the drug in terms of whether it provides no added benefit, minor added benefit, or significant added benefit compared with alternative treatments. Added benefits would include improved health status, shortened disease duration, extended life expectancy, reduced side effects, and improved quality of life.

Following publication of the draft report, there would be a 90-day public comment period. The certified organizations would release a final report after considering these comments. If a certified organization felt that additional CER trials were necessary to determine the level of added benefit, then it could petition the secretary for additional time before releasing the draft report.

The report must also include a recommended price for the drug, based on its level of clinical benefit. For most drugs, this will be presented as the average manufacturer price, or AMP, for the standard course of treatment. AMP represents the average price paid by wholesalers or retail pharmacies to drug manufacturers for a drug. The report would use AMP instead of a drug's list price or the average sales price, since list prices do not necessarily correspond to the prices actually paid, and average sales price is generally only calculated for drugs covered by Medicare Part B.<sup>5</sup> For drugs that treat chronic conditions, it would be the average price for one year of treatment.

This CER review and price recommendation process would be funded by reallocating and eventually renewing the fee on insurers that partially funds the Patient-Centered Outcomes Research Institute, or PCORI. In addition, the proposal would require that drug manufacturers pay an equivalent fee. PCORI would be eligible to apply for certification as one of the CER organizations.

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### Step 3: Public- and private-sector negotiations

Since two separate organizations would be issuing price recommendations for each referred drug, these two prices would form the recommended price range. This price range, as well as the additional comparative effectiveness research data and the CER organizations' reports, will give health care payers additional information to inform their negotiations with the drug industry. All payers—including Medicare—could negotiate with drug corporations about the price of a drug.

If the drug's price were already within the recommended range, or if payers were able to negotiate the price to a level within the range, no additional steps would be necessary. In these cases, since the drug's price reflects its benefit to patients, the payer must give the drug preferential cost sharing to consumers.

If, after negotiations, the price offered to the payer is higher than the recommended range, the drug manufacturer must submit to the secretary detailed information about its pricing decision within three months. This information would be posted publicly and include a consumer-friendly report on the following: A justification for the company's list price; detailed data on patient utilization; the costs of manufacturing the drug; the costs of developing the drug; the costs of marketing the drug; the profits the company has made and expected to make from the drug; the company's lobbying expenditures; the company's CEO pay; the company's campaign contributions; and the company's spending on patient assistance programs—both by itself and through charities and other third parties—for the drug.

Moreover, any payer—including Medicare—could request binding arbitration if the price following negotiation remains outside the range.

Once a payer requests arbitration, an arbitrator would be selected from a predetermined list. The Government Accountability Office would create the list of arbitrators, and the final arbitrator would be selected by each party taking turns striking out arbitrators until there is one arbitrator left. Arbitrators must not have financial or personal conflicts of interest. The arbitrator would have access to all of the CER and transparency data, as well as to proposed prices from the two independent organizations and the drug manufacturers.

Absent a settlement, the arbitrator would determine the price. At any time during arbitration, the manufacturer could submit further information and documentation to support its case. If a drug has already been the subject of arbitration for one payer but a subsequent payer is also unable to negotiate a value-based price and requests arbitration, then the final price from the first arbitration process will be used.

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#### Step 4: Protecting against excessive price increases

Of course, the pricing decision made by pharmaceutical executives at a drug's launch is not the only relevant factor. As shown by the recent controversy over Mylan executives' decision to repeatedly increase the price for EpiPens, drug corporations often exploit market conditions to increase prices for existing drugs dramatically, despite the drug itself remaining the same.<sup>6</sup>

For this reason, the negotiation-arbitration framework would not stop after the initial price report and negotiations. After the third year, the secretary may, at her discretion, restart the process by re-referring a drug to the independent organizations for additional review. Some things that might prompt the secretary to do this include significant price increases, the availability of new treatments, or new evidence of a drug's effectiveness. For example, a second review could be triggered by pharmaceutical executives' decision to increase the price of their drugs by more than the Consumer Price Index plus 1 percentage point.

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#### Conclusion

This framework would establish a pro-patient, value-based system for drug pricing. It would accomplish this goal by empowering Medicare and private payers to negotiate drug prices more effectively, while also addressing egregious price increases on existing drugs. Furthermore, it would give doctors more information about the clinical effectiveness of different treatment options and increase patient access to critical medicines by making these treatments more affordable. The government must act to give patients what they deserve: a drug pricing framework that puts their needs above drug corporations' bottom lines.

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## Endnotes

- 1 Bianca DiJulio, Jamie Firth, and Mollyann Brodie, "Kaiser Health Tracking Poll: October 2015," Kaiser Family Foundation, October 28, 2015, available at <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/>.
- 2 Topher Spiro, Maura Calsyn, and Thomas Huelskoetter, "Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices" (Washington: Center for American Progress, 2015), available at <https://www.americanprogress.org/issues/healthcare/report/2015/09/18/121153/enough-is-enough/>.
- 3 Letter from Peter R. Orszag to Sen. Ron Wyden, April 10, 2007, available at <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/drugpricenegotiation.pdf>.
- 4 This proposal is partially modeled after the arbitration process proposed by Richard Frank and Joseph Newhouse in *Health Affairs*. See Richard G. Frank and Joseph P. Newhouse, "Should Drug Prices Be Negotiated Under Part D Of Medicare? And If So, How?," *Health Affairs* 27 (1) (2008): 33–43, available at <http://content.healthaffairs.org/content/27/1/33.full>.
- 5 Daniel R. Levinson, "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2011" (Washington: U.S. Department of Health and Human Services, 2013), available at <https://oig.hhs.gov/oei/reports/oei-03-12-00670.pdf>.
- 6 Sarah Kliff, "EpiPen's 400 percent price hike tells us a lot about what's wrong with American health care," *Vox*, August 23, 2016, available at <http://www.vox.com/2016/8/23/12608316/epipen-price-mylan>.