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Medicare Drug-Price Negotiation — Why Now . . . and How

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Drug spending, price, and affordability problems in the United States stem directly from insufficient competition. In prescription-drug markets in which competition is weak, Medicare's purchasing rules tilt the bargaining process in favor of the pharmaceutical industry at the expense of consumers and taxpayers. That's because the rules in Medicare Part D pit fragmented private plans making purchases on behalf of beneficiaries against monopolistic sellers of drugs delivered through pharmacies. Meanwhile, Medicare Part B is required to passively accept industry prices for clinician-administered drugs. Consequently, Part B drug spending has been growing by 9% per year since 2009, roughly double the rate of Medicare spending as a whole.[1] In these specific markets, a carefully designed Medicare negotiation approach could be particularly effective.

Pharmacy benefit managers and insurers offering private Medicare Part D plans can obtain lower prices on drugs for which generic substitutes are available and on some classes of drugs in which there are brand-name substitutes. But fragmented insurers have little recourse regarding drugs that lack effective competition. Part D spending has also grown faster than average Medicare spending, at a clip of 7.3% per year since its inception.[2] The Congressional Budget Office (CBO) recently reported that in 2015, the net price (after accounting for rebates) for brand-name specialty drugs paid for by Part D was $3,590 per standardized prescription (about 30 days' worth) as compared with the average net price of brand-name nonspecialty drugs of $210.[3] The result is that 63% of the spending growth in Medicare Part D between 2010 and 2015 was attributable to new specialty drugs.

Specialty drugs are high-cost, are often aimed at smaller patient populations, require careful clinical supervision, and are delivered through specialty pharmacies. These drugs are frequently biologic products and typically have few, if any, competitors.

Today, much pharmaceutical research and development targets specialty drugs that will become de facto monopolies and remain so for a long time, distorting the balance between encouraging innovation and protecting consumers' interests. As a result, launch prices and subsequent price inflation are higher than credible measures of fair market value. We believe that a targeted bargaining strategy using tried and tested arbitration techniques could help Medicare better balance innovation and affordability. Allowing the government to negotiate on behalf of Medicare, and possibly for other drug buyers that have weak bargaining power, could lower excessively high prices, even as the parts of the market where competition works reasonably well are left alone.

It would be essential both to target the right drugs and to establish reference prices to guide negotiation. The former requires identifying drugs that lack competition and for which the payoffs of negotiation are likely to be significant. We recommend that at least one of two criteria be met

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before price negotiation is invoked. The first is thin competition and high markups. Markets with one or two competitors in the same drug class (defined by the mechanism of action) and drugs for which few manufacturer rebates are offered could be defined as having weak competition. A recent CBO study revealed that average rebates for brand-name specialty drugs amounted to 13% of the list prices, as compared with 35% for brand-name nonspecialty drugs.

The second selection criterion would be the level of Medicare spending on the drug: negotiation should be able to result in enough savings to Medicare to justify the administrative burden it imposes. For example, in 2015, the lowest spending level identified by the CBO for a top-10-selling specialty drug under Part D was $790 million. Substantial savings would probably be achieved by using current annual spending of more than $500 million on a given drug as a criterion for negotiation.

Given limited negotiation resources, a case can be made for requiring both criteria to be met as a rule, and certainly the markup will be relevant to selecting drugs that have high sales volume, since these factors together determine the level of savings. But absolutely requiring that both criteria be met would create an even stronger incentive for pharmaceutical companies to develop small-market drugs and charge very high prices — the current major problem with biologics sold through Medicare Part B.

We believe that an effective negotiation process would require three critical elements. First, Medicare would require the power to refuse to pay exorbitant prices — that is, to impose a substantial penalty on manufacturers unless a reasonable price could be obtained. This rule would encourage both parties to bargain in good faith. Medicare would like to provide effective new drugs and claim that they've been made more affordable, and drug companies would rather sell products at smaller profits than lose the revenues from such a large market. Negotiation and compromise would permit achievement of both objectives. The ability to invoke compulsory licensing (mandating that other firms be allowed to copy patented drugs), by contrast, would render intellectual property rights not worthy of investment, and the power to compel licensing if negotiations failed would compromise the government's incentives to bargain in good faith.

Second, if upper and lower limits on possible prices were set as guardrails at the outset, taxpayers would be protected from poor bargaining by the government, and industry would retain incentives to innovate. We favor reference prices that reflect incremental clinical value per dollar. Though it's not perfect, dollars per quality-adjusted life-year (QALY) gained, a commonly used measure, or a similarly constructed index of therapeutic gains, could be adopted.[4] Using such an index would improve Medicare drug-pricing policy: an upper-bound price based on dollars-per-QALY would signal to drug developers that they will get higher U.S. prices if and only if they deliver greater clinical value. Such an approach encourages development of exactly the kinds of new drugs we need most.

Third, to settle impasses, a third-party, neutral arbitrator (outside the Centers for Medicare and Medicaid Services and the Department of Health and Human Services) could evaluate competing price proposals from the industry and from Medicare and choose the one that would best balance innovation incentives and affordable access to care. Arbitration encourages negotiated settlements because of the uncertainty created for both sides by a third party's intervention. Constraining the arbitrator to select from one of the actual bids, as in Major League Baseball, would encourage reasonable bids by both parties. And the fallback for failed negotiation would not be an arbitrarily low price dictated by the government that would threaten innovation. The arbitrator would enter the process only if there were an impasse after, say, 3 months. The experiences both with Germany's drug-pricing system and with labor negotiations between local governments and unions representing public workers that are prohibited from striking indicate that only 20 to 25% of negotiations conducted according to these rules end up requiring arbitration.[5]

A relatively small number of specialty drugs account for a large part of the growth in U.S. drug spending.[1] For example, the CBO estimates that the top-10-selling specialty drugs accounted for $18.5 billion in Part D outlays in 2015. Thus, permitting Medicare to negotiate over a limited number of products that face weak market forces can have a big impact on the country's drug price and spending problem.

Setting a limit on what Medicare will pay when markets are not working will signal a certain market discipline and help focus negotiations in a way that limits the imbalance of market power between pharmaceutical manufacturers and purchasers. The negotiation process would promote voluntary settlements and redirect

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development toward higher-value clinical targets. Using negotiation for a limited number of drugs is administratively feasible and not disruptive of the overall market. Common-sense policy calls for intervening when markets fail consumers and taxpayers. Such targeted negotiation would end the blank-check approach to pricing of specialty drugs that drives our drug spending and affordability problems.

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Talking about Toxicity — "What We've Got Here Is a Failure to Communicate"

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"Safe and effective." "Manageable toxicities." "Generally well tolerated." Medical journal articles, often in the field of oncology but increasingly in other specialties as well, propagate such reassuring characterizations of new therapies. But these seemingly straightforward descriptions belie patients' complex and varied experiences. In one study comparing two treatment regimens in patients with metastatic colorectal cancer, adverse events led to discontinuation of chemotherapy in 39% of patients in one treatment group and 27% in the other. In total, 13 people died from an adverse event.[1] The investigators concluded that "treatment was well tolerated." In a study of 50 patients with advanced Merkel-cell carcinoma, 28% of participants had a grade 3 or 4 treatment-related adverse event, which led to discontinuation of treatment in 14%; one of these events was a death.[2] The therapy was reported to have "a generally manageable safety profile." Similar examples are everywhere. A Google Scholar search reveals more than 50,000 occurrences of "generally well tolerated" since 2000. We are reacting to this conventional way of writing about treatment effects from our varied perspectives as physicians and patients.

Improving physicians' communication with patients about possible risks and benefits of treatments has long been recognized as a critical priority.[3] But perhaps a necessary first step is for investigators to communicate with clinicians openly and specifically about the toxic effects of treatment. If, instead, we continue to fill medical journal articles with language that glosses over the complexity inherent in using potent treatments in sick patients who have otherwise fatal diseases, we should not be surprised that this language is adopted by the lay press, where the public reads it and our patients are left with an inaccurate picture of what lies ahead. In fact, a lay-press translation is no longer even necessary in an era when medical publications are readily available to patients and families for their own review and interpretation.

A phrase such as "generally well tolerated" can mean very different things to different reasonable people. Without many more words, the language could be made much more precise. When clinical investigators refer to a toxic effect as "manageable" or a treatment as "well tolerated," they are usually attempting to convey one of three scenarios.

In the first scenario, "generally well tolerated" or "manageable toxicity" means that many — perhaps even most — people who received the treatment may have experienced grade 1 or 2 adverse effects, defined by the National Cancer Institute as health effects necessitating no more than local or noninvasive intervention.[4] For example, such effects include anemia not necessitating transfusion and fatigue that does not limit one's ability to perform self-care activities of daily living (but might limit one's capacity for instrumental activities of daily living

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