

Economic Impact of CMS' Proposed Any Willing Pharmacy Policy

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In its Notice of Proposed Rulemaking for 2019, the Centers for Medicare and Medicaid Services (CMS) has proposed what it characterizes as a clarification of existing policy regarding the requirement that prescription drug plans (PDPs) offer a standard contract to “any willing pharmacy (AWP).” Under this “clarification,” PDPs would be prohibited from refusing to offer standard contracts to pharmacies that offered pharmacy services other than retail pharmacy services. PDPs would also be required to disclose the terms and conditions of the standard contract to all retail pharmacies by September 15 of the year prior to the contract year.

In the Economic Impact Analysis presented in Section V of the proposed rule,¹ CMS indicated that this policy, as a clarification of existing policy, would have no economic impact. The Pharmaceutical Care Management Association (PCMA) engaged us to evaluate this contention, and to provide an estimate of the potential economic cost of this if we found it to have a meaningful economic effect. Our findings are as follows:

- The economic effects of selective pharmacy network contracting flow from the willingness of pharmacies to offer discounts in exchange for enhanced patient volume.
- Any action that excludes pharmacies from the preferred network, for whatever reason, increases the patient volume available to in-network pharmacies, potentially motivating greater discounts.
- Conversely, any action that prohibits exclusion of presently non-contracted pharmacies will dilute incentives for discounting.
- The proposed policy may also affect situations where pharmacies enter into preferred network arrangements because a “standard contract” is not offered.
- We believe that the best measure of the impact of pharmacy selective contracting in Part D is the value of the “direct and indirect remuneration” (DIR) generated in network pharmacy contracts, which we estimate will equal \$7.0 billion in 2019.
- There is, at present, insufficient public information to justify a point estimate of the share of prescription drug volume potentially affected by this policy change.
- Were the total volume of services rendered in preferred pharmacies to decline by as little as 2.5% as a result of this policy in 2019, PDP pharmacy costs could rise by \$175 million, an amount sufficient to classify this policy as “economically significant” under Executive Order 12866.²

¹ Department of Health and Human Services, Centers for Medicare & Medicaid Services, CMS-4182-P, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 82 Fed. Reg. 227 (November 28, 2017) 59486.

² 58 FR 51735 (October 4, 1993).

- Since CMS presents no quantifiable evidence of benefits to offset these costs, this regulatory policy would appear to fail standards for regulatory clearance under E.O. 12866.

Our rationale for these findings is as follows:

Estimates of Pharmacy DIR in 2019

The central value in our analysis is our estimate of the amount of “direct and indirect remuneration (DIR)” attributable to pharmacies. This amount reflects the net value of economic adjustments made, during the course of a year, to payments to pharmacies under a prescription drug plan’s network contract arrangements. In our analysis, we attribute the full amount of pharmacy DIR to the share of total spending incurred under preferred pharmacy networks, since the terms of pharmacy contracts are the net result of selective contracting activity. Thus, in our analysis, if the share of total spending under selectively contracted spending is projected to decline, we predict a proportional decline in the value of DIR attributable to pharmacy contracts.

In building our estimate, we based our projections of pharmacy DIR in 2019 on the following data and assumptions:

- Our projection of the DIR share of gross drug costs is extrapolated from a CMS January, 2017 analysis of trends in DIR.
- We calculated the ratio of gross drug costs to Part D benefit spending by dividing the CMS data for 2010-2015 by corresponding data from CBO Baseline “actual” values for 2010-2015.
- We imputed the calculated 2015 value of 183.2% to the CBO January, 2017 baseline projection of Part D benefit payments in 2019.
- Based on information from several independent sources, we assumed that total DIR in 2019 would be 24% of gross drug costs, or \$46.6B.
- Based on information from the same sources, we assumed that the pharmacy share of that DIR would be 15.0%, or \$7.0 B.

Estimates of Policy Impact

In our analysis of the effects of the proposed policy, we considered the effects of the policy on three groups of pharmacies:

- Those presently being offered an AWP contract, regardless of the pharmacies’ response to that offer.
- Those presently not being offered an AWP contract, but who were successful in negotiating a preferred network contract instead; and
- Those not offered and not entering in to any contract.

In our evaluation of the proposed AWP policy, we concluded that it would have no impact on contracting activity for the first group of pharmacies, since the requirement for offer will have been already met under current contracting practices. Pharmacies not receiving an offer under current contracting practices could, however change their behavior in response to this change. Some of those not offered an AWP contract under current contracting practices would accept the AWP contract offer if it was mandated. And some share of non-offerees who would have otherwise negotiated a preferred network contract in the absence of an AWP contract offer would take the AWP contract if offered. To the extent that either of these behavioral responses eventuate, the pharmacy volume in preferred networks would decline, while the size of the combined network (preferred plus AWP) would increase. The combined effect of these changes would be to reduce the share of network volume generated by preferred pharmacies, and hence dilute the value of the pharmacy DIR preferred contracts generate.

We are unaware of any source of information that would permit us to determine what share of the pharmacy market is not presently being offered Part D AWP contracts under current contracting practices, and hence would be affected by CMS's proposed policy in 2019. CMS, in its proposed rule, cites anecdotal evidence of non-offers, but does not present an estimate of the magnitude of the problem it purports to solve. Hence in our analysis, we have framed the research question in the following way: how large would the effect of CMS's proposed policy have to be in order for the policy effect of this proposed regulation to be deemed "economically significant," and hence subject to scrutiny under Executive Order 12866?³

In the absence of evidence to the contrary, we assume that pharmacies not previously offered AWP contracts would change contracting outcomes 50% of the time if an offer was mandated. Thus, relative to the outcome under current contracting practices, we assume that half of the non-offer population previously entering into preferred contracts would shift to AWP contracts, while half of the non-offerees without contracts would now obtain an AWP contract. We also assume that the non-offeree population would be equally divided into these two groups.

Under this set of assumptions, our model estimates that a pre-policy non-offeree share of total pharmacies of 2.5% would be associated with an estimated DIR reduction of \$129 M in 2019 if the CMS policy is finalized. Thus, in almost any scenario in which non-offers of AWP contracts was material, the CMS proposed policy would have an economically significant impact, and hence should be subject to scrutiny under EO 12866.

Based on these findings, we believe that CMS was technically wrong to conclude that this "clarification" has no economic impact. While CMS may never had intended, as a matter of policy, to permit PDPs to withhold offers of AWP contracts, such "non-offers" apparently exist under current policy and contracting practices. To the extent that they have the effect of increasing incentives for discounting by preferred pharmacies, banning them will impose an economic cost. Our analysis supports the conclusion that if non-offers are material, banning them will impose economically significant costs on PDPs dependent on discounts from preferred pharmacies.

³ The threshold for EO 12866 scrutiny is a single-year impact greater than or equal to \$100 M.