# Abstract: Drug pricing, reimbursement, and drug shortages

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Prescription drug shortages continue to be a vexing US health policy issue. With more than 200 drugs in shortage, including many important oncology medications, the therapeutic implications of these shortages are serious. Some have blamed an apparent increase in the FDA's vigilance for causing these shortages, but the FDA claims its monitoring standards have not changed in over 40 years. Woodcock and Wosinska 2012 (forthcoming) suggest instead that chronic underinvestment in manufacturing quality appears to be a root cause: manufacturing quality is difficult for buyers to observe, and the FDA doesn't have the ability to ensure 100% compliance, so an incentive exists for manufacturers to avoid costly compliance measures – particularly in generic markets where competition is often on price alone. The key remaining puzzle, then, is what is driving the trend in shortages?

Some authors have pointed to Medicare for an explanation of the trend in drug shortages. Many of the drugs in short supply are, in fact, heavily reimbursed by Medicare through its Part B program. Medicare's adoption in 2005 of a new Average Sales Price (ASP)-based reimbursement scheme was a significant change from the previous AWP-based system—a change that in many cases reduced payments to doctors for Part B drugs. Yurukoglu (2012) examines the effect of these price changes and finds a positive correlation between the Medicare market share for a drug and its likelihood to be in shortage. His theoretical model of investment under uncertainty offers interesting insights into the "underinvestment" problem.

In this paper, we explore the specific mechanisms connecting reimbursement policy with pricing and shortages. This work is grounded in the basic idea that market shortages are generally tied to fixity in prices. An excess of demand relative to supply in the traditional neoclassical framework generally means that prices are simply "too low," and in a market where prices are free to adjust, they will be bid up until the point at which supply and demand are once again in equilibrium. In this sense shortages should be no more than a transitory condition as market prices adjust in response to adverse supply shocks. We ask the question: to what extent do price fixities exacerbate shortage conditions?

We therefore focus on special features of these markets, such as third-party reimbursement, that may introduce fixity into prices. A leading candidate is the Medicare ASP system, which limits upward (but not downward) mobility in prices. Under this system a provider is reimbursed by Medicare at 106% of the average price at which a Part B drug was sold two quarters before. For its average customer, therefore, the most a manufacturer of a Part B-reimbursed drug can raise price is about 6% above its prices from six months prior (about 12% per year) without forcing customers to accept a loss on reimbursements from Medicare. Although firms may nevertheless be able to impose these conditions on their customers, it is clear that the ASP reimbursement system imposes unique considerations for pricing and therefore quantity supplied to the market in the event of a supply shock. This mechanism may explain a greater severity and duration of shortages post MMA, but it would not necessarily explain why shortages appear to happen more frequently and/or outside the Medicare context. These questions may be best addressed in the context of a more complete model of endogenous investment decisions.

After introducing a simple theoretical framework for understanding the potential pricing effects of ASP-based reimbursement, we turn to empirical testing to determine whether the ASP system has indeed reduced upward flexibility in upstream prices for Part B drugs since its introduction. We will then turn to examining the empirical linkages between these price patterns and patterns of shortage. If these linkages

are demonstrated, it suggests the use of a policy that selectively allows upward price flexibility in times of shortage. Medicaid already employs a version of this when it periodically suspends the use of Federal Upper Limits and reverts to AWP-based reimbursement of generic drugs when shortages arise. With the ASP-reporting system in place, it would be relatively straightforward for Medicare to safely re-institute ASP-based reimbursement at the right time. Although this work illustrates some potential flaws in the Medicare ASP reimbursement scheme, there also exist potential solutions short of abolishing the use of ASP. We also explore alternative policy mechanisms, such as contracting for insurance from sellers against shortages. However, spillover effects and free-ridership appear to be significant roadblocks for these alternatives.