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Inside CMS - 11/10/2011

HHS Rejected ASP Hike After Weighing GPO, Drug Distribution Issues

Posted: November 9, 2011

The Obama administration decided against including Medicare Part B reimbursement changes in its plan to alleviate drug shortages after factoring in the role of group purchasing organizations and other complexities involved in hospitals' purchasing of drugs, an HHS official revealed Monday (Oct. 31). The possibility of hiking average sales price rates come up during recent administration discussions, sources say, and was also floated as an option by former White House adviser Ezekiel Emanuel in a recent op ed piece that pegged the current Medicare ASP formula as a contributor to the shortage problem.

Sherry Glied, assistant secretary for planning and evaluation at HHS, said the department looked at the economic reasons for the shortages, including Medicare reimbursement rates, but added it was not clear that increasing ASP would help. Revamping the ASP formula might not change the prices set by GPOs, she suggested. Instead, the White House issued an Executive Order calling on FDA to better monitor and respond to shortages.

A new economic analysis conducted by the HHS Assistant Secretary for Planning and Evaluation, however, did agree that prices are likely in part to blame for shortages. "In general, the number and severity of shortages in any sector depend on the extent to which the demand for a product and the supply of a product respond to price (the price elasticities of demand and supply)," the report states. "Very low price responsiveness on both the demand and supply sides for many medically necessary prescription drugs means that shortages of prescription drugs (or of upstream Active Pharmaceutical Ingredients -- API) are not an unexpected phenomenon in this sector in the presence of supply or demand changes that are not fully anticipated by manufacturers."

The report, released Monday (Oct .31), also found that drug shortages are nearly always preceded by drops in prices. "Among the group of drugs that eventually experience a shortage, average prices decreased in every year leading up to a shortage," according to the analysis. "In contrast, the average prices of drugs that never experienced a shortage over this period did not change substantially either in the earlier or later period."

In Medicare, injectable drugs are covered under Part B, which currently pays doctors ASP, plus 6 percent to cover the cost of administering the drugs. Emanuel wrote in his op-ed piece that because this system restricts drug prices from increasing by more than 6 percent every six months, prices are not allowed to increase sufficiently to entice new entrants into the generic drug market when there are shortages.

But Glied said it is not clear that raising the ASP formula would do the trick because of the complexities in the drug distribution chain might mitigate that effect. (However, the ASPE report also states that some of those interviewed said hospitals commonly buy drugs from outside GPOs.)

Most hospitals buy sterile injectable oncology drugs through group purchasing organizations (GPOs), which negotiate prices with generic manufacturers on behalf of their clients. Wholesaler buy drugs at the wholesale acquisition price, then sell them to GPO clients at the GPO-negotiated price, and drug makers give wholesalers "chargebacks" if the wholesale acquisition price is higher than the GPO-negotiated price.

The report goes on to describe the complexity of the current Part B drug acquisition process. It notes that generic drug makers could increase inventories, but that likely would increase production costs and the prices paid by consumers. "Failure to supply" clauses could induce manufacturers to hold excess inventories or to increase manufacturing capacity, but those contractual clauses typically are weak, the report states. GPO contracts typically include such clauses, which allow generic drug makers already under contract to meet lower price offers from competing manufacturers. These clauses usually require manufacturers to reimburse GPOs for the price difference between the negotiated price and purchased price, but they provide no reimbursement if there are no alternative sources for drugs, and they do not reimburse for resources expended looking for other sources, and are of limited duration.

Also, the report states that the duration of compensation required under these clauses has diminished over time. Failure to supply clauses are generally limited to 60 days and are becoming narrower. GPOs usually recover only 10 percent of losses due to failure to supply. "Section 615 of the Uniform Commercial Code suggests that failure to provide contracted products is not a breach of contract if the product is not available in the market," the report states. "The erosion of failure to supply clauses in GPO contracts is consistent with the evidence from the FDA and University of Utah data that, until the recent crisis in injectable products, the level of drug shortages was relatively stable and low." -- *John Wilkerson*