What is Causing Drug Shortages?
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Drug shortages have hit Capitol Hill. Not only are lawmakers perplexed, but also the Obama Administration is trying to figure out what has precipitated and is fueling the shortages. The media reports have exploded in recent weeks with stories from around the country about this growing crisis. Treatment delays are occurring and, in some cases, oncologists are forced to change patients’ treatment, often in midcourse, because key cancer-fighting drugs cannot be procured.

The drug shortage situation is very complicated; however, the root cause is not. The problem is grounded in economics and goes back to the way the government fundamentally changed Medicare reimbursement for cancer care in 2003.

Step back for a minute and look at cancer care—it is in crisis. Community treatment facilities are closing and the “market” for cancer care is consolidating, especially as hospitals acquire practices and hire oncologists. Now, we are experiencing an accelerating shortage of cancer drugs—most low cost, but critical injectable generics. The University of Utah Drug Information Services reports that in 2006 there were 3 anti-neoplastic drugs in short supply; in 2010, 23 were in short supply. A series of events, starting with the Medicare Modernization Act (MMA) of 2003, have altered the oncology environment, and we are seeing the “unintended consequences” of public policy play out in drug shortages.

Like any system, cancer care delivery is its own “ecosystem.” Over the past 40 years, we have witnessed an evolution of that ecosystem from largely academic–center based inpatient care to community-based, outpatient care. The evolution was aided by a push from the government in the establishment of diagnostic-related groups (DRGs), in part to use payment reform to force medical care out of the hospital inpatient setting. With the availability of anti-cancer agents with shorter infusion times and supportive care therapy, academically trained oncologists established efficient, outpatient facilities to deliver high-quality cancer care in patients’ own communities. In the process, the United States led the way in developing the cancer care treatment model for the rest of the world. Outcomes, including increased cancer survival rates, were proof of the effectiveness of the system.
Providers Feel the First Impact of the Shock to the Delivery System

In 2003, the government introduced a major shock to the cancer care delivery ecosystem by fundamentally changing the way Medicare paid for drugs. Acting on a belief that oncologists were profiting from the difference between average wholesale price (AWP) set by the manufacturer—Medicare reimbursed for drugs at 95% of AWP—and the actual sale price of a drug, Congress devised a new payment system. With the passage of the MMA, gone was the AWP-based Medicare drug reimbursement system that Congress had created and, in its place, was a new system, which policymakers devised based on the “average sales price” (ASP) of a drug. Not only was the new ASP-based system a theory that had never been tested or piloted, but also it is fraught with problems. First, it requires manufacturers, who are responsible for reporting ASPs to the government, to include manufacturer-to-distributor prompt pay discounts in the calculation of ASPs. Because these discounts are financing terms that do not get passed on to oncology practices, their inclusion has the effect of artificially lowering Medicare drug reimbursement. Also, there is a perpetual 6-month lag in updating the ASP-based payment rates. This adversely impacts oncology practices, which, in effect, subsidize the Medicare system by constantly absorbing price increases that are not reflected in reimbursement rates in a timely fashion.

The changes to Medicare reimbursement for cancer care in the MMA were also intended to better balance payments for drugs and services. While drug reimbursement was drastically reduced with the new ASP-based system, the Centers for Medicare & Medicaid Services (CMS) never carried out the intent of the law by paying for essential, but unreimbursed services, such as treatment planning and survivorship planning. Although CMS put in place two demonstration projects to provide stopgap funding on the services side, when these expired, by 2007 the payment system was unbalanced. This shock to the oncology care delivery ecosystem cascaded as CMS introduced further payment cuts as part of its annual fee-schedule update process. A study by Avalere Health found that, by 2008, Medicare covered only 57% of the cost for just the services—drugs excluded—of providing chemotherapy infusion.

As more private insurers adopted the new government ASP-based system and ratcheted down reimbursement, community oncology practices—delivering treatment to 4 out of 5 Americans with cancer—started feeling the pressures to survive. As of March 2011, the Community Oncology Alliance had tracked over 1000 community oncology practices impacted by the shock that the government introduced, including 199 treatment facilities that were closed over the past 3½ years, 369 practices in financial difficulty, and 315 practices that have merged with hospitals. In fact, mergers with hospitals were up over 40% during the most recent 6-month reporting period. Hospitals are offering the promise of financial stability to oncologists in private
practice facing declining reimbursement and the uncertainty of health care reform, as well as access to 340B drug discounts. The government’s 340B program, which provides deep drug discounts to hospitals and other institutions treating a disproportionate share of low-income Medicare/Medicaid and uninsured patients, has grown since MMA passage. The Health Resources and Services Administration reports that there were 578 340B sites in 2004, which exploded to 2650 in 2010.

Generic Drug Manufacturers Next to Feel the Shock to the System

The old AWP-based reimbursement system allowed generic drug manufacturers to compete on the margins they established by setting a drug’s AWP, which was the basis for Medicare drug reimbursement rates, and then selling the drug at a discounted rate to that AWP. The replacement ASP-based system changed the generic drug manufacturers’ means of competing to solely on actual sales price, versus on margin. That and the 6-month lag in updating Medicare reimbursement rates—requiring cancer practices to subsidize Medicare for manufacturer price increases—has resulted in a new system that is effectively price capped. This can be seen in the steady downward pricing pressure on most generic drugs, which has been obvious since 2005, the year that the ASP-based system was implemented. We have examined the ASPs for some of the top cancer drugs in short supply, and, from 2005 through 2011, have seen close to a 50% drop in prices.

Generic manufacturers have felt additional pricing pressure from an increasing volume of 340B discounts, which manufacturers are required to extend to 340B purchasers. As more oncology practices under reimbursement pressures have been acquired by hospitals eligible for 340B pricing, the volume of these discounts have increased. Furthermore, Medicaid rebates exert further downward pricing pressure on manufacturers.

Consolidating Manufacturing Market Magnifies Every Hiccup

Although, on the surface, declining prices are a positive for payers and patients, the problem is that many cancer injectable generics have reached severely low prices. You have to wonder if manufacturing a $1 sterile injectable cancer drug is economically viable in the long run. In a market that is highly regulated, both in terms of pricing and manufacturing, normal market forces are not in effect. Faced with the prospect of diminishing returns from low-priced, discounted, and rebated drugs, the incentive to stay in the market is reduced. This has led to fewer manufacturers producing these products. As a result, any manufacturing, regulatory, or quality problem that shuts down a production line has a magnified impact on the supply of product. Yes, more manufacturing problems appear to be occurring; but, they are more pronounced in a collapsing manufacturing market. Furthermore, as often happens when products are scarce,
secondary middlemen outside the established distribution chain are hoarding available drugs in short supply and reselling them at exorbitantly inflated prices.

**Solutions?**

Members of Congress on both sides of the aisle are looking for solutions. Legislation in the Senate and House looks to strengthen the warning requirements when manufacturing problems are encountered or producers simply decide to stop supplying product. Additionally, members want to call hoarders on the congressional carpet and legislate constraints on scalping. However, although useful, these efforts are aimed at symptoms and not the underlying disease.

The cancer care delivery system ecosystem has been severely damaged, and solutions have to be found to both stabilize the provider market and provide incentives to manufacturers. (More on solutions in the next commentary.) It is ironic, and very alarming, that, as this crisis unfolds, proposals floating around Capitol Hill as part of the deficit-control process would significantly worsen the problem. These include further cutting Medicare drug reimbursement from ASP + 6% to ASP + 3%, as well as extracting additional Medicaid-type rebates from manufacturers.

In the face of the crisis, the ecosystem is getting even more unbalanced as demand for cancer care is increasing with growing incidence of the disease and is outstripping the supply of oncology providers. This is a time when we need enlightened public policy that will put our nation’s cancer care delivery system back in balance so that Americans now and generations to come can continue to receive the world’s best cancer care.

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