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Reform of the Buy-and-Bill System for Outpatient Chemotherapy Care Is Inevitable: Perspectives from an Economist, a Realpolitik, and an Oncologist

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OVERVIEW

Treating patients with cancer with infused or injected oncolytics is a core component of outpatient oncology practice. Currently, practices purchase drugs and then bill insurers, colloquially called “buy and bill.” Reimbursement for these drugs is the largest source of gross revenue for oncology practices, and as the prices of cancer drugs have grown over time, these purchases have had significant impact on the financial health of practices and pose a risk that jeopardizes the ability of many practices to operate and provide patient care. Medicare Part B spending on drugs is under political scrutiny because of federal spending pressures, and the margin between buy and bill, lowered to 6% by the Medicare Modernization Act and further decreased to 4.3% by sequestration, is a convenient and popular target of budgetary discussions and proposals, scored to save billions of dollars over 10-year budget windows for each percentage-point reduction. Alternatives to the buy-and-bill system have been proposed to include invoice pricing, least costly alternative reimbursement, bundling of drugs into episode-of-care payments, shifting Part B drugs to the Medicare Part D benefit, and revision of the failed Competitive Acquisition Program. This article brings the perspectives of policy makers, health care economists, and providers together to discuss this major challenge in oncology payment reform.

Many alternatives to oncology’s current buy-and-bill system for infused or injected oncolytics have been proposed. Although no single solution has been selected, reform of the system is inevitable. Here we present observations on the current system and its possible reform from the perspectives of an economist looking at the market forces inherent in

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average sales price (ASP)-based pricing, a realpolitik focusing on what is possible in a U.S. Congress fractured by ideology and partisanship, and an oncologist.

THE ECONOMIST

Treating patients with cancer with infused or injected anticancer prescription drugs (oncolytics) is a central component of an outpatient oncology practice. Practices purchase these drugs and then bill insurers for their use to treat specific patients, a system known as “buy and bill.” Spending on these drugs by third-party payers is also increasingly important—Medicare spent approximately 5% (\$125 billion) of the 2013 federal budget on the use of these drugs.¹

From an economic perspective, reform of the buy-and-bill system is inevitable for two reasons. First, these purchases have had a substantial effect on practices’ financial health and have created significant practice risk, jeopardizing many practices’ abilities to operate and provide patient care in the community.² Second, there is widespread perception in policy circles that the system creates a perverse incentive for outpatient oncology practices to use more expensive oncolytics rather than pursuing more cost-effective treatment strategies. These incentives may also place upward pressure on the launch prices of new drugs. This section is a review of the economic rationales and extant supportive evidence underlying these drivers of reform.

An Overview of the Buy-and-Bill System

Fee-for-service (FFS) Medicare is the most prominent U.S. payer for oncolytics, followed by commercial insurers, and then state Medicaid programs. FFS Medicare pays for physician-administered oncolytics through the medical Part B benefit. By law, Medicare does not directly negotiate with drug manufacturers on the prices for prescription drugs covered under the Part B benefit, nor the oral oncolytics largely covered under Medicare’s pharmacy Part D benefit. Section 1861 of the Social Security Act, which requires that the Medicare program cover reasonable and necessary medical services, precludes consideration of cost or cost-effectiveness in coverage decisions.³ The Centers for Medicare & Medicaid Services (CMS) and commercial insurers rely on U.S. Food and Drug Administration approval and authoritative compendia to determine what uses of physician-administered drugs to reimburse, including “off-label uses determined by expert assessments of available supportive evidence.”^{4,5}

Currently, Medicare pays for Part B–covered drugs using an ASP of cancer drugs plus the 6% facilities/operations services fee reimbursement system, implemented in 2006 after the passage of the Medical Modernization Act (MMA) in 2003. ASPs for each Part B–covered drug are calculated and reported by pharmaceutical companies to CMS.⁶ The MMA sets CMS’ reimbursement for these drugs at ASP plus 6%, which preserved the buy-and-bill system while reducing the potentially substantial spread between Part B–covered drugs’ acquisition costs and reimbursement rates. Medicare beneficiaries treated with these drugs are subject to a 20% coinsurance requirement, which is covered under secondary insurance plans for the majority of FFS Medicare beneficiaries.

The Challenges of Using ASP to Reimburse Outpatient Oncology Practices

Although ASP-based MMA reimbursement has led to some of the greatest reductions in Medicare Part B spending in its history, several flaws in the methodology have become apparent to practitioners and policy makers.

First, CMS posts a new ASP every quarter based on information submitted by drug manufacturers 6 months earlier. As a consequence, drug prices commonly increase, whereas physician reimbursement remains stagnant because of the lag in ASP reimbursement policy.⁷ This mismatch between acquisition costs and Medicare reimbursement for a particular drug can result in it being underwater (meaning the buy costs more than the bill) among providers—price increases are borne by outpatient practices until Medicare reimbursements catch up two quarters later.

Second, the lag in ASP-based reimbursement may have some perverse effects on the supply of generic oncolytics that commonly act as the backbones of chemotherapy with more novel agents. Once multiple manufacturers produce a given generic drug, competitive market forces drive their acquisition costs to levels that leave manufacturers very thin margins. If a generic drug manufacturer faces increases in the prices of raw material acquisition or costs of manufacturing and/or distribution, they may wish to pass these cost increases in whole or in part to drug purchasers. The lag in ASP reimbursement, however, forces generic manufacturers to assume all or some of the financial consequences of increased production costs for a defined period of time. Facing this option, generic manufacturers may opt to cease production of these drugs or outsource them to contract manufacturers. This may have contributed to ongoing generic cancer drug shortages.⁸

Third, reliance on ASP as the basis of outpatient oncology practice drug reimbursement has had heterogeneous and unequal effects across providers. On the bill side, practices can have substantially different payer mixes because of socioeconomic characteristics of their location. Commercial payers were slow to adopt ASP pricing and generally continue to reimburse more generously than Medicare, making practices that have richer, commercially insured patients less vulnerable to ASP and its changes.

On the buy side, ASP rewards practices enjoying substantial purchasing advantages that others do not immediately enjoy. For example, institutions that are eligible for 340B drug discounts access drugs at relatively low costs, insulating them from many of the financial pressures independent practices face.⁹ When calculating ASP for purposes of Medicare reimbursement, regulations instruct manufacturers to exclude sales to 340B providers. Hence, Medicare reimbursement rates are not affected by growth in the 340B discount program, although providers' acquisition costs are reduced. Large group and institutional practices with lower drug-acquisition costs have a competitive advantage compared with smaller practices. Large practices typically have better access to capital and favorable commercial contracts compared with smaller practices, allowing them to more easily benefit from any spread between insurer reimbursements and the acquisition costs of drugs.

The risks and inequities in the ASP system have become exacerbated in recent years as the acquisition costs for newly launched Part B–covered oncolytics have increased

exponentially. Many small- to medium-size practices recognize that they cannot risk providing new, expensive therapeutics in the office. An entire clinic can be jeopardized by a failure to be wholly or partially reimbursed in a reasonable time frame for a given dose or cycle of an expensive drug. This is particularly problematic in rural and other underserved areas, where disadvantaged practices must seek size, capital, and management to survive.

Perceptions of Perverse Behavior in Response to Buy and Bill

There are several actors and associated behaviors that policy makers point to as being both related to buy and bill and symptomatic of its unintended consequences.

First, buy and bill sets up a system where oncologists who provide care to patients with cancer face financial incentives to administer intravenous anticancer drugs. In most industries, there is not much difference between wholesale and retail prices, and so they send consistent signals. But when wholesale and retail prices for drugs diverge systematically, incentives for dysfunctional behavior may be created. Oncologists and hospitals profit on the spread between the reimbursed price and the wholesale cost. Malin et al reported that many oncologists report that they face financial incentives to administer anticancer drugs.¹⁰ Evidence also suggests oncologists' drug choices do appear to be responsive to profit margins (for examples, see Jacobson et al 2010 and Conti et al 2012), although there remains controversy about the quality of this evidence.^{11,12}

On a related note, a number of authors have also questioned whether some novel, high-cost chemotherapies are being used inappropriately in clinical practice related to the incentives in buy and bill.^{13,14,15,16} The extent of inappropriate chemotherapy use is a public policy concern because of the cost and potential harms to patients from the use of toxic agents with little likelihood of clinical benefit.^{17,18} It is important to note that the results of the most recent study suggest that physician-administered oncolytics are used off label with a frequency similar to other commonly used medication classes in the nononcology setting (20% to 50%).¹⁹

Second, on the buy side, downward pressure on reimbursement levels in buy and bill may incentivize outpatient practices to substantially shift the risks associated with the buy- and-bill system and/or to seek the lowest acquisition costs available for a given drug. A recent report suggested the share of physician-owned private practices in oncology decreased 10 percentage points between 2010 and 2011, and merger and acquisition activities between community oncology groups and hospitals and large provider groups have increased substantially. According to one estimate, between 2005 and 2011, the amount of chemotherapy infused in community doctor offices decreased from 87% to 67% even as the share of Medicare FFS payments for chemotherapy administered in hospitals (as opposed to outpatient oncology practices) increased from 16.2% to 41%.²⁰

Furthermore, mergers between 340B providers and non-340B providers have substantially expanded the program's reach. One industry source (Biotechnology Industry Organization 2013) predicts that the volume of drug sales under the 340B program will increase from \$6 billion in 2010 to \$12 billion in 2016. This figure includes anticancer and non-cancer drugs. Industry sources indicate that the two therapeutic classes having the largest 340B sales are

anticancer drugs and anti-infectives. These decisions influence the number of available oncology practices in a community, and places upward pressure on the prices paid for the provision of similar services.^{21,22,23}

Finally, ASP-based reimbursement does not appear to curb the initial pricing of a branded cancer drug, most of which now meet or exceed \$10,000 per month of treatment.

Howard and colleagues²⁴ reported that the launch prices of cancer drugs increased 9% to 17% between 1995 and 2012, after controlling for inflation. Because many rebates and discounts are based on a drug's average price, the expansion of rebate and/or discount availability presents pharmaceutical companies with an incentive to set higher list prices to offset discounts. In this way, increases in the number of 340B-eligible providers may have led to upward pressure in the prices paid by noneligible providers.²⁴ This incentive likely acts to inflate the launch prices of new drugs, in part because manufacturers understand that practices may face substantial financial risk if drug prices increase after launch because of the lag in ASP-based reimbursement.

THE REALPOLITIK

It is an open secret in Washington, D.C., that when the Congress or the President are looking for substantial savings to pay for tax cuts or other spending priorities, they go to the Medicare program for the same reason that Willie Sutton robbed banks: that is where the money is. In an ideal world, savings would be achieved through careful consideration of the intended and unintended consequences of the proposed policy reform, but that is not how the process usually works. Typically, a savings target (the amount of money needed to pay for other policy priorities) is established, and the policies that are most likely to be scored by the Congressional Budget Office to achieve this target are chosen. Formulas such as ASP and ASP plus are an ideal target for this type of approach because the math is straightforward. Combine simple math with a strong feeling by many health policy analysts and economists that ASP plus-based reimbursement creates perverse incentives for oncologists to preferentially choose drugs with the highest ASP to maximize revenue, and you have an irresistible target.

Although there are certainly members of Congress who are sympathetic to the havoc that would be created to the financial viability of oncology practices if ASP were to be eliminated, this sympathy has not led to a strong defense of cuts that have already gone into effect. As part of the 2012 budget sequester, Congress mandated CMS to cut Part B drug reimbursement by 2%—the result of which is that drugs are now paid at ASP plus 4.3%. Congress has had two subsequent opportunities to fix this problem with bipartisan budget agreements in November 2013 and November 2014, but not only did the problem go unfixed, Congress extended the cuts to 2024. Specific legislation, HR 1416, was introduced to fix this cut in the 113th Congress and never made it out of any of the three committees to which it was referred, despite having 124 cosponsors. In addition to lack of Congressional support, ASP reductions to ASP plus 3% have been part of the President's annual budget for the last several years. Finally, in a November 2014 hearing of the Medicare Payment Advisory Commission (MedPAC), the commissioners were in agreement that ASP policy

creates a perverse incentive for providers to use more expensive medications rather than trying to control costs.

This leaves two choices for the oncology community: fight any further cuts to ASP and hope that we, as a community, have enough political clout to stop further cuts to ASP, or offer alternatives to ASP that shift our financial model from margins on drugs to one where we get paid to care for complicated medical patients. Receiving new budget allocations from Congress to do this is highly unlikely in the current environment. This means that money already in the system must be reapportioned. The ASP plus formula is not the only source of that revenue, but it is a logical one. However, we can only reapportion that money if it is actually in the system. If we wait too long, and ASP receives further cuts, then that is money we will never get back.

Recent proposals for the reform of outpatient oncology care, including the American Society of Clinical Oncology's (ASCO's) Consolidated Payments for Oncology and the Community Oncology Alliance's oncology medical home-based payment reform, have not received the serious attention that they should have garnered from policy makers, in part because they did not include a proposal for the direct reform of the outpatient chemotherapy administration reimbursement.

Freeing oncologists from dependency on drug revenues while keeping outpatient oncology viable requires a focus on reimbursement for services that are uncompensated or undercompensated in the current system. By seizing on the opportunity to participate in policy makers' active debate on the reform of the outpatient oncology reimbursement system, we can ensure the long-term sustainability of community-based outpatient oncology practice for current and future providers and patients.

THE ONCOLOGIST

At the core of cancer medicine is the delivery of oncolytic therapies and supportive care. For the medical oncologist this means pharmaceuticals, the majority of which are administered in hospitals and clinics. In contrast to oral medications, where direct physician ownership of pharmacy is largely prohibited, oncologists in private practice buy and bill the drugs that they then prescribe and administer. These drugs represent the largest single item expenditure and the largest source of gross revenue for these practices, and, until recently, the margin between purchase price and sale price was the financial driver of oncology infusion suites and oncologist incomes.²⁵ Similarly, hospital- and institutionally-owned oncology clinics gain substantial revenues through outpatient administration of oncolytics, which contributes to the growth of hospital-based cancer programs.²⁰

It would be naive to expect that the medical oncology community would be represented by a single sentiment or opinion about the buy-and-bill system. Varied sentiment may be shaped by physician experience and philosophic or political leanings, site of service, geography, and practice demographics. Likewise, it is naive to believe that payment reforms will impact only one sector of oncology. ASP-based pricing was developed initially for private practice oncology and Medicare, and now it permeates all oncology sites of practice and all payers.

Before the implementation of the MMA in 2003, chemotherapy was paid as a percentage of Average Wholesale Price (AWP). AWP was anything but average wholesale pricing, and it could better be characterized as a suggested retail price set by the manufacturer. Before MMA, there had been steady decreases in Medicare drug payments, and by 2003 Medicare paid AWP — 15%. The mechanics of the process, however, allowed manipulation of the system, and physician margins were commonly 30% to 50% of their purchase price and even sometimes up to 200% to 300% in well-publicized, isolated circumstances.²⁶

With implementation of the MMA's ASP plus 6% drug reimbursement, the margin between buy and bill for Medicare patients substantially decreased for oncologists in private practices. The effect was initially buffered by Medicare demonstration projects, temporary increases in infusion fees, and relatively lucrative commercial contracts. However, over time Medicare discontinued the demonstration projects and allowed deadlines to permanently adjust infusion fees to fall by the wayside, and commercial payers, in efforts to combat escalating oncolytic drug prices, adopted ASP-based reimbursement contracts of their own. Further, the inclusion of approximately 2% prompt-pay discounts to distributors in the ASP calculation, in addition to the inexorable inflation in drug prices combined with a 6-month lag in ASP updates, meant that the margin on Medicare was never really 6%. In 2012, the application of the budget sequester to Medicare reimbursement decreased reimbursement to ASP plus 4.3%. The cumulative effect on the average oncologist's drug margin is such that it is less than 2.3%.²⁷

As margins decreased, the risks inherent to the buy-and-bill system increased. Underwater drugs became common. On the surface, expensive drugs may appear more attractive than a cheaper alternative, but when a drug costs \$5,000 and margins are ASP plus 6% minus 2% (prompt-pay discount), minus 1.7% (sequestration), minus 1.3% (price increase), the reimbursement equals 2% or \$100. If a patient fails to inform the practice of a new Medicare Advantage Plan with a 20% or \$1,000 copay that they cannot pay, the risks are too high. Increasingly, small practices, and even larger ones, report sending some therapies—and more often certain patients, such as those with Medicaid, Medicare with no supplement, and Medicare Advantage Plans with copays on Part B drugs—to hospitals for infusion.²⁸ Brown bagging, the practice of having patients acquire chemotherapy through their pharmacy benefit and bringing it to the clinic to have it infused, or white bagging, the outsourcing of chemotherapy to a specialty pharmacy that delivers it to the practice for infusion, has become increasingly attractive for small practices, some of whom have had difficulty obtaining credit.²⁹

Larger practices, particularly those in mid-size metropolitan communities with a large community presence, have survived and may continue to thrive in this environment. They have greater buying power and may be able to buy drugs at less than ASP, though the average in ASP requires that their largess be to the detriment of the smaller practice who will find that they then buy at more than ASP. The mega-practice may also have an upper hand in negotiations with commercial payers and benefit from diversification of revenues, capturing downstream revenues such as imaging and pharmacy.³⁰ Likewise, hospitals with 340B discounts, facility fees, inpatient and outpatient downstream revenue, and commercial

contracting leverage do not feel the same pain wrought by the decreasing margins in buy-and-bill chemotherapy.³¹

Given the history, it should be no surprise that the oncologist's sentiment is shaped by personal circumstances. Stereotypical as it may be, it appears that there are four popular responses to the notion of reforming the way we pay for chemotherapy: (1) discouraged and resigned, (2) embittered and angry, (3) removed and aloof, and (4) engaged and innovative.

Discouraged and resigned oncologists have seen and are dismayed by an inexorable increase in the price of oncolytics. The only response they see from policy makers and payers is to decrease the margins available to physicians. They take note that every White House budget proposes paying a lower margin on ASP and they fully anticipate that there will eventually be no margin. Many of them practice in small groups of less than five medical oncologists. They already shift as much risk as possible to hospitals, are acutely aware that they cannot administer the drugs that are underwater this month, brown bag when necessary and are arranging for white bagging, and have a tenuous, at best, line of credit with their distributors. They have or plan to cut staff to bare bones and are actively exploring retirement or negotiating a new employment arrangement. They are too busy generating Evaluation and Management Services to participate in ASCO or state societies. They just wish buy and bill would go away.

To be embittered and angry, physicians have to have practiced long enough to remember buy and bill the way it used to be. Many of the most successful and largest private practices are populated by the embittered and angry. Proud of their independence and the good care that they give their patients, community oncology is a way of life to be defended and fought for. To criticize buy and bill is to criticize their culture, and they feel that ASCO has failed to adequately defend and fight for it. As hospitals grow through acquisition of independent oncologists, they feel further threatened by the relative wealth afforded by facility fees and 340B and angrily seek to level the playing field.

Removed and aloof could be used to characterize many of our young oncologists, indifferent because they do not know better and are content with avoiding the fray through employment. These terms could also be used to describe some oncologists who have left independent practices for the refuge of hospitals, but these should be lumped in with the discouraged and resigned; instead, think of the oncologist who has always been employed and has felt above the fray because of it. They can be found among new hospital partners and in academic institutions. They are proud that their salaries are not tied to how much chemotherapy they prescribe or how expensive the drugs they use are, and they are convinced that their private practice brothers and sisters have succumbed to practice by the margins. They seem oblivious to the fact that the administrators who negotiate their institutional contracts are very much aware of the margins on the drugs they order, or that, should the profit center they work in become a cost center, it may well turn their well-ordered world upside down.

Many oncologists are engaged and innovative. They are growing medical oncology homes, communicating with their local accountable care organizations, engaging with payers to

explore payment reform pilots, and building relationships with their representatives in Congress. Many have recovered from discouragement and resignation or evolved beyond bitter and angry, and the lines between community and institution have been blurred. Work is being done by the Clinical Practice Committee's Payment Reform Workgroup to explore alternatives to ASP-based reimbursement to include bundled payments, least costly alternative, shifting Medicare Part B drugs into Medicare Part D, invoice pricing with oncolytics management fees, government/payer negotiation of drug prices, value-based payment, and revamping the Competitive Acquisition Program.

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KEY POINTS

- Reform of buy-and-bill chemotherapy is inevitable due to the financial risks it poses on practices and the widespread perception that it incentivizes increased utilization of the most expensive oncolytics.
- Challenges imposed by ASP-based reimbursement include underwater drugs, generic drug shortages, direction of underinsured and uninsured patients from private practice to more expensive hospital outpatient departments, and consolidation of oncologists into mega-practices and hospital employment.
- Although the U.S. Congress has not yet heeded regular calls for reductions in ASP plus 6% by presidential budgets and MedPAC, neither has it succeeded in removing prompt pay discounts from its calculation after 10 years of lobbying, and calls to fix the disproportionate impact of sequestration on oncology have been given only lip service by legislators.
- Though the failings of the buy-and-bill system impact all oncologists, small independent practices shoulder the greater burden, and their very existence, and with it access to care for many of our most vulnerable patients, is threatened.
- Oncologists are encouraged to be engaged and innovative in seeking alternative payment systems for buy-and-bill chemotherapy that will complement reforms of fee-for-service medicine. Possibilities include bundled payments, least costly alternative reimbursement, shifting Medicare Part B drugs into Medicare Part D, invoice pricing with management fees, government/payer-negotiated drug pricing, value-based payment formulas, and revamping the Competitive Acquisition Program.