Under Pressure:
Oncology Drug Costs in the State of Maryland

Focus Paper

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Healthcare in the United States is an affair of state. Health insurance is regulated by state authority; Medicaid regulations vary by state; and state boards of physicians, nurses, and pharmacists, among others, dictate practice guidelines, supervision requirements, and education. Certificate-of-need regulations vary by state. Maryland has proven to be among the most innovative in involving itself in the form and function of healthcare services, and this innovation in healthcare services delivery and reimbursement has been extremely effective in limiting costs and refocusing hospitals and healthcare provider efforts toward improving population health, increasing access to care for all patients, and creating collaborative care models between institutions. Although these accomplishments should be lauded and the concept of regulated rates for hospitals could very well be replicated in other states, unforeseen consequences have created enormous cost pressures in some of the most critical care-delivery systems for patients. This paper explores the impact of Maryland's cost-control measures on oncology drugs dispensed in the hospital setting that have caused a tremendous shift of financial risk from payers to hospitals and created a threat to financial stability as well as the ability to provide critical hospital-based services to its community. The interventions taken by one Maryland community hospital to address this issue and the results of those interventions illustrate the challenges of reconciling the impact on hospital finances. Healthcare administrators can study this situation to better understand the nexus of cost and reimbursement outside of the fee-for-service system. This complex issue provides a warning to policymakers that reducing costs in healthcare simply defers the impact to other stakeholders. Just as every joke has a victim, so too every healthcare cost reduction has a victim. In Maryland, that victim is the community hospital.

**History of the Maryland Regulated Healthcare System**

In response to rising hospital costs, in 1971 the state of Maryland decided to develop an alternative structure for hospital reimbursement. The goal was to establish a revenue cycle that seemingly ignored individual insurance reimbursement levels and incentivized hospitals to provide comprehensive and complete levels of care regardless of payer. This process established a state commission named the Health Services Cost Review Commission (HSCRC), essentially applying the model of a regulated state utility to hospital payments. The system became known as the “all payer system,” as all insurance payers reimbursed hospitals at the same level through the rate system. The trade-off was that reimbursement to hospitals was strictly regulated and did not follow Medicare (and thus private payer) increases, thereby creating a nearly impossible business environment for for-profit and physician-owned hospitals. As Medicare pays hospitals through its Part A system, and physicians through its Part B system, separating payment from Medicare Part A gave the Maryland system another nomenclature, the “Medicare Waiver.”

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Establishing healthcare reimbursement for hospitals as a state-regulated utility required definitions of what facilities and what specific space within each facility would be regulated or unregulated by the state commission. The system governed only hospital inpatient and outpatient services. Therefore, physician practices and the services provided within a practice would always be considered unregulated because reimbursement was not through the Medicare Part A system but rather through Medicare part B reimbursement. As many physician practices were located on hospital campuses and even within regulated hospital space, it became necessary to delineate and specify how regulated and unregulated spaces could be considered separate. In general, this differentiation relies on the specification of the individual institution and requires a definitive separation of physical space, such as a prominent hallway that divides a suite or separate suites or units on a floor. Nevertheless, the delineation is ambiguous, and given certain financial and regulatory benefits for unregulated and regulated space, the system engenders a fair amount of “creativity” on the part of stakeholders.

The HSCRC establishes rates for hospital reimbursement based on several factors, including national rate of inflation, Medicare reimbursement factors, cost of graduate medical education, payor mix, and a hospital’s designation as a “disproportionate share hospital” (defined below), number of beds, and the economic situation of community served. Every year, the rates are evaluated on these factors as well as on any special-cause variation that individual Maryland hospitals may bring to the attention of the HSCRC, necessitating additional adjustments to their rate reimbursement. Hospitals monitor their rates through their internal charge master (CDM) and can appeal to the HSCRC on individual charge rate amounts. According to Maryland state law, the Medicare Waiver remains in place as long as the total cost curve of hospitals in Maryland remains under the national cost curve of Medicare. The HSCRC is officially tasked with maintaining that lower cost curve through the rate-reimbursement system. Numerous times throughout its nearly 50-year history, the HSCRC has had to implement strategies to reduce costs because the cost curve has come close to Medicare. The easiest way to do this, simply, is to reduce reimbursement to hospitals.

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In 2012, with the Maryland cost curve anticipated to exceed Medicare, the HSCRC implemented a new cost-reduction system, which would be known as global budget revenue, or GBR. This system, which became based on Maryland hospitals’ profit and loss statements and total inpatient and outpatient volumes for fiscal year (FY) 2013, would hold future operating performance of the following five years to FY2013 levels, with small adjustments for inflation and market shift (explained below). This essentially “capped” system forced hospitals to maintain profit margins through cost control rather than through volume, while providing additional revenue opportunities through participation in quality and outcomes-based reimbursement models offered through the HSCRC. It is important to note that in 2016 these strategies were incorporated into the Oncology Care Model, a voluntary Medicare quality model that incentivizes physicians for meeting quality measures while ostensibly reducing drug and overall oncology care costs.

To incentivize hospitals to focus on caring for their surrounding communities, the HSCRC, within the GBR model, implemented a “market shift” program to account for hospital volume growth and decline. The market-shift calculation measures geographic volume change between hospitals, down to the ZIP code, for medical episodes of care and procedures. It also accounts for natural growth and decline and for epidemiologic incidence of disease within a given population. For example, if a patient in one hospital's primary market ZIP Code elects to undergo a cholecystectomy at a hospital in another primary market area, the case is attributed as a market shift to the second hospital from the first, and the reimbursement dollars are transferred from one to the other. Under this system, however, the reimbursement dollars have a variable cost factor of 50% or less applied to account for cost but not for mark up. The HSCRC's intention was not to incentivize hospitals on volume but on cost and to incentivize them to focus on caring for their surrounding community. In the oncology arena, the market-shift calculation is based on individual patients, and the geographic boundary is by county, not by ZIP code. The episode of care for oncology is based on the cancer therapies that the patient received in a 12-month period, including chemotherapy, radiation, or both.

For example, if a patient living near Hospital A (in western Baltimore County) receives only chemotherapy for stage 3 lung cancer at Hospital B (in northern Baltimore County), and the total cost of that chemotherapy is $50,000 + $60,000 markup/regulated revenue payment, then the patient is credited

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7 Oncology Care Model. Overview and Background. Retrieved from https://innovation.cms.gov/initiatives/oncology-care/
as a market shift from Hospital A to Hospital B in the amount of $55,000 to Hospital B, and Hospital A has $110,000 reduced from its rates, netting a savings of $55,000 to Maryland’s healthcare costs. Taking this example further, if the chemotherapy cost at Hospital B is $50,000 and is so budgeted, and the FDA approves a new treatment that costs $150,000, but the state only pays $55,000, then the problem becomes acute. Because the GBR system never factored in the exceptional price increases of oncology drugs, this hypothetical situation became a reality for Maryland hospitals in 2015, as will be explained in greater detail below.

**Background on Oncology Drugs**

Drug dispensing and utilization is a complex system of ordering, supply-chain management, and revenue cycle/reimbursement. All of these activities are briefly summarized below to provide context for the discussion and scope of this paper.

The physical function of chemotherapy is to infuse into the body a toxic element that, while targeting the tumor specifically, also causes serious and significant side effects to the whole body, including, among others, severe nausea, diarrhea, hair loss, neutropenia, and immune-system weakness. Throughout the research and development of these drugs, investigators have sought to reduce side effects and offer patients a less toxic but more targeted therapy with which to fight cancer. Over the decades, the cost of research and development skyrocketed and became part of the drug-pricing equation and one, but not the only factor, affecting the drastic increases in drug cost. Other factors include exorbitant marketing budgets established to promote and publicize a drug, to educate both physicians and consumers, and to run national clinical trials to test drug efficacy.

The “latest generation” of oncology drugs is known as immunotherapy. Immunotherapeutic drugs harness capabilities within the body’s immune system to target the tumor. With much less severe side effects and major improvements in progression-free survival for a number of cancers, these drugs offer tremendous promise for patients. They also come with a steep price tag: on average, $150,000 annually for treatment, with treatment in many cases proceeding for several years. In the traditional fee-for-service system, this cost is a pass-through to the insurance companies, with a small margin built into reimbursement to the physician or hospital. In Maryland, this cost is, like all other hospital-based costs, factored into the GBR rate calculation, with the cumulative increase from FY2013 absorbed by hospitals’ bottom lines.

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9 Siddiqui, Mustaqeem MD, Rajkumar, S. Vincent MD. The high cost of cancer drugs and what we can do about it. Mayo Clinic Proceedings. 87(10). 935-943
Unlike many other developed nations, the United States does not have a nationalized, federalized, or centralized healthcare system. Based on a third-party payer system, the United States relies on a state-based regulated insurance system, with Medicare often accounting for 50% of payment within every state and the remaining 50% paid by a mix of private payers, Blue Cross Blue Shield/not-for-profit, HMOs, and Medicaid. As a result, hospitals and practices must navigate a complex system of referrals, authorizations, billing codes, and related revenue processes for reimbursement, all of which differ depending on the type of payer. A unique but critical quirk of Medicare is that it is prevented by law from negotiating prices for drugs. As the other payers follow suite with Medicare, given its dominance in the payer market, this non-negotiation is the primary reason for uncontrolled drug costs and has led to the current situation in which drug prices in the United States have no market pressure from payers. Given that those entities who pay the cost are crippled with no negotiation ability, pharmaceutical companies are in the enviable position of facing no barriers to raising prices or entering the market.10 (Their only barrier is gaining FDA approval.) Thus, certain “blockbuster” drugs such as Rituxan and Herceptin are met with little to no competition. In the last couple of years, a newly developed class of drugs known as “biosimilars” basically function as generic drugs when the brand-name drug’s patent expires.11 It remains to be seen if biosimilars will have an impact in reducing drug costs in the United States.

**Drug Reimbursement**

Drug reimbursement is accomplished via two methods in the US healthcare system. The first method, Medicare Part A, covers drugs that are dispensed or delivered in a hospital setting, both inpatient and outpatient. In inpatient care, drug reimbursement is subsumed within the reimbursement for the DRG of the admission. In outpatient care, drugs are reimbursed within the definition of ICD 10 and CPT codes for the patient encounter. The second method, Medicare Part B, is used for reimbursement for drugs dispensed or infused in a physician practice.

Of note is Medicare’s 340b program, which allows hospitals that serve large Medicaid populations to qualify as “disproportionate share hospitals” and thus purchase all hospital-dispensed drugs at a steep discount, sometimes up to 30% off of average wholesale price. However, the program guidelines are strict, defining purchasing and dispensing as that taking place only within the hospital setting. Physician practices cannot participate in 340b, and the drugs ordered through 340b cannot be dispensed in a physician practice. As the full force of this program was realized by hospitals and as drug reimbursement in the physician practice setting declined, beginning in the early 2000s, hospitals embarked on a

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11 Glode, Ashley E. and May, Megan Brafford. Rising cost of cancer pharmaceuticals: Cost issues and interventions to control costs. Journal of Clinical Oncology. 31(28). 3600-3870
protracted process of purchasing physician practices, employing the physicians, and ordering drugs through their central hospital pharmacy under the 340b program. This strategy was particularly adopted by medical oncology practices, in which the profit margin for oncology drugs was significantly higher.

Under the GBR, drug reimbursement underwent significant changes. First, under the Medicare waiver that allows an HSCRC rate reimbursement, the HSCRC rolled drug expenses under the GBR and held reimbursement to the FY2013 rates plus inflation, which effectively passed the risk directly onto hospitals for any drug cost increases. The goal of GBR was to hold costs steady at or below the Medicare cost curve while reining in incentives for growing volume or increasing demand beyond natural growth rates. In the case of oncology drugs, however, cost was not based on natural factors in the Maryland healthcare environment, but rather, on a hugely variable set of factors based on both state and national environments. At the same time, as drug costs increased an average of 18% annually, more than 20 new cutting-edge and costly oncology drugs and drug combinations were approved by the FDA in 2015. As a result of (a) revenue being capped in spite of rising drug costs, (b) newly available therapies, and (c) Medicare being unable to negotiate drug prices, Maryland hospitals with cancer programs became immediately at risk for absorbing drug cost increases within their existing margins. Hospitals were now faced with an immediate crisis in that they had to absorb millions of dollars of unbudgeted expense with little to no recourse to resolve the situation within the Maryland regulated system and GBR.

Stakeholders

- Hospitals are the largest purchasers of drugs, and in Maryland they are also the most exposed to price changes and newly approved drugs. With 340b, prices are mitigated by the discounts and, therefore, have less of an effect on the overall hospital bottom line. HSCRC and the state of Maryland are responsible for maintaining the Medicare waiver by controlling hospital spending through the GBR and rate-setting infrastructure. The increased cost of oncology drugs both increases Maryland hospital spending and puts pressure on the other cost-saving measures developed by the HSCRC to improve care.

- Third-party payers have a stake in drug costs because they agreed to participate in the Maryland rate system and are exposed to price increases.

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Patients are exposed to the issue in that they receive little to no education and information on drug costs when they are diagnosed with cancer and receive a treatment plan from their physicians and, thus, are unable to fully consider costs when making decisions. In addition, patients are exposed to co-pays for the drugs they receive, and with cost increases, co-pays can easily reach into the thousands of dollars.

Providers are stakeholders in a number of ways, including as ordering physicians and prescribers on the Part B side and as stewards of responsibility for hospitals for prescribing standards of care in evidence-based treatment. Variations in practice can account for tremendous cost and risk for hospitals. The development of treatment pathways in oncology is a promising opportunity for cancer programs.

Crisis
For Maryland hospitals, crisis occurred in FY2016 with the unforeseen rapid and tremendous increases in approvals of new drugs and increases in drug prices. These issues, combined with hospitals’ failure to budget for such increases, created a major financial crisis that applied pressure on hospital finance departments and cancer programs to address the cost increases.

Greater Baltimore Medical Center (GBMC) is a 255-bed community hospital located in Towson, Maryland. Its cancer program is one of the largest in the state in terms of patient volume and new cancer patients, with nearly 2000 new patients beginning treatment each year. The program has all of the components of a Commission on Cancer–accredited, comprehensive community cancer center. Facilities include radiation oncology center with three linear accelerators, a breast care center with full diagnostic imaging suite, a clinical trials program, surgical oncologists, medical oncologists, and a 22-chair infusion center. The center also has five billing and authorization staff members who are dedicated to ensuring approval and reimbursement for infused and injected drugs. Their work has resulted in a very low denial percentage of 0.1%. This infrastructure is critical to ensuring that GBMC makes every effort to collect on its drug expense. Annually, the cancer program spends approximately $20 million on oncology drugs for its patients. This line item is one of the largest non-labor line items in the hospital, and with an overall operating margin of $1 to $2 million annually, GBMC must adhere very closely to its expense budget.

In the middle of FY2016, the hospital realized that the cost increases in oncology drugs could erode the hospital’s bottom line into the red for the year. Drug costs were running an annualized unfavorable variance to budget by nearly $2 million. Realizing that the six-month trend was likely to continue without a way to reduce the variance, oncology leadership worked with the finance department to better
understand the trends and what was driving them. It became apparent that both cost increases over historical levels and the newly approved drugs already in use were driving the variance against a fixed bottom line. At GBMC, senior administration and oncology leadership strategized ways to reduce cost without negatively impacting treatment and reducing oncology volume. In consultation with other cancer programs in the state, oncology leadership developed a list of strategies that could potentially reduce cost. The internal strategies developed and their impact are illustrated in Table 1.

Table 1. Internal Tactics

<table>
<thead>
<tr>
<th>Tactic</th>
<th>Impact</th>
<th>% of total cost reduction (approximate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change site of service</td>
<td>Significant reduction in cost</td>
<td>65%</td>
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<tr>
<td>Switch formulary from brand name to generic</td>
<td>Significant reduction in cost</td>
<td>15%</td>
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<tr>
<td>Implement automatic referrals to palliative care</td>
<td>Reduction in drug utilization and cost</td>
<td>5%</td>
</tr>
<tr>
<td>Establish Oncology Pharmaceutical &amp; Therapeutic Subcommittee</td>
<td>No attributable reduction in cost; Effective multidisciplinary review of cost and efficacy</td>
<td>n/a</td>
</tr>
<tr>
<td>Educate providers and staff</td>
<td>Increased awareness of cost among clinical staff; unclear if any reduction in cost</td>
<td>n/a</td>
</tr>
<tr>
<td>Conduct financial analysis</td>
<td>Modeling of drug pricing impact; more accurate cost budgeting</td>
<td>n/a</td>
</tr>
</tbody>
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Leadership also evaluated steps that could be taken with external parties to reduce costs. The medical director of GBMC’s cancer program, a practicing medical oncologist, engaged the state medical oncologist society, the Maryland DC Society of Clinical Oncology (MDSCO) in speaking with state lawmakers about this issue and bringing it forth to their respective hospital leadership teams. GBMC oncology leadership also met with representatives of the pharmaceutical companies and the drug distributors to explain the issues and negotiate volume discounts. These external tactics and their results are listed in Table 2.
Table 2. External Tactics

<table>
<thead>
<tr>
<th>Tactic</th>
<th>Impact</th>
<th>% of total cost reduction (approximate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negotiate price decreases with pharmaceutical companies</td>
<td>Reduced drug costs</td>
<td>10%</td>
</tr>
<tr>
<td>Negotiate with distributor</td>
<td>Achieved volume discounts</td>
<td>5%</td>
</tr>
<tr>
<td>Engage state policymakers</td>
<td>Increased in revenue to offset drug expense</td>
<td>n/a</td>
</tr>
<tr>
<td>Engage physician advocates</td>
<td>Contributed to HSCRC revenue offset</td>
<td>n/a</td>
</tr>
<tr>
<td>Educate pharmaceutical companies on drug cost issue</td>
<td>None</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Impact of Cost-Savings Measures

The easiest cost-saving tactic to accomplish was to substitute brand-name drugs with generic alternatives. Given that the Oncology Care Model enacted this exact tactic, a national precedent was established. However, opportunities to employ this tactic are limited, owing to the number of newly approved, groundbreaking oncology drugs, specifically, immunotherapies such as Opdivo and Keytruda. Many of the still-costly foundational oncology drugs used for many years such as Rituxan, Herceptin, and Avastin have no generic alternatives. Nevertheless, GBMC took every opportunity to use these generics, which yielded significant savings.

The second cost-saving tactic was to change the site of service. Changing the service-providing location from the regulated hospital setting to an unregulated setting would allow billing of drugs through the physician billing system rather than through the hospital regulated system, thus, not under the GBR. Doing so would reduce drug costs but would also result in reduced reimbursement rates by the amount deregulated. Thus, in any given fiscal year, the drug expense would be reduced.

The last set of internal tactics involved more qualitative steps to raise awareness, develop analytics, and find alternatives to drug therapy. They included implementing a subcommittee of the hospital pharmaceutical and therapeutics (P & T) committee that focused exclusively on oncology drugs. This subcommittee, composed of medical oncologists, pharmacists, nurses, and administrators, was tasked with reviewing all newly approved oncology drugs for efficacy, utilization, evidence, and cost. Findings and recommendations were documented and sent to the hospital P & T committee for approval. In

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addition, all providers and clinicians were educated about the cost increases and their impact on the hospital bottom line. This tactic engaged the entire team around the issue and created awareness and opportunities for utilization reduction where appropriate. Buy-in from the clinical team is critical in any hospital effort to reduce cost. Given new awareness and knowledge concerning the change in drug costs under the GBR and its impact on GBMC's bottom line, financial modeling helped leadership to understand potential future drug-cost scenarios, allowing the hospital to more properly budget for and strategize on managing drug costs. Previously, an inflation factor was assumed from national benchmarks and built into the budget. In the new paradigm, new analytic models were developed and leadership decided on the most reasonable model for budgeting. Lastly, palliative-care triggers for patients meeting certain criteria were created in the GBMC EMR, which allowed for automated referrals to the palliative-care team. This step helped patients to make more informed decisions about their disease and quality of life, in some cases electing not to pursue additional lines of treatment or forgoing some drug regimens based on long-term outcomes. Although difficult to quantify, this step did result in some reduction in drug utilization.

External tactics had a mixed impact. At the annual MDSCO meeting, the director of the HSCRC fielded several questions from community oncologists about rising hospital drug costs and promised that the HSCRC would investigate this issue and provide relief if warranted. The director also suggested the strategy of some hospitals deregulating or shifting some or all drugs to an unregulated setting, allowing the HSCRC to simply remove the revenue from their GBR allotment and freeing cancer programs to earn incremental revenue for drug costs on the Part B side. The HSCRC soon thereafter requested that Maryland hospitals provide data showing the impact of oncology drug cost increases. After these data were provided, the HSCRC, in spring 2017, announced a one-time revenue allotment to Maryland community hospitals to account for increasing drug costs. GBMC’s oncology leadership met with representatives from approximately 15 pharmaceutical companies to educate them on the unique Maryland drug cost issue and its impact on the hospital. Many of the representatives were surprised at the issue, and they pledged to educate their respective executives and determine what could be done from the corporate side to alleviate it. GBMC requested the opportunity to negotiate pricing or receive 340b-equivalent discounted pricing. Only two companies were willing to negotiate pricing based on volume, but those negotiated contracts were effective in reducing cost. Lastly, the drug distributor was able to offer additional discounts based on volume for certain oncology drugs, which resulted in small savings.

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The internal and external tactics combined to achieve success at reducing overall FY2017 costs by nearly $3 million from a 12-month run rate. Some tactics had immediate tangible results. Others had more qualitative benefits, such as enhancing the evaluation of new drugs and creating greater awareness of the cost issue among providers, which theoretically led to downstream reductions in variation of drug utilization and, therefore, some degree of cost reduction. Most of these tactics produced tangible enhancement to patient quality of care. As volume of dispensed drugs remained flat in FY2016 to FY2017, volume decrease was not a factor in judging the success of reducing costs. However, the most significant impact was moving drugs from the regulated setting to the unregulated setting. Additionally, this impact involved cost only and did not account for a presumed eventual market shift or reduction in variable cost factor that might occur with HSCRC reconciliation of volumes.

The Maryland regulated healthcare system model has been effective at reducing costs and increasing access for Maryland residents who receive care in hospitals. Under the guidance of the HSCRC, the GBR model has kept Maryland hospital costs under the national Medicare cost level, while incentivizing hospitals to improve quality and population-health management. However, an unforeseen consequence of capping reimbursement has been the lack of a solution to help hospitals absorb massive increases in oncology drug costs. The tactics employed by GBMC illustrate the trial-and-error nature faced by administrators of attempting to deal with this challenge. Although several tactics were successful in reducing drug costs, the ongoing GBR system and the inability at the national level to control increases in drug costs means that this crisis, while temporarily averted, will likely reoccur. As the US Congress and the Executive branch debate issues surrounding the Affordable Care Act, overall drug costs, and the ability of patients to maintain access to affordable care, Maryland is already dealing with one vision of the future that restricts healthcare costs through a global budget. However, unless the national issues surrounding oncology drug costs are resolved, this model is flawed at the state level.
Bibliography


