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Evolutions in Outpatient Cancer Care

Anne Ormerod, PharmD; Brian G. Cochran, PharmD, BCOP; James A. Jorgenson, RPh, MS, FASHP; and James G. Terwilliger, MPH

In recent years, changes in legislation have altered the reimbursement model of Centers for Medicare and Medicaid Services (CMS); these changes have had an impact on the world of outpatient oncology practice. For many years the main source of profit for privately owned outpatient cancer centers was reimbursement for administration of intravenous medications. Oncology practices and oncology cooperatives commonly listed treatment options for individual cancers by the profit available via the gap between acquisition cost and reimbursement fee.[1] Legislative changes in the last decade have diminished the margin of profit from chemotherapy drugs and in some situations have led to financial loss.[2] At the same time, many new therapies for cancer have emerged, driving up the cost for cancer treatment.[3] Together, these issues have created a situation in which many private practice physician groups are unable to generate enough revenue to match the cost of cancer care, and as a result, they have joined hospital-owned oncology clinics and managed care groups.[4]

In this article we review changes that have contributed to this altered practice model, examine differences between practice settings, highlight an example of a cancer center converting to hospital ownership, and discuss future possibilities for outpatient cancer care.

In 2003, the Medicare Prescription Drug, Improvement and Modernization Act (MMA) was passed by Congress and signed into law by President George W. Bush. This legislation attempted to reform reimbursement for Medicare services in part by reducing payments for oncology-related drugs.[2] A critical feature of MMA as it relates to outpatient oncology practice is the conversion of Medicare Part B drug reimbursement from average wholesale price (AWP) to average sale price (ASP).[5] The AWP has been published by a variety of sources since the 1970s and is generally based on information obtained from both manufacturers and distributors. Third-party payers have used AWP as a primary source of cost information on which to base payment plans. However, AWP has been far from accurate and has in fact been found to overstate the actual prices of drug products.

Physician groups and hospitals typically purchase their drugs at a cost lower than AWP based on contracts through their group purchasing organization or a similar entity. The ASP was introduced as a more accurate cost base to replace AWP. Essentially, ASP is the average of all final sales prices that are charged for prescription drugs in the United States to all buyers with the exception of those sales that are exempt from CMS best price calculation, such as 340B pricing. CMS reimburses at an additional percentage of ASP to cushion the impact this change has had on profit margins, with the intention of transitioning to straight ASP. In 2011, physician-based programs were paid at ASP + 6% while hospital-based programs were paid at ASP + 5%.[6] Hospital-based programs will transition to ASP + 4% starting January 2012. It is expected that physician payments for Part B drugs will become even more convoluted in 2012. Currently CMS pays ASP + 6%. Current law allows CMS to substitute the average manufacturer price as an alternate cost base if it is lower than ASP. If ASP exceeds average manufacturer price by 5% or more for 2 quarters, CMS will base physician payments on the average manufacturer price + 3% rather than ASP + 6%. The full impact of this rule is unknown, but it is expected to further reduce physician payments.

Private practice oncology clinics in most cases purchase drugs at the higher end of the ASP and hospitals generally purchase many drugs at the lower end of this average. Hospitals that are 340B eligible enjoy further purchasing discounts on covered outpatient drugs that approach 20% to 30% less than prices paid by group purchasing organizations. Program restrictions on for-profit entities such as physician practices make them ineligible for participation in the 340B program.[7] Additionally, for

practices to acquire full reimbursement from Medicare patients, they must be able to collect patient copays. In hard economic times more patients are unable to cover this expense. Medicare reimbursement without the patient copay is 80% of ASP + 6%, which is equivalent to 84.8% of the actual average cost of the drug. As a result, private practice clinics have struggled to cover the cost of some medications, much less derive a profit as before.[2]

The degree of loss is illustrated when comparing the AWP and ASP for various chemotherapy agents. The AWP of a 100 mg vial of bevacizumab (Avastin), which is approved by the US Food and Drug Administration (FDA) for use in colon cancer, among others, is $669.90. However, the October 2011 ASP + 6% was $611.38, representing a decrease of $58.52 per vial. Trastuzumab (Herceptin), an agent FDA approved for breast and gastric cancer, has a stated AWP of $3359.47 per 440 mg vial. The October 2011 ASP + 6% was $3187.36, a decrease of $172.11 per vial.[8-10(pp483,704)] These examples illustrate the decrease in possible drug revenue due to the shift from AWP to ASP.

At the same time that drug reimbursement rates have decreased for physicians, payment for the actual infusion has also been reduced. Payment for Current Procedural Terminology (CPT) code 96413 for the first hour of infusion (chemotherapy, therapeutic monoclonal antibody, or biologic response modifier) dropped from $161.36 in 2008 to $150.04 in 2009 and $143.07 in 2010.[11] For 2011 there was a slight increase to $146.44, but this falls far short of making up the difference in loss of drug revenue. A similar situation for CPT code 94615 for each additional infusion hour is also seen for the corresponding years with $37.17 in 2008, $34.26 in 2009, $30.31 in 2010, and $31.26 in 2011.

Prior to MMA, reimbursement for services other than drug administration accounted for approximately 30% of the total oncology physician practice revenue. These services include physician evaluation and management of the practice.[1] To supplement the significant loss of daily revenue when reimbursement changed, CMS began the Physician Quality Reporting System (PQRS). This initiative reimburses physicians for the tasks they perform on a daily basis and not for the quantity of drug administered.[12,13] Some PQRS initiatives specific to oncology for 2011 included documenting cytogenetics with a new diagnosis of myelodysplastic syndromes, documentation of estrogen receptor/progesterone receptor status and stage for breast cancer, and the use of adjuvant chemotherapy in stage III colon cancer patients.[11] The success of this voluntary program has not yet been established, and current reimbursement does not account for the loss of revenue from continually rising drug product costs.

A 2007 article in the *Journal of Clinical Oncology* showcases the logarithmic growth in cancer care costs. Prior to the development of several more recent FDA-approved options, the standard chemotherapy regimen for colon cancer was fluorouracil and leucovorin alone; the cost for these 2 drugs over 6 months is around $100. The addition of oxaliplatin to this regimen increased the drug cost for 6 months of treatment to nearly $30,000.[3] New drugs continue to be approved by the FDA that are enhancing response rates and extending patient lives. These same important drugs are significantly increasing the total cost of care and decreasing the likelihood that a smaller private practice group could carry the products on their shelves to dispense.

Privately owned oncology practices have adapted to this changing landscape in a number of different ways. Some individual practices have created coordinated efforts with other private practices to lobby Congress for better reimbursement, while others are becoming a part of a larger system under managed care ownership or hospital-based practices.[2]

The Association of Community Cancer Centers—a network of physicians working in private practice and hospital-owned oncology centers—is working to prevent further narrowing of the reimbursement gap and to maintain patient access to outpatient oncology care. This organization provides a communication network for oncology practices across the country to stay up-to-date on changes in reimbursement, improve the efficiency of billing and payment of their practice, and provide a forum for discourse on current events in oncology practice.

Managed care cancer centers such as US Oncology are another option for outpatient cancer center ownership. Roger W. Anderson, DrPH, chief pharmacy officer at US Oncology, describes his company as supporting privately owned groups in their practice without compromising their autonomy. On the most basic level, US Oncology provides a more competitive pricing scheme for medications than what most private practice offices could obtain. US Oncology then closely tracks the percentage of reimbursement received to ensure the gap between billing and payment is minimized. Practices can choose to maximize the involvement of US Oncology by adopting their pathways for treatment, which are constructed to reflect the most up-to-date evidence-based practices. Utilization of US Oncology's treatment pathways allows for the tracking of quality initiatives in an attempt to improve

care and control cost. From 2007 to 2008 the percentage of physician-owned practices decreased from 87% to 74% in a survey of 208 physician practices. Conversely the percentage of management company–owned facilities doubled from 3% to 6% of the respondents who participated.[4] The Association of Community Cancer Centers, US Oncology, and similar groups continue to support community oncologists, but many practices are in a state of transition. Based on 2010 data, the National Oncology Practice Benchmark 2011 report showed that 24% of practices could foresee their business structure changing immediately or over the next 12 months.[8]

Indiana University Health (IU Health), based in Indianapolis, Indiana, has recently acquired several cancer infusion centers previously considered to be private practice settings. Some motivations for this change (eg, declining physician profit margins, better hospital-based reimbursement) mirror those of other oncology practices. The past decade has seen an increase in regulation regarding intravenous oncologic drug compounding and administration; to help meet these demands, it was necessary for IU Health to make an immediate evaluation of the practices' current facilities upon acquiring them. The pharmacy leadership assessed each location for USP 797 compliance and identified what necessary updates and construction work would be necessary to meet regulations. Throughout this process it has been important to work closely with nursing in order to determine the most efficient work flow.

Currently, IU Health is working toward becoming an Accountable Care Organization and is actively working to synchronize physician and hospital goals around improved patient outcomes and reduced costs of care. The IU Health program extends across the state of Indiana and now provides care to approximately 35% of the state's oncology patients. The oncology pharmacy team has taken this opportunity to work toward standardizing oncology services throughout our Indiana service area and ensuring that patients treated at every IU Health location receive the same high level of oncology care. At the same time, IU Health has worked to preserve the benefits of these private practice groups, such as clinic efficiency and practice autonomy. While we have implemented order sets and are in the process of pathway implementation, physicians are still able to use medical evidence and their clinical expertise to determine the best course of treatment for their patients.

Historically, an oncology-trained pharmacist played a limited or nonexistent role in daily operations in the private practices that recently joined the IU Health team. The pharmacy team now has a board-certified oncology pharmacist at each location who is integrated into the cancer care team with oncologists and nurses to more effectively address all facets of the oncology medication use process, including prescribing, dispensing, administering, and monitoring these medications. Pharmacists have been primarily responsible for the creation of more than 168 standard order sets for chemotherapy medication and 98 investigational medication order sets to improve order accuracy and safety. In addition, the IU Health Oncology service line is actively engaged in creating care pathways to help drive best practice around these complex treatment regimens.

The transition to hospital ownership has included multiple obstacles that the IU Health team has worked to address. Coordinating hospital ownership requires compliance with certain regulations including those of the Joint Commission, the state health department, and the State Board of Pharmacy. To comply with these regulations, the cost for facility improvements and staffing has increased.

The transition for the majority of these physician-based outpatient centers has meant a large-scale alteration in the work flow process for nurses and physicians alike. As oncology pharmacists, this transition has provided us with an opportunity to be a consistent part of the outpatient care team. These outpatient cancer centers each have their own electronic medical records and billing processes. In the short term, IU Health continues to work on the challenge of transitioning each of these centers onto one electronic medical record system that works in conjunction with the inpatient facilities they partner with and a centralized Revenue Cycle process.

Outside of the responsibilities of direct patient care, billing processes had to be quickly streamlined and coordinated. Outpatient clinic billing processes can be quite different from hospital inpatient billing; in response to this challenge IU Health has increased both the number of staff and their training to more accurately execute outpatient billing nuances. Additionally, a thorough assessment of drug and supply inventory was conducted at each location prior to the first day of transition. Based on these assessments, determining what products and supplies would no longer be available and training staff on how to use substituted products helped reduce staff anxiety.

Oncology practice has been and will continue to be greatly impacted by healthcare reform and Medicare

reimbursement changes; and although the full impact of the new healthcare law has yet to be determined, we can expect reimbursement for drugs to continue to decline and cost containment and efficiency efforts to increase. As the country shifts from a volume-based reimbursement system to one based on efficiency and objective outcomes, the location where the care is delivered is likely to continue to change. Within the last 5 years, private practice oncology clinics have aligned themselves with larger entities in order to preserve their profit margins and maintain their practices. These changes will continue in the next decade as reimbursement is likely to change in response to these newer models, and accordingly the care model will shift again.

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Address correspondence to: Anne Ormerod, PharmD, Post Graduate Year-2 Hematology/Oncology Pharmacy Resident, Indiana University Health, University Hospital, 550 N University Ave, Indianapolis, IN 46202. E-mail: aormerod@iuhealth.org.

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