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The Impact of APCs on Hospital Outpatient Cancer Care

by Lee E. Mortenson, D.P.A., Lane Koenig, Ph.D., Dean Rossiter, Stephen Chan, and Allen Dobson, Ph.D.

A research team from the Association of Community Cancer Centers (ACCC), ELM Services, Inc., The Lewin Group, and Orion Consulting recently completed a series of studies that estimate the impact of the Health Care Financing Administration's (HCFA) proposed Outpatient Prospective Payment System (OPPS) on the viability of hospital outpatient cancer care. The results served as a foundation for ACCC's comments to HCFA on the proposed regulation and suggest major implications for outpatient cancer care should the regulation be implemented without significant modifications.

In this article, the authors present their methodologies, analytic findings, and conclusions regarding the expected impact of the OPPS. The authors find that the proposed system, which sets payment rates for groups of procedures, or Ambulatory Payment Classifications (APCs), will generate significant losses for the nation's community cancer programs. Of particular concern is the system's inability to appropriately compensate those areas of medicine characterized by rapid change and innovation, such as chemotherapy.

The authors note that the OPPS reimbursement levels for chemotherapy and supportive care drugs, radiation oncology, and chemotherapy administration are likely to produce perverse incentives for hospital outpatient departments to minimize the use of newer, more effective therapies. After reviewing HCFA's methods and their implications for innovative cancer therapies, the authors conclude that the rapidly changing area of chemotherapy drugs cannot be adequately compensated under a fixed price system, such as the OPPS. They argue that chemotherapy drugs provided in the outpatient setting should be exempted from the proposed regulations. Without such an exemption, the OPPS threatens to jeopardize the overall quality of cancer care received by Medicare beneficiaries.

On September 8, 1998, the Health Care Financing Administration (HCFA) issued proposed regulations for the implementation of an outpatient prospective payment system (OPPS) for hospitals. The OPPS is based on a procedure classification system developed by HCFA called Ambulatory Payment Classifications (APCs). APCs are an attempt to group related procedures into categories and pay a predetermined price for each category. HCFA currently plans to implement OPPS in June 2000. After several extensions, final comments from the public on the proposed OPPS regulations were due on July 30, 1999.

In preparation for its response to the proposed regulations, the Association of Community Cancer Centers engaged in a series of studies in the fall of 1998. Initial studies using hospital data from a cross section of ACCC institutions were conducted by ELM Services, Inc., an oncology consulting company in Rockville, Md. Analysts compared current payments on cost reports with the proposed APC payment rates. Initial results suggested significant deficits in cancer program reimbursement.

Subsequently, the Association contracted with The Lewin Group and Orion Consulting, two health care consulting firms, to estimate the impact of OPPS at the CPT level and ascertain what methodological issues might have caused the formulation of the rates that were being proposed. This paper focuses on these second generation studies and their implications for hospital-based outpatient cancer care.

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BACKGROUND

Since the successful implementation of Diagnosis Related Groups (DRGs) in the early 1980s, Congress and HCFA have had a continuing interest in developing a similar system of reimbursement for the outpatient hospital setting. Work that started at The Johns Hopkins University and Yale University evolved into a contract with 3M-Health Information Systems (3M) to classify outpatient services into related groups for purposes of an outpatient prospective payment system. The system developed by 3M arranged services into Ambulatory Patient Groups (APGs).

In the mid-1990s, HCFA funded several limited experiments of

the APG concept. These demonstration projects were significantly different from the current OPPS proposal, exempting drugs and including a stop-loss provision that assured participating hospitals at least 95 percent of their existing compensation. Working from 3M's APGs, HCFA modified the payment groups using more recent Medicare data to create the APC system. The OPPS sets a single payment rate for the group of procedures under each APC.

Throughout the course of 3M's work on APGs, much attention was given to the issue of chemotherapy. Commentators from ACCC and the American Society of Clinical Oncology noted that any proposal for chemotherapy drug compensation was likely to become quickly outdated.

The cancer community's concern about APGs, and now APCs, stems, at least in part, from its experience with attempts by commercial insurance plans to capitate drug benefits. Physicians and insurers who attempted to develop capitated chemotherapy benefits in the early 1990s often found their attempts thwarted by rapid changes in chemotherapy drug use. New drugs were constantly introduced and a steady stream of proven off-label uses altered the utilization of drugs and the cost of chemotherapy. This made budgeting for the costs of drugs nearly impossible and caused severe cash flow problems for both insurers and physicians.

Direct evidence of the rapid introduction of new drugs is illustrated by data from ACCC's *Compendia-Based Drug Bulletin,* a quarterly update of oncology drugs and their indications. A recent review documented the introduction of 43 new drugs with 49 FDA-approved indications since 1992. Over that same time period, the three (now two) reference compendia that are the standard setters for Medicare, Medicaid, and the thirty-seven states that have passed legislation on the topic, added 171 new off-label indications.

Given the difficulties in developing a commercially capitated system of cancer drug reimbursement with data that were often only one-year old, ACCC leadership was wary of the potential negative impacts of a federal system that was based on data that are several years old. This concern was amplified when the proposed regulations were issued. Noted within the proposed regulations were HCFA's estimates that ten hospitals dedicated to cancer care would lose 29.2 percent of their revenues if the rule were implemented.

THE LEWIN-ORION ANALYSES

ACCC contracted with The Lewin Group and Orion Consulting to conduct a series of analyses of OPPS. This work included evaluating HCFA's methodology and estimating the impact of OPPS at the CPT level. ACCC requested that The Lewin Group-Orion Consulting team look at chemotherapy drugs, supportive care drugs, chemotherapy administration, and radiation oncology. In constructing the analytic database, The Lewin Group-Orion Consulting team used 1996 HCFA data files and, to the extent possible, HCFA unit edits.

In addition, The Lewin Group-Orion Consulting team examined the impact of eliminating the formula-driven overpayment (FDO). The elimination of FDO was required by the Balanced Budget Act (BBA) of 1997. Under the law, Medicare must subtract the full co-payment due from beneficiaries (i.e., 20 percent of billed charges) rather than 20 percent of Medicare allowable costs. According to preliminary work by The Lewin Group, the full effect of eliminating FDO is expected to reduce hospitals' Medicare compensation by roughly 8.5 percent. The effects of eliminating FDO are crucial in considering the full impact of outpatient payment regulations on cancer care, especially radiation oncology.

FDO REDUCTIONS: A SEVERE BLOW TO RADIATION ONCOLOGY

The analysis shows that the FDO reduction affects radiation oncology and chemotherapy payments in distinctly different ways. For chemotherapy, there is no difference in the payments from the FDO reduction.[1] Current chemotherapy payments before and after FDO remain the same, at $111 million, compared with reported costs of $93.5 million, with the difference covering the hospital's general operating costs, bad debt for uninsured patients, or uncollectible co-payments. For radiation oncology, however, the FDO reduction drops reimbursement from $585 million to $461 million, compared with reported costs of $685 million. Thus, the FDO reduction leaves radiation oncology with Medicare reimbursements that are $224 million *below* reported costs.

The significant and differing impacts of FDO stem from the different reimbursement formulas used by HCFA for radiation oncology and chemotherapy. The FDO reduction affects only those services paid under the blended payment formulas. Blended rates are a mixture of actual costs and federal fee schedules, in this case the physician fee schedule. Because chemotherapy payments are not based on the blended payment method, the elimination of FDO had no effect on these payments. In contrast, radiation oncology reimbursements, which are based on blended payment methods, are far short of reported costs, fully 32.7 percent below Medicare-allowed costs.

THE EFFECT OF OPPS ON CHEMOTHERAPY DRUGS

APC categories are an attempt to group various procedures into categories and pay a predetermined price for each category. These categories are quite different from the Diagnosis Related Group (DRG) system that covers inpatient care for Medicare patients. The DRG system provides hospitals with a payment for a clinically cohesive set of treatments that affect a patient with a specific diagnosis. The DRG system gives hospitals wide latitude to treat patients with a variety of different approaches and encourages them to look for critical pathways

[1]In all our analyses, "costs" are allowable costs as justified on the Medicare cost reports by submitting hospitals, "current payments prior to FDO" are the payments hospitals received for services before the implementation of the FDO provisions, and "current payments after FDO" are the payments that hospitals would receive in years after the elimination of FDO.

to minimize costs. In some cases, DRGs have encouraged the use of new treatment protocols, especially if these shorten the length of stay or lower other costs in the standard treatment pattern.

APCs, on the other hand, do not provide this type of latitude. Under APCs, the focus on combining specific procedures into categories serves primarily to control costs, not to encourage better or more efficient treatment planning. Thus, while it could be argued that DRGs encouraged better and more efficient care, APCs are likely to encourage only the use of low-cost care. In fact, if certain groups of procedures are inappropriately priced, hospitals may reduce or even eliminate entire categories of care. APCs for chemotherapy illustrate the difficulties of devising a universal methodology for setting single payment rates for groups of procedures.

The Lewin Group-Orion Consulting simulation of 1996 hospital outpatient data shows that overall payments under OPPS for the four chemotherapy drug APCs (061, 062, 063 and 064) are 3.2 percent less than current payments. Despite this apparent modest reduction in payments for chemotherapeutic agents, a careful look at the findings indicates a number of areas of concern. Specifically, within each APC category, the analysis found drugs with very different costs. In addition, different dosages of the same drug are grouped into more than one APC category and have payment-to-cost ratios that will significantly alter reimbursement margins. New drugs, which are assigned to the APC with the lowest level of reimbursement, are likely undercompensated to the extent that newer drugs cost more than existing products.

Other negative incentives also appear in the proposed APC categories. For example, APC 061 includes drugs with wildly different cost-to-payment ratios, from 28 percent of costs to 1,595 percent of costs. APC 062 has a similar range of costs to payments, from 29 percent of costs to 1,167 percent of costs. Likewise, in APC 063, payment-to-cost ratios range from 55 percent to 374 percent. And in APC 064, payment-to-cost ratios range from 37 percent to 764 percent.

These wide variations imply that HCFA's APC categories are not cost homogeneous and likely do not reflect comparable clinical meaning. This has far-reaching implications for use of drugs in these four key APC categories. In particular, in each of these APC categories, newer drugs, which typically cost more, are likely to lose significant amounts of money. While this loss might be offset by gains from some older drugs that make money, the economic incentives are strong and unbalanced. Payment systems should be incentive neutral across clinical options, and this is clearly not the case.

This lack of balance in economic incentives can lead to perverse outcomes. Cyclophosphamide in one dosage is assigned to APC 061 and is reimbursed at 179 percent to 494 percent of its costs. The same drug in different dosages was also assigned to APC 062, where reimbursement ranges from 229 percent to 1,167 percent of costs. Reimbursement for cisplatin in APC 062 is 161 percent of its costs, while the same drug in different dosages in APC 063 is reimbursed at just 98 percent of costs.

In addition, we note that all the new drugs since 1995 are assigned to APC 061, the chemotherapy category with the lowest reimbursement. Using 1996 costs, the reimbursement for these drugs would be 58 percent of costs, on average. This same category of payment is proposed by HCFA for use with all future drugs as they are introduced.

Obviously, older drugs are overcompensated and newer drugs, presumably more costly yet more effective, are undercompensated. These facts suggest that OPPS would provide strong incentives for hospitals either to use older drugs or to sharply control the provision of new chemotherapy drugs in the outpatient setting. Neither of these possible outcomes is in the interest of Medicare beneficiaries or promotes the new beneficiary-centered Medicare program.

ADDITIONAL ANALYSES INDICATE SHARP DROP IN CHEMOTHERAPY COVERAGE BY 1998

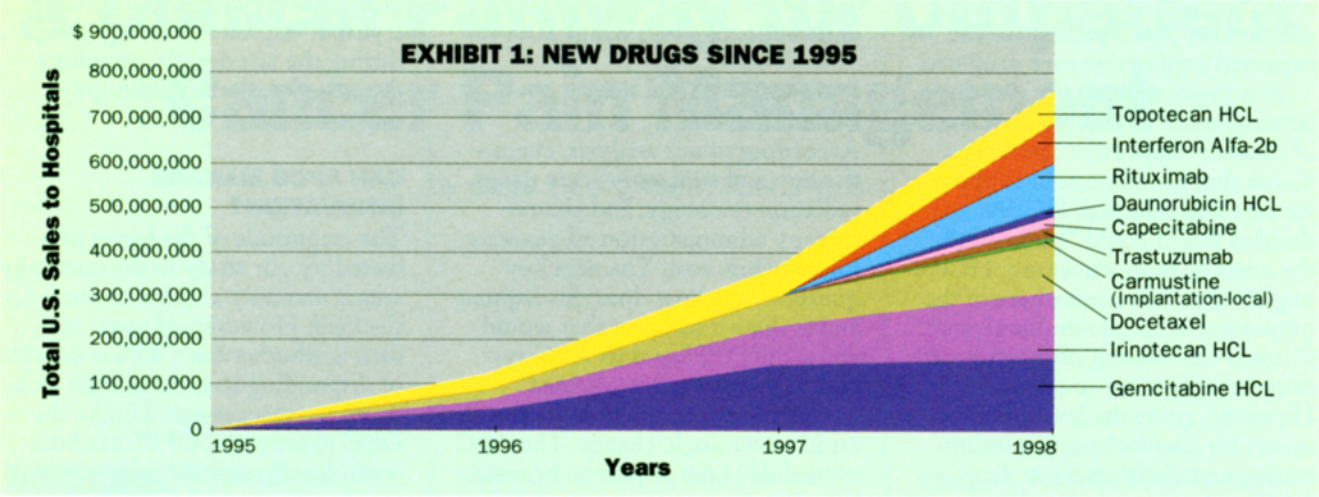
To further determine the effect of the OPPS, ACCC obtained actual sales data from IMS Health on each of the therapeutic products in each of the four APC categories for 1995 through 1998. IMS Health is a nationally recognized source of actual sales data, which is used by the pharmaceutical and biotechnology industry to track sales to hospitals and other locations. Since these data are available in significant detail, staff were able to compute specific percentage changes in drug utilization for each product at each dosage for each year. This information allowed a determination of which products increased in use between 1996 and 1998 and which decreased in use.

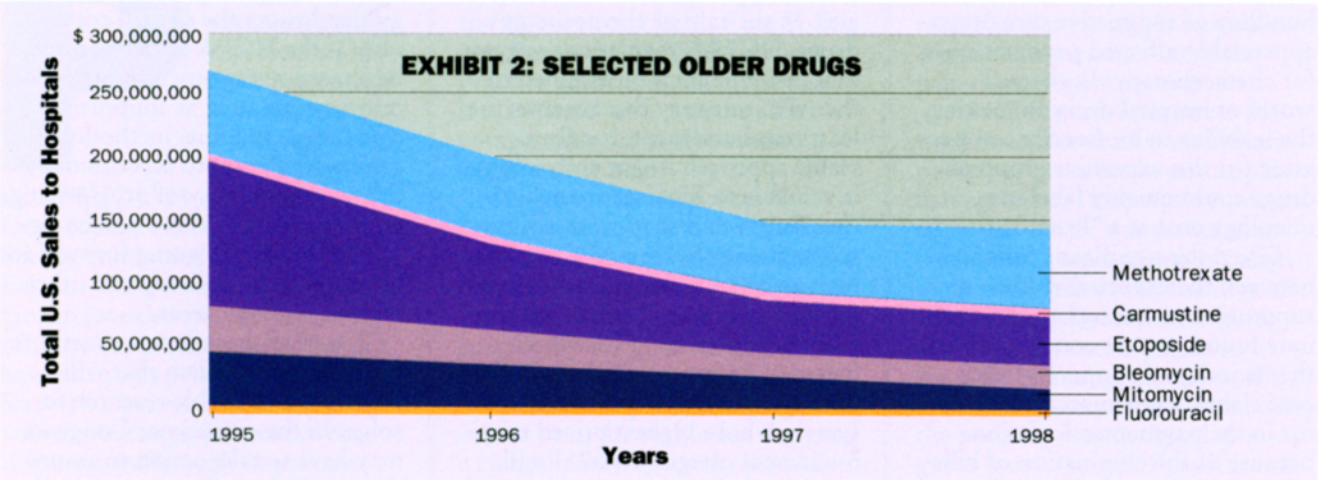
It was then determined how those changes in drug utilization would have affected hospital cancer program reimbursement within each APC chemotherapy category if the OPPS had been in place.

As Exhibit 1 illustrates, a number of new drugs with significant sales have entered the market since 1995. Exhibit 2 suggests that, while new drugs accelerated in use, some older drugs declined in use. Indeed, on a volume basis, between 1996 and 1998, those drugs that were "winners" (i.e., those that were reimbursed at greater than cost) in the four APCs increased in utilization by 41 percent. On the other hand, those drugs that were "losers" (i.e., reimbursed at less than cost) increased in use by 311 percent.

This kind of clinical cycle is exactly what one would expect. Indeed, some older drugs increase in use after a new multidrug regimen suggests that their use may be effective. On the whole, however, use of older drugs is likely to remain stable or decline over time. New drugs, however, which are presumably of equal or greater efficacy than existing drugs, should see a rapid increase in use as oncologists become aware of their availability and clinical efficacy.

Using data from IMS Health on actual product sales within each APC category for each year, a team from ACCC and ELM calculated the increase or decrease in use of





each product and its effect on volume, costs, current payments, and APC payments under OPPS. According to this analysis, the four chemotherapy APC categories, which would have been only slightly affected by OPPS in 1996, would generate significant losses in 1998. If OPPS had been in place in 1998, hospitals would have been reimbursed at $25 million *below* Medicare-allowed costs. Ignoring changes in the patterns of care, cost increases, or further introductions of expensive new agents, we estimate that the drug products in APCs 061 and 062 will cost hospitals at least $37.6 million more than Medicare will reimburse for these drugs in 1999 and 2000. The other two chemotherapy APC categories do little to ameliorate these losses, with all four categories losing $25.7 million relative to costs.

Another methodological issue that adversely affects radiation, medical oncology, and chemotherapy drugs is the method HCFA used to simplify their estimation of cost at the procedure level. HCFA chose to eliminate all those claims that included more than one procedure. While this practice reduced all claims to one-quarter of their original number, The Lewin Group-Orion Consulting team found that oncology claims were reduced to roughly one-eighth of their original number. Under this approach, many claims that included supportive care drugs likely were eliminated, as were most batch bills. Consequently, the data used by HCFA to develop the OPPS payments may not be representative of therapeutics or supportive care drugs. Indeed, our thinking is that HCFA's data may be highly nonrepresentative in that single bills for oncologists are the exception, not the rule. Most likely the bills remaining after excluding multiple procedure claims would be error correction bills, or an occasional drug not given as part of the more common multi-drug chemotherapeutic combinations.

MISSING SUPPORTIVE CARE DRUGS GENERATE SIGNIFICANT LOSSES

One of the most significant findings of The Lewin Group analysis was the extremely small amount of supportive care drugs in the HCFA database. In 1996, only $2.8 million of supportive care drugs (based on average wholesale price) were identified by a J-code in the HCFA database. During this same year IMS Health reported there were $822 million in supportive care drugs sold to U.S. hospitals. Using a variety of step-down assumptions (that 64.6 percent of oncology drugs are given outpatient [IMS Health, Trinity Partners, Inc.]; that Medicare is the payer 21 percent of the time [Tamden Research]; that the ratio of supportive care drugs in the outpatient area is the same as hospital and office ratios of use [ELM Services, Inc.]), one would expect $89 million in supportive care drug costs in hospital outpatient settings during 1996.

Thus, the HCFA records directly account for just 3 percent of the expected supportive care drug use.

It is important to consider the consequences of this apparent lack of data for supportive care drugs. Given that the amount of supportive care was minimal, HCFA decided that it could "bundle in" the costs of supportive care. HCFA might argue that somewhere in the outpatient hospital reimbursement formula the missing supportive care drug payments are covered. However, given the level of payments for chemotherapy administration and chemotherapy drug APCs, it is not apparent that the bundling of supportive care drugs appreciably affected payment rates for chemotherapy. In the real world of hospital decision making, the inability to be directly compensated for this expensive group of drugs could quickly label the oncology area as a "loser."

Given the significant variance between the expected volume of supportive care drugs and the volume found, we are concerned that the majority of supportive care cost claims were unaccounted for in the payment calculations because of the elimination of bills with multiple procedures. If we conservatively assume that the costs of supportive care drugs are only 30 percent of the cost of chemotherapy drugs, the total cost of chemotherapy and supportive care drugs would have been $290 million in 1998. (The cost of chemotherapy drugs in 1998 was estimated by projecting 1996 IMS cost data using actual 1996 to 1998 growth rates for each drug.) Based on an estimated payment for the chemotherapy drug APCs of $197 million, the loss to hospital cancer programs would have been $93 million, or 32 percent of the cost of chemotherapy and supportive care drugs. (APC payments for chemotherapy drugs were estimated by projecting The Lewin Group-Orion Consulting estimated payment using IMS drug cost growth rates.) Using a more likely assumption, based on IMS data, that the cost of supportive care drugs was 79 percent of the cost of chemotherapy drugs, the loss to hospital cancer programs would have been $202 million, or 51 percent of the cost of chemotherapy and supportive care drugs in 1998.

CONFLICTS WITH NEW TECHNOLOGY

According to our analysis, chemotherapy and supportive care drugs, radiation oncology, and chemotherapy administration all generate losses below cost. The next key questions are how does this happen and is there a solution that would allow the OPPS and its APC system to go forward as planned?

Oncology treatment is an area of rapid technologic change. The APC system does not appear to provide an easy approach to new technologies. In the case of chemotherapy drugs, HCFA's regulations suggest that new therapies be assigned to the APC category that receives the least reimbursement, hardly a viable approach if new technology is valuable to Medicare beneficiaries. But even if they were assigned to the chemotherapy APC with the highest reimbursement, many new technologies would still be underpaid. For instance, if four treatments of Rituxan significantly alter life expectancy, but cost $9,000, a system whose highest priced reimbursement category is $211 will severely undercompensate hospital providers. From a disease management perspective, since the use of drugs such as Rituxan lead to reductions in direct costs, morbidity, and mortality, APCs become especially problematic.

Moreover, since HCFA by necessity must continue to use data that are several years old to develop its APC relative prices, HCFA's approach to drug reimbursement will continually lag far behind the innovation curve. As we noted previously, in seven years more than 40 new drugs were introduced and more than 220 new indications listed. The Pharmaceutical Manufacturing and Research Association lists more than 300 new cancer drugs currently under development, suggesting that drug use in oncology is likely to continue with a high degree of variability. New drugs will be released, drugs midway through their life cycles may be rejuvenated with new indications for use, and older drugs may continue, decrease, or even radically increase. Thus, as many oncologists and companies found while trying to capitate oncology drugs during the last decade, oncology drug use is volatile, and highly unpredictable.

CAN APCS MANAGE INNOVATION?

The magnitude of the losses predicted by our study in the oncology area is certainly a major concern for the field. However, of equal concern is whether the OPPS is capable of responding to areas of high technologic advancement. Unlike the DRG system, the OPPS has little room for altering the pattern of care by using a high-cost technology that lowers the overall cost of care. If the HCFA database cannot be altered to capture appropriate information, such as supportive care drugs, and if its methodologies cannot be altered to accommodate the wide variability of drug pricing, efficacy, and use, there will be significant problems going forward for oncology drug delivery and other high technology areas.

Together these issues constitute a significant problem that will require considerable research to solve. In the meantime, Congress may have to take action to assure that Medicare patients receive adequate care in hospital outpatient settings. Certainly in a time of budget surpluses, this is no time to cut benefits to Medicare patients in critical areas such as oncology.

It is our conclusion that the APC system will not work for oncology drugs and rapid innovations. Recalculation of the existing APC payments is not a workable solution. Given the continuous innovations in cancer care, HCFA's data will always lag behind reality in significant ways. Additionally, a methodology that excludes multiple procedure bills will, by its very nature, miss important areas of care that are frequently, or always, billed as a multiple procedure, such as many supportive care drugs and the seeds for brachytherapy. Thus, chemotherapy drugs, supportive care drugs, and other areas of ongoing innovation should be exempted from APCs. To do otherwise is to threaten the quality of cancer care available to Medicare beneficiaries.