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APCs Threaten Hospital Outpatient Cancer Programs, Use of New Agents, and Supportive Care Drugs

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The Health Care Financing Administration (HCFA) has issued for comment proposed regulations for the Outpatient Prospective Payment System (Outpatient PPS). The specific reimbursement mechanism for oncology and other outpatient services is the Ambulatory Payment Classification (APC) system. In preparation for release of the regulations, the authors of this study analyzed data from a wide variety of hospital cancer programs to determine the impact of the new system on outpatient cancer care. On the whole, the authors found significant disincentives for oncologists at hospital programs to use newer agents and supportive care drugs. At the same time, the APC system rewards use of older, less effective chemotherapy agents.

This analysis suggests that under APCs most hospital-based outpatient cancer programs will incur losses of 30 percent or greater from their current revenues. Such losses will force hospitals either to radically limit their service to less toxic (and less current) therapies or to consider closing their chemotherapy outpatient facilities. In addition, programs will have strong incentives to curtail use of supportive care drugs.

The authors also reviewed information from hospital-based radiation oncology departments and found losses in operating margins that parallel those likely to be generated by HCFA's practice expense regulations, published earlier this year. These losses would likely close a significant proportion of radiation oncology facilities.

APCs are likely to cause many hospitals to curtail or close their oncology programs. More significantly, APCs will affect university-based cancer centers, which engage in significant levels of outpatient research with newer agents. With losses of 30 percent and greater in addition to other losses experienced by all academic medical centers under APCs, these facilities will no longer be able to afford to engage in clinical research. Finally, rural cancer care would be eliminated with the closure of most rural radiation oncology centers and hospital-based chemotherapy clinics.

Based on the same concept as Diagnosis Related Groups (DRGs), the recently released draft regulations for Ambulatory Payment Classifications (APCs) propose to give hospital outpatient areas incentives to use the lowest cost alternative method of adequate patient management. In developing the proposed rule, the Health Care Financing Administration (HCFA) has used its hospital payment data from 1995 and 1996 to develop categories of similar procedures, which can be paid at a fixed rate. In a number of cases, HCFA has bundled multiple procedures together. For example, in the case of oncology, chemotherapy administration is bundled with supportive care drug reimbursement. Supplies, blood products, and facility fees are also bundled within other APCs.

The APCs concept, as with DRGs, is intended to fix the price of each category based on experience. Congress mandated the rapid implementation of APCs as a mech-

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anism to curtail growth in outpatient hospital expenditures. Since HCFA is now wrestling with Year 2000 computer problems, the planned implementation of APCs has been delayed until the end of the first quarter of 2000.

Over the last five years, HCFA's contractor on APCs, 3M Health Information Systems, has attempted to develop categories of chemotherapy drugs for use under the APC system. Oncology reviewers noted several problems during the preliminary stages of development that are also apparent in the proposed final implementation of the regulation.

METHODOLOGY

To assess the impact of APCs on hospital cancer programs, the leadership of the Association of Community Cancer Centers (ACCC) asked the consulting staff of ELM Services, Inc., to gather data from a cross section of community and university hospitals. ELM staff selected hospitals on the basis of a variety of characteristics, including the ability to provide complete data on acquisition costs, access to cost report information, availability of data, size of hospital, type of hospital practice, and relationship with oncologists. ELM sought hospitals that represent the basic types of facilities known to provide outpatient chemotherapy: community hospitals with bonded physicians who provide chemotherapy exclusively in the hospital outpatient department, rural hospitals with chemotherapy clinics, university hospitals, and community hospitals with outpatient clinics that are a secondary location for chemotherapy.

Each hospital contacted was provided a list of codes corresponding to the APC codes for chemotherapy, chemotherapy administration, radiation oncology, and supportive care drugs. Hospitals were asked to provide information on Medicare patient units, acquisition costs (costs based on the Medicare cost report), and Medicare payments (including co-payments and federal payment). ELM worked with each facility to assure that the reported information on acquisition was appropriate and accurate. Multiple clarifications of actual charges and costs were required. Because some codes are omitted from APCs, ELM asked hospitals to provide additional information on supportive care drugs, facility fees, clinic visit fees, and supply costs. ELM then calculated the reimbursement under the APCs and the variances between the proposed APC reimbursement and the current hospital reimbursement under the cost report.

RESULTS

Hospital data systems were at various levels of sophistication and ability to provide the data needed to perform the analysis. Each of the surveyed hospitals had difficulty with at least one of the required manipulations. Careful questioning was required to assure that hospitals provided the correct distribution of Medicare payments versus co-payment amounts under the current system.

Despite the difficulties in accessing information from the complete cross section of hospitals, data at the facilities studied are remarkably consistent and reveal several significant problems that oncology programs will face under APCs.

APCs reward use of older drugs and financially punish programs that use new therapies. In this era of cost containment, it is difficult to combat the notion that the lowest cost alternative is the best alternative. Promoting the lowest cost alternative has been the goal of many managed care plans and a source of congressional concern. Yet, the federal APC system, when applied to chemotherapy and supportive care drugs, produces a series of perverse incentives for physicians and hospitals to use older, less effective therapies, while abandoning state-of-the-art cancer therapies and supportive care drugs because of their higher costs. While this potential outcome is not the intention of the system, its application in oncology has this direct effect.

Therapeutic drug data from three large hospitals (one university and two community institutions) under study illustrate the problem. Within the four APC categories for chemotherapy, the three institutions lost substantial amounts of money on nine major cancer agents: paclitaxel (Taxol®), irinotecan (Camptosar®), mesna, ifosfamide, docetaxel (Taxotere®), vinorelbine (Navelbine®), topotecan (Hycamtin®), gemcitabine (Gemzar®), and cisplatin. With three exceptions, these drugs have been approved by the Food and Drug Administration for safety and efficacy since 1994. Several of these drugs (paclitaxel, gemcitabine, vinorelbine, and docetaxel) represent the first new advances in the management of common cancers seen over the last two decades. Overall these nine drugs account for a loss of $2.9 million from the facilities' current reimbursement levels.

On the other hand, seven other drugs provide these institutions with significant increases in reimbursement. These drugs are leucovorin, cyclophosphamide, carboplatin, methotrexate, doxorubicin, 5-FU, and interferon alfa-2b. With the exception of one of these drugs, all were FDA approved in the early 1980s. These seven drugs generate APC reimbursements that are $3.0 million above current reimbursement levels. Thus, from a clinical perspective, the APC system gives hospitals every incentive to use combination therapies two decades old over newer and often more effective therapies.

The proposed APC system does not adequately adjust for the broadened use of existing drugs for which new indications have been approved. Since 1996, more than two dozen chemotherapy drugs and biologics have been reviewed and approved for indications other than those in their original labeling. These changes are not reflected by adjustments to the standard market basket HCFA is proposing. Obviously, the APC system's reliance on historic data does not account for these rapid changes.

Moreover, the proposed APC system does not adequately adjust for the rapid changes in treatment brought on by the introduction of new therapeutic drugs. Currently more than 300 new drugs and biologics for oncology indications are in the developmental pipeline. As these new agents emerge and therapeutic advances are made, hospitals and physicians will want to use them. Indeed, one new drug can significantly alter the care available

to patients with cancer and the costs associated with managing their cancer.

The recent introduction of three new cancer drugs illustrates how the proposed APC system fails to adjust for the introduction of new therapeutic agents.

- Gemcitabine (Gemzar®) was introduced in late 1996 for use in pancreatic cancer. Prior to its introduction, no effective therapy was available for palliation of patients with advanced pancreatic cancer. Gemcitabine has now made therapy available where no prior therapy existed.
- Rituximab (Rituxan®) recently became available for use with low-grade non-Hodgkin's lymphoma patients. Prior to its introduction, when patients failed conventional chemotherapy, there was no recourse. Now, rituximab (at approximately $9,000 for a course of therapy of four doses over four weeks), significantly alters the survival of these patients, where no therapy was previously available.
- Trastuzumab (Herceptin®) is the third agent. This biological has been shown to alter the life span of metastatic breast cancer patients in a significant proportion of cases. At $575 per patient dose per week for the life of the patient, this drug will have a significant impact on hospital costs.

All three drugs fall into the lowest priced chemotherapy category and would be reimbursed a mere $56, well below their acquisition costs. The use of any one of the most recently released drugs could drive a hospital cancer program into rapid debt.

There appears to be little clinical coherence to the four APC categories that have been proposed for chemotherapy. One of the key issues in the debate over whether APCs can be used with chemotherapy is the lack of substitutability between various agents. Hypothetically, HCFA is attempting to encourage providers to use the lowest cost-effective alternative. In the case of chemotherapy, however, there are many new drugs with significant therapeutic value for which there are no substitutes. Thus, providers are compelled to use Herceptin®, Rituxan®, and other drugs and combinations of drugs where they are the only appropriate choice, regardless of the cost. Given that these drugs are sole-source drugs with high costs during their patent life, hospitals will find that their costs continually outpace HCFA's updates.

Hospitals will incur losses from supportive care drug use, clinic visit code, and supplies. In each of the reviewed institutions, there is substantial use of supportive care drugs. Under the APC system, supportive care drugs are "bundled" into the chemotherapy administration fee codes, along with costs for facility fees, clinic visits, supplies, and blood products. These drugs have no separate codes of their own and may be used at the sole discretion of the hospital and provider.

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Analysis of the chemotherapy administration fee codes shows two major problems.

1) While there are three codes (APC 987, for all injections; APC 988, for infusions up to eight hours; and APC 989, for infusions over eight hours and other procedures), HCFA has only correlated Q-codes (codes that the hospital could bill) with the 987 and 989 APC categories. There is no Q-code and, therefore, no hospital payment under APC 988 in the proposed regulations. Hospitals will be able to bill only the two lowest-paying visit codes.

2) HCFA staff, in conversations with another professional society, suggest that hospitals will be allowed to bill the APC 989 code (for infusions over eight hours) only once during a visit.

Review of chemotherapy administration code compensation under these constraints suggests that "at best" hospitals will cover their costs for the basic service. In other words, the codes will not cover the lost revenue currently generated for clinic visits and facility fees (the 510 code), supplies, and supportive care drugs. These drugs include the antiemetics (granisetron [Kytril®], ondansetron [Zofran®], and dolasetron mesylate [Anzemet®]), the colony stimulating factors (filgrastim [Neupogen®] and sargramostim [Leukine®]), the antifatigue medicine (epoetin alfa [Procrit®, Epogen®]), and the medicine for bone metastases and hypercalcemia (pamidronate disodium [Aredia®]). In each case, the study institutions will lose between $500,000 and $1.1 million in supportive care drug reimbursement. Additional losses will be generated because HCFA has bundled in reimbursement for facility fees and supplies.

There are significant disparities in the APC formulation for chemotherapy and supportive care drugs. The misformulation of the APC categories relating to chemotherapy has several explanations. First, as already noted, new drugs are continuously introduced. About a dozen new agents have been introduced to the market in the last two years, agents that would not have been included in the 1996 market basket. Second, about two dozen new off-label indications for drugs released in the past five years have been approved by the compendia and FDA since 1996. These changes would not have been reflected by adjustments in the 1996 market basket used by HCFA in its calculations. Third, in its attempt to formulate the APCs for chemotherapy and other outpatient procedures, HCFA threw out any bill for multiple procedures. Only single pro-

cedure bills were analyzed. One analytic firm has studied this sampling technique and found that 95 percent of all chemotherapy bills were excluded from analysis by this process. This exclusion may explain why a number of older drugs have been reimbursed at higher levels than many newer therapeutic drugs: These specific drugs are often administered without other drugs and, thus, pass the single procedure screen.

The methodology that HCFA used for formulation of the current four APC groupings does not take into consideration the rapid changes that are occurring with therapeutic drugs. Indeed, APCs reward use of older, single agent and combination drug therapies while discouraging use of newer, more effective combination therapies.

On average, the community and university hospitals that were surveyed will experience losses in oncology outpatient revenues in the 30 percent range under APCs. Most oncology outpatient departments will no longer meet hospital criteria for a supportable service and are likely to close. Those facilities that choose to offer the service will see a significant cut in their revenues from chemotherapy and supportive care drugs. Hospitals will certainly identify drugs that are financial losers and winners. When they do, they will find that there is a set of incentives built into the APC structure that discourages the use of newer agents and promotes the use of older agents.

On the basis of the data now under review, we believe that HCFA's estimate of a 30 percent loss for the larger cancer hospitals is a figure that is likely to hold for most other hospital outpatient cancer programs. These types of losses will cripple the majority of hospital outpatient programs and will be a significant blow to university cancer hospitals that conduct a significant share of the nation's clinical research efforts.

RADIATION ONCOLOGY TECHNICAL CUTS

During the summer of 1998, staff at ELM Services, Inc., developed a model of outpatient non-hospital affiliated radiation oncology services for use by the Association of Community Cancer Centers in responding to HCFA's practice expense regulations. ELM applied the same model to a hospital-based radiation oncology program and found similar results. Using this *pro forma* model, radiation oncology programs in hospitals seeing thirty-five patients per day with a 60 percent Medicare case mix would experience a 28 percent operating margin shortfall under APCs. At these levels, radiation oncology facilities will not be able to replace equipment or keep up with the state of the art. Indeed, a high percentage will stop operation shortly after enactment of the regulation.

Indeed, APCs reward use of older, single agent and combination drug therapies while discouraging use of newer, more effective combination therapies.

Using actual coding data from existing institutions, we checked the model against current billing data. In these cases, without provision for any replacement equipment or updates, there was a 29 to 31 percent loss in reimbursement for Medicare patients. Thus, federal APC cuts are likely to cause another significant proportion of radiation oncology centers to close. We believe APCs will threaten one-third of radiation oncology centers in hospital-based settings.

LIKELY CONSEQUENCES

Proposed implementation of APCs may force hospitals to close their outpatient chemotherapy services in an effort to limit liability. Patients in their service areas will be more likely to receive therapeutic and supportive care drugs in a physician's office; institutions may choose to generate more hospital stays.

Current pharmaceutical and biotechnology pipeline data suggest that 25 percent of all chemotherapy is delivered in outpatient hospital settings. The loss of this location for chemotherapy and supportive care drug delivery will have a number of consequences. The most devastating effects are likely to be at teaching hospitals, rural hospitals, and large community facilities that have purchased physician practices or in which physicians provide the bulk of their chemotherapy through the hospital outpatient department and bill under the hospital's provider number. In each of these settings, a significant reorganization of the way services are currently delivered will be required.

Teaching hospitals. HCFA itself estimates a loss of 9.4 percent at these institutions. The loss from chemotherapy and radiation oncology shortfalls is likely to force university hospitals to jettison their current arrangements, passing revenues to physician practice plans or to other joint ventures. This action will cut into the hospital revenue base and jeopardize much of the clinical research currently conducted through university cancer centers.

Rural hospitals. HCFA has noted that rural hospitals will receive a disproportionate cut under the new system. At rural hospitals, chemotherapy is often delivered in an outpatient ambulatory area by oncologists who travel from their central office locations once a week to treat patients. Such arrangements would likely end, given that the hospital will no longer be able to afford to participate.

Large community hospitals. A number of larger community hospitals have bonded oncologists in an attempt to develop integrated cancer programs. A recent survey of ACCC member institutions indicates that approximately 35 percent of these institutions have one or more physicians who use an outpatient chemotherapy area for most of their patient care activity. These physician/hospital relationships would have to end or be radically

restructured under the current APC compensation structure.

Radiation oncology centers at hospitals tend to be larger than their freestanding counterparts. However, the idea that one can "lose a little on every customer, but make it up in volume" is inaccurate. Hospitals that have patient volumes below seventeen patients per day (approximately 22 percent of radiation oncology centers) will be in immediate jeopardy. Those hospitals with patient loads up to thirty-five patients per day are likely to see significant losses in a short period of time. Because HCFA's proposed APC system is likely to result in the closing of a significant number of radiation oncology units, patient loads at the remaining centers are likely to increase. Greater proportions of Medicare patients in their case mix, however, will not necessarily make the survivors healthier.

Overall, APCs are likely to have a devastating impact on the cancer research and delivery infrastructure that has been established over the past two decades. While members of the administration and Congress tout their willingness to support cancer research, they are supporting legislation and regulations that will ensure that those research advances are not delivered to Medicare patients. Further, the research infrastructure at medical schools is likely to be seriously impaired, since these institutions will no longer be able to afford to conduct clinical trials. Indeed, these hospitals will not be able to afford to deliver the control arm of many studies.

APC regulations will damage another long-cherished goal of the nation's cancer effort: to assure that cancer patients and their families need not leave their home communities to receive state-of-the art care. APCs will eliminate radiation oncology and chemotherapy in rural hospitals and radiation oncology in rural freestanding settings. With significantly fewer radiation oncology facilities in urban areas and many hospitals no longer providing chemotherapy in outpatient settings, patients may have a great (and unnecessary) distance to go before they will be able to receive treatment.

Second Opinion: APCs May Put Patients At Risk

by David Regan, M.D.

The draconian view of the proposed Ambulatory Payment Classifications (APCs) foresees a significant alteration in the patterns of care available to cancer patients at hospitals, a change that might turn back progress and put patients at risk. For example, if hospitals cannot afford to give the newer (and far more expensive) antiemetic drugs, they may be forced to use older and far less effective methods of emesis management (such as treatment with prochlorperazine, chlorpromazine, and lorazepam). Less effective management of a patient's emetic needs means that many patients will be unable to tolerate the full (and most effective) therapeutic dosage of their chemotherapy medications. Without the more effective supportive therapies, past experience shows that more patients will run the risk of dehydration at home, and more will require rehydration as a hospital inpatient.

The absence of appropriate reimbursement for supportive care drugs will be damaging to hospital programs in a number of other ways.

- *A rise in hospitalizations for septic episodes.* It is well documented that growth factors reduce hospitalization for septic episodes. With the huge financial losses under the APC system that the colony stimulating factors will generate, hospitals may be forced to admit patients for septic episodes instead of allowing them to stay at home. In the elderly patient, the use of growth factors is often vital to maintain standard dose intensity. Without the availability of growth factors, hospitalizations for septic episodes will go up, and dose intensity will decline.
- *More transfusions.* Epoetin alfa has altered the need to expose patients to blood products. Clearly, loss of access to epoetin alfa under the APC system will translate into more transfusions, increased risk for elderly patients, and increased financial burden.
- *Increases in overall cost of care.* Loss of access to pamidronate disodium (Aredia®) will be another blow to patient care. If hospitals cannot afford to use this drug in multiple myeloma patients with bone metastases or in breast cancer patients with osteolytic bone metastases, overall costs of care will increase because of bone breakage and subsequent hospitalizations for surgeries.

Clearly, under the proposed APC system the absence of appropriate reimbursement for supportive care drugs will be damaging to hospital programs. In combination with losses generated from use of newer therapeutic drugs, these losses are likely to make hospitals reconsider what types of cancer services they can provide. One option might be to provide a lower level of service. In this scenario, hospitals would provide only older, less toxic drugs on an outpatient basis. Of course, given their margins, hospitals might also switch to a lower level of nursing personnel, eliminating a number of oncology nursing positions.

A more likely scenario, in my opinion, will be for hospitals to determine that the service does not meet their current thresholds for service continuation, which will lead to the closing of a number of outpatient cancer facilities. This outcome turns back the clock in the war on cancer. Hospital cancer programs are an indispensable component of a complete cancer program. By destroying their ability to compete and provide current services, the Health Care Financing Administration does a significant disservice to cancer patients and their families throughout the country.

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