

The data from the four centers was projected to 3,990,495 million chemotherapy infusions administered to a national Medicare population. When multiplied by the average cost of preparation of infusions determined by the current study (\$36.03), the total annual cost to Medicare for chemotherapy preparation by pharmacists is estimated to be \$143,777,534.85.

These data provide scientific support in the consideration of appropriate reimbursement for the provision of chemotherapy services to the health care providers of Medicare beneficiaries.

**Introduction:**

The Medicare Modernization Act (MMA) of 2003 will significantly impact payment for oncology drugs and their administration. It is commonly recognized that current reimbursement for the administrative aspects of providing chemotherapy infusions is low and not necessarily reflective of the comprehensive resources and costs involved in the process. However, these low reimbursements have traditionally been compensated by generous reimbursements for pharmaceuticals when directly billed via the oncology practice. The MMA alters Medicare reimbursement from an Average Wholesale Price (AWP) for reimbursement to an Average Sales Price (ASP). The ASP will take into account the price from the manufacturer to the first point of sale (either to wholesaler or direct to oncology practice) and allow for all subsequent distributors to only apply a total 6% mark up. Although in principle, this may appear to balance reimbursement to an oncology practice overall, National Patient Advocate Foundation (NPAF) has appropriately raised concern that these changes may pose access problems for Medicare Beneficiaries. NPAF also believes that it was the intent of Congress to establish a reimbursement system for Part B drugs and drug administration services that would ensure payment to oncology practices at levels sufficient to assure that patients will continue to have access to high quality community cancer care. In a letter dated September 23, 2004, to the Honorable Mark McClellan, M.D., Ph.D., NPAF presented comments on Regulatory Impact Analysis (<http://www.npaf.org/news.php?p=297>, Accessed November 30, 2004). A copy of the letter is included in Appendix 1. Comments relevant to this project are included below.

***Changes in Reimbursement for Drug Administration Services:***

The MMA provides for increased work and practice expense Relative Value Units (RVUs) for those drug administration services typically billed by oncologists. Payments for those drug administration services would receive additional temporary increases of 32% for 2004 and 3% for 2005. These changes were in addition to MMA-mandated across-the-board updates to all physician fee schedule services of 1.5% in both 2004 and 2005. The payment rates for drug administration services set forth in the Proposed Rule reflect these MMA-mandated revisions. Due to the reduction of the transitional payments from 2004 to 2005, Medicare reimbursement for oncology drug administration services will experience a net reduction of approximately 22%

next year. CMS estimated that these services will account for nearly one-third of typical oncology revenues in 2004.

*Changes in Reimbursement for Drugs and Biologicals:*

The MMA instructed CMS to collect data from pharmaceutical manufacturers about the Average Sales Price (ASP) of their Part B drugs that are not paid on a cost or prospective payment basis and to begin reimbursing oncologists and other physicians who administer injectable and infusible drugs in their offices at 106% of ASP beginning in 2005. Assuming no changes in utilization, CMS estimates that the switch from AWP-based reimbursement in 2004 to ASP-based reimbursement in 2005 will result in a one-year decrease in drug revenues to oncologists of approximately 8%. This decrease is significant since CMS has estimated that drugs were responsible for about 70% of the typical oncologist's revenues in 2004. In addition, this decrease comes on top of what CMS has estimated to be an approximately 12% reduction in oncology drug revenues in 2004.

On September 8, 2004, the American Society for Clinical Oncology (ASCO) held a Congressional briefing to present the results of a nationwide survey conducted by Muse & Associates of actual drug purchasing experience at 93 oncology practices. The study suggests the impact of the ASP-based reimbursement system could be even greater than CMS projects. Assuming reimbursement at the rate specified in the Proposed Rule, for the practices surveyed, the Muse Study shows the actual reduction in drug payments will average 15%, ranging from a low of 7.5% to a high of 26.3%, rather than the 8% estimated by CMS. Further, in 2005, about a quarter of the cancer drugs included in Table 28 of the Proposed Rule will cost the typical oncology practice more than the Medicare allowable amount. For example, 73% of practices will be unable to cover the cost of epoetin, a drug used to treat chemotherapy-induced anemia. Seventy percent will have to pay more than the Medicare allowable cost for pamidronate, a drug used for bone metastasis, which commonly occurs in many advanced-stage cancers. For irinotecan, an essential drug in the treatment of colon cancer, 56% of practices will have to pay more than Medicare allows and 53% will be unable to cover the cost of gencitabine, which is used to treat lung and pancreatic cancer, furnished to their Medicare patients.

*Limits on Prompt Paying Discounts in ASP:*

NPAF has asked that prompt pay discounts extended by pharmaceutical manufacturers to wholesalers and distributors be excluded because those entities do not pass these fees through to their customers. Requiring manufacturers to subtract the standard 2% prompt payment discount that they extend to wholesalers when ASP is calculated effectively reduces the Medicare reimbursement rate for incident to drugs to ASP+4%.

At issue is the appropriateness of the levels of payment for the drugs and their administration under these regimens pursuant to the Medicare reimbursement changes. Altered reimbursement may impact the viability of oncology practices, which may affect patient access to care. In order to understand the adequacy of the current and planned reimbursement, one must have a thorough understanding of the total costs associated with the administrative services involved in the preparation and delivery of oncology drug regimens.

**Study Purpose:**

In specific, this study was focused on the drug-related handling costs involved in preparation and delivery of oncology drugs and regimens (i.e., management costs). The cost of purchasing the drugs and physically administering them to patients was not included.

Drug-related handling costs were assessed via a local pilot study and then expanded to three additional oncology practice centers in the United States. The data from these four centers was then applied toward a national population who had received oncology treatment in order to project the impact of these costs on national reimbursement.

**Study Objectives:**

- 1) Establish an Advisory Board, including a study steering committee and outside experts;
- 2) Determine the top oncology drug regimens, individual oncology agents and concomitant supportive agents at the sites;

- 3) Develop comprehensive surveys to capture all potential drug-related handling costs associated with the preparation and delivery of oncology drugs identified in first objective, to include at least handling, storing, mixing, packaging, transferring, disposal, cost of collection, bad debt, and waste, but not the cost of purchasing the drugs or administering them to patients;
- 4) Implement surveys in four selected centers across the U.S.;
- 5) Compile the data across the four sites by drug regimens, patient characteristics and geography;
- 6) Apply the collective data from four sites to a population with matched drug regimens for patients being treated in oncology practice centers using a national dataset (i.e., Medstat MarketScan database);
- 7) Project these findings to the U.S. population to understand the potential impact on national reimbursement by Medicare for oncologists and the impact this may have on patient access to care.

**Description of Site Selection and Study Centers:**

The four selected sites were identified and selected by location (distribution throughout the country), practice setting (academic vs. community), and the ability to achieve 10 production occurrences of each of the identified top utilized oncology and concomitant supportive drugs within a one month collection period. A general description of the four sites is as follows:

Montgomery Cancer Center (MCC) is a community-based oncology practice serving Montgomery, Alabama, and its surrounding communities for a total population of approximately 600,000 people. The practice consists of four medical oncologists and three radiation oncologists at the main center. MCC also has a satellite clinic established in Selma, Alabama, that is staffed by one oncologist and radiation oncologist. MCC supports an Oncology clinic held once a week in Troy, Alabama. MCC provides advanced radiation, chemotherapy, nutritional guidance and psychological support to its patients, along with an onsite breast care and imaging center. MCC has been dedicated to providing comprehensive oncology care for its community since 1990.

The Huntsman Cancer Institute (HCI) is an academic research and National Cancer Institute-designated clinical cancer center affiliated with the University of Utah Health Science Center and Hospitals and Clinics. HCI provides both inpatient and outpatient services to cancer patients throughout Utah, Western Wyoming, Southern Idaho, and Eastern Nevada providing access to care to approximately 3 million people. Inpatient services are provided by Huntsman Cancer Hospital consisting of 50 patient care suites, and high tech imaging, radiation oncology and surgical services which are connected to HCI outpatient center. Outpatient services and departments include chemotherapy infusion center, Family Cancer Assessment Center, Brain, Spine, Skull Base Tumor Service, Center for Children, Facial Prosthetics, Gastrointestinal Center, Melanoma Program, Radiation Oncology, and Sarcoma Service, and Pain and Palliative Care Service. There are over 55 cancer specialists, including 19 oncologists involved in research and patient care. HCI has been dedicated to research, prevention, diagnosis, treatment and cure of cancer since 1995.

Fairfax-Northern Virginia Hematology/Oncology is a community-based practice of hematologists/oncologists serving the Western suburban Washington D.C. area. The practice consists of 18 medical oncologists with 7 office locations throughout Northern Virginia serving the communities of Fairfax, Alexandria, Prince William, Loudoun and Fauquier counties, a total population of 1.2 million people. The practice also includes a FACT (Foundation for the Accreditation of Cellular Therapeutics) -accredited outpatient stem cell transplant program. The practice has had a presence in the community for over 30 years.

University of Wisconsin Comprehensive Cancer Center (UWCCC) is an academic cancer center founded in 1973 and serves 2.5 million people in southern and central Wisconsin and adjoining portions of Illinois. The UWCCC holds the unique distinction of being the only comprehensive cancer center in Wisconsin, as designated by the National Cancer Institute. An integral part of the UW Medical School, the UWCCC unites over 200 physicians including 26 medical oncologists, 13 radiation oncologists, 10 surgical oncologists, 3 gynecological oncologists, and other scientists who work together in translating discoveries from research laboratories into new treatments that benefit cancer patients.

## Methods:

### *Study Committee and Advisory Board:*

A study committee was formed early in the study process. This study committee was comprised of the core staff from PORC involved in this study, including outcomes researchers Dr. Diana Brixner, Dr. Gary Oderda and Dr. Nancy Nickman. The study committee also contained two individuals from each site with expertise in oncology practice and/or administration. Other study committee members from Utah included Dr. Keri Fakata, with expertise in pain/palliative care research, James Jorgensen M.S., R.Ph. with expertise in hospital administration, and Scott Silverstein R.Ph., M.S., oncology pharmacotherapy specialist. The committee members from Alabama were Ashley Lambert R.Ph., oncology pharmacotherapy specialist, and Fletcher Bancroft, MMC administrator. The committee members from Fairfax-Northern Virginia Hematology/Oncology were Robert Bretzel RPh., oncology pharmacotherapy specialist, and Dr. Roy Beveridge, director and medical oncology specialist. The committee members from UWCCC were Lee Vermulen, R.Ph. M.S., director of the Center for Drug policy and Sara Lentz, Pharm.D., oncology pharmacotherapy specialist, and Tom Kirschling (Pharmacy Resident).

An advisory board of experts was also established to confirm study design and to review and interpret study results. This board included three national experts in oncology practice and Medicare Reimbursement strategy. Professional society representation from groups such as American Society of Health-System Pharmacists (ASHP) and the American College of Clinical Pharmacy (ACCP) were also present. This panel convened periodically throughout the study. The members of this board came from the study committee and also included oncologist Dr. John Ward from the Huntsman Cancer Institute. Information on each member of the board can be found in Appendix 2.

The first advisory board teleconference consisted of an overview of the purpose of the study, discussion of methodology (event-based cost analysis), and data collection process including what was to be collected and who was to collect the data for each site. Four additional advisory teleconferences were held to develop and finalize the three part data collection survey.

***Institutional Review Board:***

The University of Utah required expedited review through the Institutional Review Board (IRB) and Clinical Cancer Investigational Committee for this study; all other sites were provided a waiver with no formal IRB evaluation due to the fact that patients were not being followed for this study and no identifying data was collected. A letter was obtained from each site indicating such.

***Drug Selection Process:***

Each study site was instructed to review infusion schedules and identify the most commonly used chemotherapy and concomitant agents. Commonly used drugs were reported by each site at the first teleconference. A survey was compiled from these results and sent to each site to confirm the top selected oncology and concomitant supportive agents common to all sites. A total of 22 chemotherapy and concomitant drugs were selected by highest volume of utilization as determined by each site. Concomitant supportive drugs were represented by classes of drugs including the 5HT-3 antagonists, erythropoietic agents, colony stimulating factors, steroids and bisphosphonates to take into consideration different formulary requirements of similar agents. (Appendix 3) The project goal was to collect data on 10 production occurrences of each drug or regimen in a one month data collection period in order to assess the staffing time and associated costs of preparation and delivery.

***Survey Development Process:***

A multi-center, comprehensive, three-part survey was developed to capture all potential pharmacy-related costs associated with the production of oncology drug therapies, such as cognitive services, handling, storing, mixing, packaging, transferring, disposal, cost of collection, bad debt, and waste. The cost of purchasing the drugs and physical administration to patients was not captured in this study. The first survey was a Fixed Cost Survey that evaluated the fixed ancillary costs of drug-related handling in the delivery of chemotherapy to oncology patients (Appendix 4, Sections I and II). Development of the first survey involved identifying modules for the fixed costs of production and delivery of chemotherapy and concomitant agents. The modules were identified by consulting with James Jorgensen, M.S. R.Ph, hospital pharmacy administrator from Utah, and Robert Bretzel R.Ph., an oncology pharmacotherapy specialist

from Virginia. The identified modules were discussed and confirmed by teleconference with both advisory and study committees.

Fixed costs were collected as annualized data from each site regarding identified activities associated with the preparation of chemotherapy infusions. The key activities identified included, drug storage, space, inventory management, insurance management, waste management, space, payroll, equipment and supplies, information resources and shipping.

The second survey was a Time-and-Motion (TM) study to evaluate the drug-related cost of processing chemotherapy, by capturing tasks performed by the pharmacist and technician during preparation of chemotherapy and concomitant drugs (Appendix 4, Section IV). The tasks involved were identified through input from the advisory committee, practicing oncology pharmacists and technicians, and administrators from the four sites. The initial tasks were identified by consulting with oncology pharmacotherapy specialist Scott Silverstein R.Ph. from Utah and Robert Bretzel R.Ph. from Virginia. A production flow chart was developed and presented to advisory board and study committee via email for discussion in teleconferences. These tasks included therapy management, patient care, consultation, order entry and compounding, and production.

The third part of the survey was an observational TM study developed to evaluate the constitution of a typical shift for an oncology pharmacist (Appendix 4 – Section III). This included the principle tasks involved in drug preparation, as well as two additional categories of “other” and “interruption” to capture the full shift of a pharmacist and put the time spent on drug preparation into perspective.

Once data collection forms were finalized, a beta test of both TM surveys was conducted over a one week period at each site. A final collection process was identified through discussion between sites. Initially, one TM survey was developed to capture tasks performed by pharmacists or certified pharmacy technicians during preparation of chemotherapy and concomitant drugs selected by the four sites. The beta test determined that information could be missed if the TM was based only on tasks associated with top identified drugs. Therefore, a second data collection instrument was developed to follow a pharmacist through a typical work day, timing all activities. A comment box was included to list drugs and dosage forms the pharmacist was

working on during that task. Three separate beta tests were conducted: the first was the drug-task based approach observing only the top identified drugs, the second was observation of an individual pharmacist, listing all drugs and dosage forms, and the third was the combination of the two surveys. On the third beta test, pharmacist activity was observed, but relation to drug and dosage form was not collected on this form. The advisory board had a teleconference to finalize the TM data collection process and decided to utilize both the drug-task observation survey and the pharmacist observation survey for one typical shift. The TM data collection process is described below.

***Data Collection Process:***

***Fixed Costs:***

A pharmacist or pharmacy manager at each individual practice site spent a period of several weeks collecting a wide variety of information regarding annual patient counts and patient demographics, total annual doses of drugs administered, and the costs specific to each practice site for the most recent fiscal year that were associated with the preparation and delivery of oncology drugs. The fiscal year for which data was provided at the Virginia site ran from January 1, 2003 to December 31, 2003. The fiscal year for which data was provided at the Utah and Wisconsin sites ran from July 1, 2003, to June 30, 2004. The fiscal year for which data was provided at the Alabama site ran from November 1, 2003 to October 31, 2004.

Detailed information was collected at each site on the total floor space utilized; the value of the utilized space; the annualized value of storage facilities and preparation equipment; the cost of supplies; annual payroll and specialized labor costs; the annualized value of computers, phones and fax machines; telecommunications costs; total inventory values; and costs associated with waste management, shipping and information resources. The collection of data was followed by a rigorous verification and fine-tuning process to ensure that all costs reported were accurate and that all of the comparisons were consistent across practice facilities. Once the integrity of the collected data had been assured, the annual fixed costs information was analyzed in combination with the information on annual chemotherapy dose counts to determine a total cost per dose at each practice site and for all sites combined.

*Time-and-Motion:*

Once the most common drugs across sites were identified, pharmacy staff were observed in a TM study. A minimum of ten production occurrences of each drug or drug class (chemotherapy drug, regimen or concomitant care) were observed. Selected drugs were either recorded as single agents or as part of a regimen; all concomitant drugs related to the observation were also recorded. The TM observations were conducted at each individual site over a three week period, with the exception of a 10-day collection period in Alabama, until a minimum of 10 observations per drug per site were collected.

The observer assigned by each individual site utilized a digital watch that displayed hour, minutes, and seconds in order to capture actual time in task. Actual start and stop times were recorded for each task listed on the oncology drug survey. A start time was entered when a pharmacist or technician began processing an order for a drug selected for observation in this study. As the individual would switch tasks, a stop time would be entered for the previous task and a start time would be entered for the new task. This process continued until drug was delivered to patient or final check by the pharmacist occurred. If other communications or activities occurred during an observation after delivery of drug, this was also captured on the same survey form with actual start and stop times recorded.

The second TM survey was done to assess all tasks conducted by a pharmacist in a specified period of time (one shift). Actual times were recorded through out the day as the observed pharmacist changed tasks. This was an evaluation of time spent in task only; no drug information was recorded. If the pharmacist performed a task not listed on survey, this was noted in the comment column and the specific task was listed.

***Methodology for National Projection:***

The proportion of Medicare patients with supplemental commercial insurance and on the same drug regimens observed in the study sites was estimated from the Medstat Marketscan database; this data has been used to project the results to a national U.S. population. Medstat Marketscan is a national database that includes health care claims for approximately 8 million patients.

Medstat used its MarketScan Medicare Supplemental and Coordination of Benefits (COB) Database to develop counts of Medicare-eligible individuals who received the specified chemotherapeutic agent previously described and counts of the total number of chemotherapy infusions administered during 2003. This database contains health insurance claims from current and former employer-sponsored health plans that provide supplemental insurance to Medicare-eligible employees, retirees, and their dependents. In 2003, the year from which the data were obtained, the MarketScan Medicare Supplemental and COB Database contained information on 782,000 covered lives. From this database, all claims for outpatient administration of the indicated chemotherapeutic agents were selected, based on the indicated national HCPCS codes.

Each claim was assumed to represent a single infusion (dose) of the coded agent, except where more than one claim for a given agent appeared for the same patient and date of service. This situation occurred in only 1.4% of selected claims; therefore, a single infusion was counted from that claim.

In addition to counts of infusions for each agent, counts of patients who received each agent at any time during 2003 were also generated. Counts of infusions and patients were then projected to the national Medicare population in a two-stage procedure. The first stage involved projection to the population of Medicare beneficiaries with employer-sponsored supplemental insurance. This was accomplished using person-level weights developed by Medstat for use with its MarketScan Medicare and COB Database. Briefly, the covered lives represented in the database are treated as a stratified sample (by age, sex, region, and relation to policy holder) drawn from the national population with similar coverage, the size of which is estimated from the National Medical Expenditures Survey (NMES). The weights are calculated as the inverse of the sample proportions within each stratum.

The second stage of the projection was from the population with employer-sponsored Medicare supplemental insurance to the entire Medicare population. The latter was accomplished by calculating the ratio of the latter to the former within age-and sex-specific strata in NMES, then multiplying the age-and sex-specific counts of infusions and patients estimated in the first stage by these ratios.

Drug storage items were similar across all three sites consisting of fixed shelving, refrigerators, and dispensing cabinets. However, Alabama had built in cabinets, no PIXIS system and only a refrigerator for storage where Utah had all of the above plus an exceptionally large (and costly) dispensing cabinet.

***Space Rental:***

Space Rental was calculated for total space (square footage) used, including clean rooms, storage and office space. Rental fees incorporated maintenance and utilities. The summarized costs per category for each site, divided by the annual number of doses given at each site for Space Rental are presented in Table 4.

**Table 4: Space Rental Costs**

Site	Total SqFt	Cost Per SqFt	Total Costs	Number of Doses per Year	Cost per Dose
Alabama	967	\$20.31 / Year	\$19,639.77	28,236	\$0.70
Utah	203	\$19.00 / Year	\$3,857.00	5,965	\$0.65
Virginia	730	\$38.58 / Year	\$28,163.40	32,636	\$0.86
Wisconsin	125	\$72.89 / Year	\$9,111.25	17,072	\$0.53
Total			\$60,771.42	83,909	\$0.72

Between the two community centers Virginia had a much higher cost per square foot than Alabama, as would be expected due to differences in Cost of Living (COL). Between the academic centers Wisconsin had a higher fee than Utah, however Wisconsin actually owns the building and their costs were calculated based on building depreciation as opposed to rent. The cost per dose across all four sites for space is very similar, once the costs are divided by the doses given at each site.

***Inventory Management:***

Inventory Management costs were calculated by taking the annual physical inventory for chemotherapy and all concomitant agents provided as part of that treatment at one point in time, multiplied by a 7%

opportunity cost plus the labor cost (hours time salary plus benefits) of personnel involved in inventory management. Detailed costs of each line item for Inventory Management are presented in Appendix 5. The summarized costs per category for each site, divided by the annual number of doses given at each site for Inventory Management are presented in Table 5.

**Table 5: Costs of Inventory Management**

Site	Total Costs	Number of Doses per Year	Cost per Dose
Alabama	\$139,887.40	28,236	\$4.95
Utah	\$30,191.51	5,965	\$5.06
Virginia	\$84,495.92	32,636	\$2.59
Wisconsin	\$39,420.81	17,072	\$2.31
Total	\$293,995.64	83,909	\$3.50

Physical inventories at each site balanced well against the number of doses given between sites. The labor costs for Virginia were significantly higher as they had more staff to manage a higher turnover of inventory. All four sites agreed that inventory management is a balance between the amount of inventory you are willing to keep on hand vs. the amount of investment in staff to better manage that inventory.

***Insurance Management:***

Insurance management was calculated based on staff hours spent on this task multiplied by the salary plus benefits. Labor costs were the only cost collected for Insurance Management. The labor costs for insurance management by site, divided by the annual number of doses given at each site for Insurance Management are presented in Table 6.

**Table 6: Costs of Insurance Management**

Site	Total Costs	Number of Doses per Year	Cost per Dose
Alabama	\$235,996.00	28,236	\$8.36
Utah	\$43,050.00	5,965	\$7.22
Virginia	\$289,536.00	32,636	\$8.87
Wisconsin	\$64,575.00	17,072	\$3.78
Total	\$633,157.00	83,909	\$7.55

As can be seen in the data variance, Virginia and Alabama have a significant amount of staff dedicated to insurance management, coding and reimbursement, again driven by a substantially larger patient base more typical of a community cancer setting. On the other hand the hospital outpatient setting sites reported that their insurance management is more decentralized across the health system which perhaps lowers their costs, but does not necessarily lead to greater efficiency.

***Waste Management:***

To calculate annual waste management costs uncompensated annual drug waste (drug prepared but not given to patient) was added to all other listed items related to drug waste management (see Appendix 4, Section II, page 44; Fixed Costs Survey Question #18 items a. – k.). To this total, the hours of staff involved in waste management were multiplied by salary and benefits. Detailed costs of each line item for Waste Management are presented in Appendix 5. The summarized costs per category for each site, divided by the annual number of doses given at each site for Waste Management are presented in Table 7.

**Table 7: Costs of Waste Management**

Site	Total Costs	Number of Doses per Year	Cost per Dose
Alabama	\$100,413.00	28,236	\$3.56
Utah	\$28,327.00	5,965	\$4.75
Virginia	\$125,843.00	32,636	\$3.86
Wisconsin	\$104,912.00	17,072	\$6.15
Total	\$359,495.00	83,909	\$4.28

As determined in our analysis waste management is handled differently between sites. Labor cost of waste management varied depending on who is responsible. As for drug prepared and not used, this is a process related outcome that also varied between sites. At Utah, the majority of waste disposal is handled centrally through the campus and the oncology unit is not charged back, whereas this was not the case at the other sites.

***Payroll:***

Payroll was calculated based on hours worked by pharmacists and pharmacy technicians, multiplied by hourly wage and then the cost of benefits were added. Labor costs for pharmacists and technicians were the only costs collected for Payroll. The labor costs for payroll by site, divided by the annual number of doses given at each site for payroll are presented in Table 8.

**Table 8: Costs of Payroll**

Site	Total Costs	Number of Doses per Year	Cost per Dose
Alabama	\$305,565.00	28,236	\$10.82
Utah	\$147,172.48	5,965	\$24.67
Virginia	\$351,876.00	32,636	\$10.78
Wisconsin	\$377,580.00	17,072	\$22.12
Total	\$1,182,193.48	55,673	\$14.09

The ratio of pharmacy staff to output varied among sites. The staff per dose costs were very similar between the two academic medical center sites, and then between the two community centers. This could be due to the greater expectation of academic medical center oncology pharmacists to be involved in teaching and clinical consultation in line with the academic mission of the University.

***Equipment:***

Annualized costs for equipment were calculated for two main items: vertical flow hoods and ventilation equipment. This equipment is used for the aseptic and sterile production of injectable drug products and protects workers from dangerous and toxic contamination due to airborne drug particles. Data on the cost of infusion pumps was collected; however, it was not included in the analysis as this

was considered to be a direct cost associated with the administration, not the preparation of the chemotherapy agent. The cost for hoods was calculated by taking the cost of the hood, divided by the years of useful life. To this, the price of venting installation was added, also divided by the years of depreciation. The cost of annual inspections was also included. Additional minor equipment including computers, phones and faxes were added along with annual telecommunication costs. Detailed costs of each line item for Equipment are presented in Appendix 5. The summarized costs per category for each site, divided by the annual number of doses given at each site for Equipment are presented in Table 9.

**Table 9: Costs of Equipment**

Site	Total Costs	Number of Doses per Year	Cost per Dose
Alabama	\$24,453.00	28,236	\$0.87
Utah	\$6,894.00	5,965	\$1.16
Virginia	\$9,703.00	3,2636	\$0.30
Wisconsin	\$7,691.00	17,072	\$0.45
Total	\$48,740.00	83,909	\$0.58

***Supplies:***

Data on supplies were provided as annual costs per item therefore the quantity of each item was multiplied by unit or bulk costs to provide the annual costs for all supplies listed. The summarized costs per category for each site, divided by the annual number of doses given at each site for Supplies are presented in Table 10.

**Table 10: Costs of Supplies**

Site	Total Costs	Number of Doses per Year	Cost per Dose
Alabama	\$98,122.00	28,236	\$3.48
Utah	\$135,943.00	5,965	\$22.79
Virginia	\$77,382.00	32,636	\$2.37
Wisconsin	\$40,102.00	17,072	\$2.35
Total	\$351,549.00	83,909	\$4.19

An interesting determination was the unique use of the Phaseal<sup>®</sup> system by Utah which protects healthcare workers against exposure to chemotherapy agents. This is a very expensive system which in itself attributes approximately \$15 to \$20 per dose to the aggregated cost for Utah.

***Shipping:***

A final cost collected was shipping, although only one site used carrier services extensively (Virginia) to deliver chemotherapy infusions to clientele. This cost was included and calculated as part of the total average cost per dose for Virginia, since efficiencies in other areas were most likely realized due to this process of delivery. Shipping costs for the Virginia site were \$74,288.00 for one year.

***Information Resources:***

The cost for each site's drug information access was determined as \$500.00 in Virginia. Due to uncertainties in allocation from various sources for Utah and Wisconsin, this same value was used for these sites. However, Alabama did report a \$1,200 cost for drug information resources per year.

***Fixed Cost Data Summary:***

The costs for each category by site divided by the number of doses given at each site are all presented together in Appendix 5. The aggregate drug preparation cost across all categories collected in the four sites is \$36.03 per dose provided. The aggregate number was \$32.80 for Alabama, \$67.19 for Utah, \$38.05 for Wisconsin and \$32.08 for Virginia. Recognizing the excessive cost of the Phaseal system used in Utah (\$15.00 per dose) the comparable aggregate cost for Utah would be \$52.19 and this would bring the total preparation cost per dose down slightly over one dollar to \$34.97. Across the categories the most expensive items calculated as part of the cost of drug preparation is payroll for the oncology pharmacists and technicians (\$14.00), followed by insurance management, an additional labor cost at \$7.55. Inventory, waste management, and supplies all contribute between \$1.00 and \$10.00 to the aggregate cost of preparation. Space rental, storage, equipment, shipping and information resources all contribute less than one dollar.

***Observed Chemotherapy Drugs/Regimens/Concomitant Supportive Agents:***

As previously described, TM observational data was collected at each of the four sites. As part of this analysis, data was collected on the production occurrences of the most frequently occurring/prescribed chemotherapy drugs, regimens and concomitant agents as reported by each of the sites during methodology development. Drugs used in each category were collected over a three week period of time to determine frequencies. Table 11 represents a frequency distribution of those drugs therapies, regimens, and concomitant agents observed during the TM analysis. A more detailed description of these drugs is available in Appendix 6.

**Table 11: Observed Chemotherapy Drugs, Regimens, and Concomitant Agents in the TM Analysis**

	Alabama	Virginia	Utah	Wisconsin
<b>Chemotherapy Agents</b>	151	163	161	212
<b>Concomitant Agents</b>	179	58	153	188
<b>Drug Regimens</b>	34	23	26	38
<b>Total Observations</b>	364	244	340	438

For chemotherapy drugs, most had well over ten observations per site in the preliminary observation period. Only topotecan came well below expected observations, which could have been due to a change in commonly used regimens between the time of estimation and actual observations. For concomitant blood cell stimulator therapy, darbopoetin was consistently observed more often than epoetin and pegfilgrastim was used more often than filgrastim. For anti-emetic therapy, Dolasetron was used primarily at Utah and granisetron was used primarily at Alabama. Zoledronate was observed more often than pamidronate in advanced stage cancer patients requiring treatment of bone metastases. In general, the resulting observations of chemotherapy and concomitant drugs assured investigators that the TM analysis accurately observed commonly used chemotherapy agents and concomitant agents used in the treatment of cancer.

***Time-and-Motion Analysis:***

Summaries of TM data collected from Alabama and Virginia (the community-based sites) and Utah and Wisconsin (the academic medical centers) are shown in the following tables. Seventeen categories of activities were used in the TM data collection process. However, for

ease of evaluation, TM results were consolidated into the five general categories of activities listed in Table 12.

**Table 12: Summary of Time-and-Motion Observation Categories**

<b>Therapy Evaluation</b>	<b>Patient Care</b>
Order Review by Pharmacist	Patient Communication
Collect Patient Data	Patient Counseling
Evaluate Adverse Events	Oral Premed Administration
Manage Adverse Events	Continuity of Care
<b>Consultation</b>	<b>Order Entry/Compounding</b>
Physician Consultation	Order Entry
Other Health Care Professional Consultation	Compounding
Drug Information	
Insurer Communication	<b>Production/Evaluation</b>
	Product Verification
	Production Check
	Product Special Handling

A one-day TM study of pharmacists' cognitive and production activities was conducted at each of the four sites. Results in Table 13 indicate that a majority of the pharmacists' shift activities were related to the clinical and professional provision of oncology pharmacy services. In conjunction with other key medical intermediaries (nurses, physicians, insurers, patients), pharmacists evaluated medical orders for appropriateness, supervised production and compounding, and provided direct patient care (communication, counseling, and premedication administration) during their shift.

**Table 13: Time-and-Motion One-Day Pharmacist Activity Summaries (in hours)**

	Alabama	Virginia	Utah	Wisconsin	Average
<b>Therapy Evaluation</b>	1.12	3.58	3.76	1.63	2.52
<b>Consultation</b>	3.15	1.16	2.26	3.47	2.51
<b>Patient Care</b>	0.05	0.95	1.18	2.53	1.18
<b>Order Entry/Compounding</b>	2.61	4.22	1.44	2.14	2.60
<b>Production/Evaluation</b>	0.98	0.09	1.38	1.31	0.94
<b>Interruption/Other</b>	0.33	0.24	0.85	0.28	0.43
<b>Total Hours</b>	8.25	10.25	10.87	11.37	10.19

Over a three-week period of time (with the exception of Alabama which collected TM data over a 10-day period), TM observations were collected for an oncology pharmacist and accompanying

oncology certified pharmacy technician at each of the four sites until a minimum of 10 production occurrences of each drug or drug class (chemotherapy drug, regimen or concomitant care) were collected. Table 14 contains the results of these observations. Details for tables 12 and 13 are in Appendix 7.

**Table 14: Time-and-Motion Pharmacist (PharmD)-Certified Pharmacy Technician (Pharm Tech)**

Activity Comparisons (average minutes +/- S.D.) by Site								
	Alabama		Virginia		Utah		Wisconsin	
	PharmD	Tech	PharmD	Tech	PharmD	Tech	PharmD	Tech
Therapy Evaluation	1.85 (2.04)		2.12 (2.48)		6.29 (6.41)		2.37 (1.40)	
Consultation	2.63 (4.28)		2.03 (0.95)		1.75 (2.72)		3.34 (2.62)	
Patient Care	0.71 (0.24)		0.53 (0.26)		2.11 (1.92)		4.68 (5.91)	
Order Entry/Compounding	1.78 (4.29)	2.25 (1.87)	2.12 (2.27)	3.42 (2.61)	4.21 (5.14)	10.19 (7.64)	2.22 (1.34)	5.00 (3.66)
Production/Evaluation	0.69 (2.10)		0.61 (0.47)		2.23 (1.77)		2.38 (1.41)	
Other		1.07 (1.08)		0 (0)		4.63 (6.84)		5.00 (3.65)

**Comparisons:**

Across sites, both pharmacists and technicians spent a variable amount of time performing activities in each of the five categories of activity. The community sites (Alabama and Virginia) and the academic medical center sites (Utah and Wisconsin) were more similar than different in the scope of their oncology pharmacy practices. Per TM observation of activity, each site spent similar amounts of time in cognitive and production functions. The academic medical centers appeared to spend a larger proportion of their time per observation in direct patient care and cognitive professional functions than the community sites. However, the great variability in the amount of time spent per observation in each activity was most likely due to the variability of chemotherapy complexity and oncology pharmacy practice structure, leading to variability in the actual duties performed by pharmacists at each site. In general, one would expect each site to be unique, with some commonalities in the manner of oncology pharmacy practice. However, given the highly technical nature of oncology pharmacy practice, it is more reasonable to expect high variability across professional practices sites due to structural and functional differences.

The observation of the time at all tasks for pharmacists involved in an oncology infusion practice determined that in fact the majority of their day is related to tasks associated with drug handling and preparation. In all four sites less than one hour was spent on other activities or interruptions outside of the tasks involved in drug preparation. This provided assurance that 100% of payroll costs for pharmacy staff should be included in the fixed cost analysis portion of the study.

**National Projection Results:**

From the MedStat MarketScan database, claims for a total of 63,542 infusions of the selected agents during 2003 were found for Medicare patients with supplemental commercial insurance. These are projected to a national total of 2.7 million infusions administered to Medicare beneficiaries. Fluorouracil is the most frequently administered agent, followed by leucovorin, carbaplatin, and paclitaxel. Drug-specific counts of infusions and patients are provided in the Table 15. Similar counts for specific HCPCS codes are provided in Appendix 8 of this report.

**Table 15. Counts of Medicare Persons and Infusions by Chemotherapeutic Agent.**

Chemotherapeutic Agent	Unweighted Counts		Projection to Population with Medicare and Commercial Supplemental Insurance		Projection to Total Medicare Population	
	Persons	Infusions	Persons	Infusions	Persons	Infusions
Carboplatin	1,453	6,415	21,928	97,648	59,389	263,194
Cisplatin	363	1,550	5,786	24,654	15,160	63,377
Cyclophosphamide	909	4,449	13,841	68,522	38,187	190,421
Docetaxel	849	5,040	12,869	76,849	35,333	211,862
Doxorubicin	694	2,488	10,603	37,354	29,256	103,356
Fluorouracil	1,341	11,998	20,653	187,448	56,202	507,111
Gemcitabine HCL	872	5,405	13,244	81,693	36,769	226,345
Irinotecan	398	3,004	6,155	47,212	16,223	123,198
Leucovorin Calcium	787	8,408	12,154	132,415	32,721	351,443
Oxaliplatin	12	33	245	792	724	2,573
Paclitaxel	1,070	6,006	16,121	91,360	43,601	245,757
Rituximab	864	4,297	12,791	62,484	35,700	174,878
Topotecan	126	1,158	1,828	17,171	5,256	49,745
Trastuzumab	116	1,857	1,692	28,049	4,855	78,178
Vincristine Sulfate	436	1,434	6,585	21,718	18,229	60,387
<b>Totals</b>	<b>10,290</b>	<b>63,542</b>	<b>156,495</b>	<b>975,369</b>	<b>427,605</b>	<b>2,651,825</b>

To complete the national projection it was determined from two of the four sites what proportion of total chemotherapy doses did the fifteen observed drugs represent as shown in Table 16.

**Table 16. Chemotherapy Drug Proportion of Total.**

	UT	VA
Top 15 Chemo Drugs % of Total	0.74	0.58
Mean Top 15 Chemo Drugs % of Total	0.66	

This number was then used to project the national number of chemotherapy infusions given to Medicare patients and then multiplied by the average cost of preparation of infusions determined by the current study (\$36.03). These calculations are outline in Table 17.

**Table 17. National Projection of Drug Preparation Costs for Medicare Patients Receiving Chemotherapy.**

		Patients	Infusions
Total (from MedStat Projection)		427,605	2,651,824
Proportion of Chemotherapy Infusions from top 15 agents*	0.66		
Projected Medicare Chemotherapy Infusions			3,990,495
Infusions times calculated cost/infusion from current study (\$36.03)			<b>\$143,777,534.85</b>

Based on this projection drug preparation for chemotherapy infusions for the Medicare population would be expected to be in the range of \$140 to \$150 million dollars per year.

**Discussion:**

This study was designed to assess the costs attributed to drug-related handling in the preparation and delivery of chemotherapy agents and to provide accurate, scientifically sound data in support of appropriate reimbursement of these services to health care providers for Medicare patients. There were several critical steps to assure these goals.

The selection of sites was performed in order to provide a balance between two key areas, geographical distribution and type of cancer care service. Sites were selected from the East, South, Midwest and West. Two sites provided outpatient cancer care as part of an academic medical center and two sites were community-based cancer centers.

In order to assess the total costs of drug preparation, a significant amount of dialogue was undertaken to determine the steps involved, including fixed costs (e.g., storage, rent, inventory,

insurance and waste management, payroll, equipment, supplies shipping and information), as well as tasks specifically conducted by the pharmacy staff (e.g., therapy evaluation, consultation, patient care, order entry and compounding, and production and quality assurance). Most of the fixed costs were available through financial reports produced by each individual site from various departments responsible for the individual components. These were then collected via a central administrative person with assistance from the clinical staff.

To assess the time involved on behalf of the pharmacist in drug preparation activities, a TM study was deemed to be the most appropriate. Therefore, data on pharmacy staff time spent on preparation-related tasks as well as the total time spent within a typical day shift was collected. For consistency across sites and greatest representation of the data collected, historical records were reviewed at each site to determine the most commonly prescribed agents, both chemotherapy and concomitant medications given at the time of treatment. Pharmacists and certified pharmacy technicians were then observed in the TM portion of the study as they prepared these specific agents.

As was determined by the TM analysis, the oncology pharmacist spends almost their entire day related to tasks associated with the preparation of chemotherapeutic agents. This validates the need for the consideration of these services for reimbursement and for this study, acknowledged that full pharmacy staff payroll should be included in the aggregate costs.

The fixed costs analysis confirmed significant costs across all sites for each of the individual components identified. In aggregate, across all sites, these production costs account for \$36.03 per dose of chemotherapy provided with a range of \$32.08 for Virginia and \$67.19 for Utah, with values of \$32.80 for Alabama and \$38.05 for Wisconsin. Considering that Utah uses the unique worker safety device (Phaseal) which accounts for a minimum of \$15.00 per dose, equivalent costs without that system for Utah would be \$52.19.

Considering the diversity of the sites, the variance between these numbers is relatively low and validates the methodology for an accurate estimate of the costs involved in drug preparation to allow for a more accurate assessment of the appropriate reimbursement values for health care providers of Medicare oncology patients.

The primary purpose of the national projections were to provide a sense of the magnitude of cost related to drug preparation across the entire Medicare population. By extrapolating figures from a national Medicare population with supplemental commercial insurance to the national group an estimated four million doses over chemotherapy agents are delivered annually at a preparation cost of \$144 million dollars. With annual Medicare spending anticipated at \$6.5 billion, this is a substantial portion for a small segment of the population receiving intravenous chemotherapy<sup>1</sup>.

***Limitations:***

The study was conducted in only four oncology centers across the United States. Although type of service and geography was taken into account, these results may not be truly representative. For the fixed cost analysis contract negotiation and cost of goods may vary across the sites. Variance in practice would also be expected across each of the four sites which should be noted when considering the direct observations of oncology pharmacists and technicians.

The MarketScan® Medicare and Coordination of Benefits Database was used as the basis for national projections of chemotherapy utilization. This database is most representative of the population of Medicare beneficiaries who have employer-sponsored supplemental insurance, and thus projections to this population segment can be made with a high level of confidence. Further projection to the entire Medicare population requires the assumption that employer-sponsored supplemental insurance coverage does not substantially alter oncology treatment relative to other types of supplemental coverage or lack of secondary insurance. We are not aware of any research that has addressed this particular question, although the correlation between medical service utilization and level of insurance coverage is well established in general. However, it is not certain that oncology treatment is as sensitive to coverage effects as, for example, mental health treatment.

These estimates should be used cautiously, with the understanding that they may potentially overestimate chemotherapy utilization among Medicare beneficiaries. However, they may provide a useful first approximation pending further research using other sources such as the SEER/Medicare database.

---

<sup>1</sup> J.D. Kleinke "Health Affairs" Web Exclusive Dec. 8, 2004 W4-561 to W4-571.

Appendix 1:

Letter from National Patient Advocate Foundation

NATIONAL PATIENT ADVOCATE FOUNDATION

A National Network for Healthcare Reform

Headquarters: 700 15th Street, NW, Washington, DC 20005 (202) 462-1373

District Office: 1000 Dunwoody Street, Dunwoody, GA 30328 (770) 415-2000

EMAIL: [info@patientadvocate.org](mailto:info@patientadvocate.org) INTERNET: [www.patientadvocate.org](http://www.patientadvocate.org)

Nancy Davenport Davis  
CEO, President

EXECUTIVE BOARD

Leah Arrett  
President, LE Associates  
Waukegan, IL

Bruce Avery, MD  
Hematology/Oncology Knoxville  
Knoxville, TN

Roy A. Beveridge, MD  
Co-Director

Neurology Transplant Center  
Inova Fairfax Hospital  
Fairfax, VA

Richard D. Carter, Esquire  
Carter & Coleman  
Alexandria, VA

The Honorable Mary L. Christian  
Virginia House of Delegates

Edward L. Connette, Esquire  
Lescault & Connette  
Charlotte, NC

The Honorable Pat Dougherty  
Missouri State Senate

John B. Emms, Jr.  
Co-Founder, Executive Vice President  
of Corporate Development  
Patient Advocate Foundation  
Newport News, VA

Dianne Lamb  
Patient Advocate  
Huntsville, TN

William T. McGivney, PhD.  
Chief Executive Officer  
National Comprehensive  
Cancer Network  
Rockledge, FL

John L. Murphy  
Gene Hooker Partners II  
Stamford, CT

Leo T. Sands  
Executive Vice President &  
Chief Administrative Officer  
U.S. Oncology  
Hempstead, NY

Sheldon Wolfhans, Esquire  
of Counsel to the Firm of Wolfhans  
Dubrow, Goldberg & Mandel  
St. Louis, MO

SCIENTIFIC BOARD

Shirley Avery, MD, PE  
Physician  
Knoxville, TN

Jeffrey J. Wolf, MD  
Director, Bone Marrow  
Transplantation Unit, M.D. Anderson  
Comprehensive Cancer Center  
Houston, TX

HONORARY BOARD

Nancy Emerson  
Director of Elder Programs  
Elder Comprehensive Care Center  
Durham, NC

Pearl Moore, RN, MN, FAAN  
Chief Executive Officer  
Oncology Nursing Society  
Pittsburgh, PA

Doris Simonson

September 23, 2004

VIA FEDERAL EXPRESS

The Honorable Mark McClellan, M.D., Ph.D.  
Office of the Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: CMS-1429-P

Dear Dr. McClellan:

The National Patient Advocate Foundation (NPAF) is a non-profit healthcare organization dedicated to the mission of creating avenues of patient access to insurance coverage for evolving therapies, therapeutic agents, and devices through policy reform. Every day, our companion organization, Patient Advocate Foundation (PAF) is contacted by patients with chronic debilitating or life-threatening diseases who are having difficulty accessing care. In fiscal year July 1, 2003 through June 30, 2004, PAF received 3.4 million requests for information and/or direct intervention in the resolution of access disputes.

On behalf of the people with cancer we serve, we are writing to respond to Proposed Rule CMS-1429-P: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. We would like to thank the Centers for Medicare and Medicaid Services (CMS) for the considerable resources the agency has brought to bear in publishing this proposed rule. We recognize the enormity of the agency's mandate and the formidable time constraints under which it has been placed.

NPAF is especially concerned that potential reductions in reimbursement will pose access problems for Medicare beneficiaries. NPAF strongly believes it was the intent of Congress to establish a reimbursement system for Part B drugs and drug

administration services that would ensure payment to oncology practices at levels sufficient to support continued access to high-quality community cancer care.

## **I. Comments on Regulatory Impact Analysis**

### **A. Changes in Reimbursement for Drug Administration Services**

Section 303(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended Social Security Act §1848(e)(2) to provide for increased work and practice expense Relative Value Units (RVUs) for those drug administration services typically billed by oncologists. MMA §303(a)(4) also provided that payments for those drug administration services would receive additional temporary increases of 32% for 2004 and 3% for 2005. These changes were in addition to MMA-mandated across-the-board updates to all physician fee schedule services of 1.5% in both 2004 and 2005.

The payment rates for drug administration services set forth in the Proposed Rule reflect these MMA-mandated revisions. Assuming no changes in utilization, CMS estimates the volume-weighted average of the MMA-mandated permanent increases in Medicare payments to oncologists for drug administration services from 2003 to 2005 at 109%. Further, when the transitional payments are considered, the volume-weighted increases in Medicare payments for these codes are approximately 170% from 2003 to 2004 and approximately 110% from 2003 to 2005. Due to the reduction of the transitional payments from 2004 to 2005, Medicare reimbursement for oncology drug administration services will experience a net reduction of approximately 22% next year. CMS estimates that these services will account for nearly one-third of typical oncology revenues in 2004.

### **B. Changes in Reimbursement for Drugs and Biologicals**

MMA §303(b) amended Social Security Act §1842(o)(1) to reduce the Medicare payment rates for most drugs and biologicals furnished by oncologists from 95% of Average Wholesale Price (AWP) to 85% of AWP in 2004. More significantly, MMA §303(c) added §1847A to the Social Security Act. This new section of the Act instructed CMS to collect data from pharmaceutical manufacturers about the Average Sales Price (ASP) of their Part B drugs that are not paid on a cost or prospective payment basis and to begin reimbursing oncologists and other physicians who administer injectable and infusible drugs in their offices at 106% of ASP beginning in 2005.

Assuming no changes in utilization, CMS estimates that the switch from AWP-based reimbursement in 2004 to ASP-based reimbursement in 2005 will result in a one-year decrease in drug revenues to oncologists of approximately 8%. This decrease is significant since CMS has estimated that drugs are responsible for about 70% of the typical oncologist's revenues in 2004. In addition, this decrease comes on top of what CMS has estimated to be an approximately 12% reduction in oncology drug revenues in 2004.

On September 8, 2004, the American Society for Clinical Oncology (ASCO) held a Congressional briefing to present the results of a nationwide survey conducted by Muse & Associates of actual drug purchasing experience at 93 oncology practices. The study suggests the impact of the ASP-based reimbursement system could be even greater than CMS projects. Assuming reimbursement at the rate specified in the Proposed Rule, for the practices surveyed, the Muse Study shows the actual reduction in drug payments will average 15%, ranging from a low of 7.5% to a high of 26.3%, rather than the 8% estimated by CMS. Further, in 2005, about a quarter of the cancer drugs included in Table 28 of the Proposed Rule will cost the typical oncology practice more than the Medicare allowable amount. For example, 73% of practices will be unable to cover the cost of epoetin, a drug used to treat chemotherapy-induced anemia. Seventy percent will have to pay more than the Medicare allowable for pamidronate, a drug used for bone metastasis, which commonly occurs in many advanced-stage cancers. For irinotecan, an essential drug in the treatment of colon cancer, 56% of practices will have to pay more than Medicare allows and 53% will be unable to cover the cost of gencitabine, which is used to treat lung and pancreatic cancer, furnished to their Medicare patients.

### **C. Comparison of the Projected Impact and Congressional Expectations**

The regulatory impact analysis provided in the Proposed Rule suggests that the net effect of MMA revisions to drug and drug administration reimbursement could be between two and three times greater than the \$4.2 billion 10-year savings projected by the Congressional Budget Office (CBO). If such an impact were in fact realized, the result would be a significant divergence from the level of savings expected and intended by Congress. To achieve this objective, Congress relied on CBO's projection that Section 303 would net \$4.2 billion in savings over 10 years. If the aggregate reimbursement cuts are two to three times that level, we seriously doubt whether the MMA reform of Medicare reimbursement for Part B drugs can be carried out without fundamentally disrupting patient access to community cancer care. As a result, it is our hope that CMS's ongoing work to update payments for drug administration services and refine payments for drugs under the

ASP system prior to publication of the 2005 Physician Fee Schedule final rule will result in payment policies that do not reduce funding below the levels consistent with Congressional intent, thus seeking to ensure that patients burden with debilitating and life-threatening illnesses are not faced with the further burden of extended travel to access cancer care. While NPAF understands the fiscal constraints of the Medicare program, to minimize the negative impacts to patients who deal with chronic fatigue, nausea and pain on the very best of days, we urge the agency to take all possible administration actions to improve payments to oncologists.

#### **D. Access and the Impact on Beneficiaries**

NPAF appreciates the fact that implementation of MMA provisions related to drugs and drug administration services will reduce Medicare beneficiary liability for Medicare-covered services. We disagree, however, with CMS's assertion that MMA-driven reductions in beneficiary coinsurance and deductible liability for oncology drugs will likely improve beneficiary access to cancer care. Rather, we fear that cuts in Medicare cancer care spending of the magnitude currently suggested by the Proposed Rule, compounded by reductions in oncology reimbursement from commercial payers, could affect adversely the ability and/or willingness of a significant number of oncologists to continue making drugs and drug administration services available in their offices.

Because of our serious concerns about the access implications of the depth of the projected reimbursement cuts for community cancer care, we applaud CMS's decision to consider making further changes to Medicare payment for drug administration services, based on the results of the CPT Panel's review of the issue and/or in response to public comment, before the 2005 Physician Fee Schedule Final Rule is issued. We hope the CPT/RUC process will involve the establishment of new billing codes and related payment amounts that cover the costs of all of the services furnished in cancer care. We also endorse ASCO's call for the immediate release of projected 2005 payment amounts for all drugs to facilitate effective planning for the coming changes based on a more complete analysis of the MMA's impact on cancer care reimbursement in the community setting. We urge CMS to take every step within its administrative authority to ensure that a reimbursement reduction in excess of CBO's projections does not come to pass.

## II. Comments on Section 303 – Payment for Covered Outpatient Drugs and Biologicals

### A. Coding and RVU Changes for Drug Administration Service

Social Security Act §1848(c)(2)(J), as added by MMA §303(a), requires the Secretary to “promptly evaluate existing drug administration codes for physicians’ services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption.” It also states that existing processes should be used for considering coding changes and assigning relative value units (RVUs) to new or revised codes and that affected specialties should be consulted. Finally, §1848(c)(2)(B)(iv) decrees that “any changes in expenditures in 2005 and 2006 resulting from this review are exempt from the budget neutrality requirements” normally applicable to structuring of the physician fee schedule.

To implement these provisions, CMS began consulting early this year with the AMA’s CPT Editorial Panel and with physician specialty groups, including ASCO, affected by changes in payment for drugs and drug administration services. As a result, the CPT Editorial Panel established a workgroup with representatives from the affected specialties to make recommendations on drug administration coding to the full Panel.

The workgroup held public meetings in June 2004 to receive input and comments about proposed revisions to existing drug administration codes that it had under consideration. Based on the proposals available for public review, the workgroup appeared to be particularly interested in ensuring the availability of codes that allow for adequate recognition of the resources need to administer drugs with high toxicity or potential for serious side effects for diagnoses other than cancer. It also seemed interested in exploring whether the chemotherapy administration codes adequately capture all of the support services provided by oncology practices to their patients and/or whether new codes such as a chemotherapy management code are needed.

The workgroup reported to the full CPT Editorial Panel at its August meeting and the RUC will meet at the end of September to make recommendations on RVU assignments to any new or revised codes suggested by the CPT Panel. According to the Proposed Rule, CMS intends to review the recommendations of the CPT Editorial Panel and the RUC to determine whether it should make coding changes effective January 1, 2005 through the use of G codes.

NPAF applauds CMS's efforts to coordinate the MMA-mandated review of drug administration codes and RVU assignments on a timeline consistent with the implementation of appropriate coding changes in calendar 2005. Further, we acknowledge that the discussion of §1848(c)(2)(J) in the preamble to the Proposed Rule, explaining CMS's plan to use G codes to implement those coding and RVU revisions that the agency deems appropriate, satisfies CMS's obligation under the Administrative Procedures Act to provide stakeholders with notice and an opportunity to comment on payment and policy changes that will be effectuated through the 2005 Physician Fee Schedule Final Rule.

The placeholder approach is also consistent with the MMA-directive given to CMS in section §1848(c)(2)(J) of the Act to "promptly evaluate existing drug administration codes for physicians' services." Inclusion of a reference in the Proposed Rule to its intent to revise drug administration payment rules, codes and RVUs provides CMS with the time that is necessary to consider, before the 2005 Physician Fee Schedule Rule must be finalized, temporary codes reflective of input received from the CPT Panel and the RUC review of any new drug administration codes recommended by the AMA. Absent the placeholder approach and the subsequent use of temporary codes, any recommended coding and RVU changes could not be integrated into the Physician Fee Schedule before January 1, 2006, a timeline arguably inconsistent with the requirement imposed by MMA to complete the required reevaluation promptly and also inconsistent with the goal of ensuring adequate total reimbursement for cancer care in 2005 when drug payments shift to ASP+6% and the transitional adjustment to drug administration fees drops.

#### **B. Global Access Project: Coding Methodology Study**

In January 2004, NPAF convened the Global Access Project (GAP), a collaborative group of over forty patient advocacy organizations, health care providers, and members of the pharmaceutical and biotechnology industries, organized to develop a comprehensive information resource to assist key policymakers in Congress and at CMS as they examine the implementation of the MMA. GAP also reached out to include MedPAC, the three Congressional committees with jurisdiction over Medicare, CMS and the Administration in private meetings to review and discuss intended study topics, proposed authors, and processes of completion.

Many aspects of the provision of cancer care services – where services are delivered, to what socioeconomic groups, the availability of community-based

access to clinical research, the availability of physician-funded charity care, and the identification and measurement of the costs of providing cancer care, are not well understood. To improve policymakers' understanding of how cancer care is provided today and what is currently known about the cost of delivering cancer services, NPAF, on behalf of GAP, has initiated six studies<sup>1</sup> to examine over time, the provision of cancer care at community-based oncology centers and hospital outpatient departments. The studies being done now are the first of a multi-year effort to document and measure changes in key aspects of cancer care during the implementation of the MMA. The initial studies will be completed between September 2004 and January 2005 and the next generation of studies, which will largely repeat the protocols used in the 2004 work, are scheduled to begin in early 2005.

In the process of assessing the need for these studies and developing the appropriate research protocols, a GAP steering committee met with senior staff from the Administration, CMS, and MedPAC, as well as senior committee staff of the House Energy and Commerce, House Ways and Means, and the Senate Finance Committees. GAP shared the research protocols and methodologies of the studies and received feedback that the collection and detailed analysis of baseline data would improve understanding of the future impact of the MMA changes on cancer care delivery. To undertake these studies, NPAF and GAP have contracted, or are in the process of contracting, with researchers at five independent research organizations and universities.

One of the GAP studies will look at the allocation of resources among procedure codes and, in its initial iteration, assess whether MMA-mandated changes made to the Medicare Physician Fee Schedule codes for drug administration services in 2004 adequately captured all relevant elements of drug administration practice

---

<sup>1</sup> Study 1: Geographic Access to Care, being conducted by the University of North Carolina at Chapel Hill.

Study 2: Assessment of Charity Care, author to be determined.

Study 3: Patient Enrollment in Clinical Trials in the Community Setting, being conducted by the Aspen Group.

Study 4: Documenting the Costs of Pharmacy-Related Services in Oncology Care, being conducted by the University of Utah Pharmacotherapy Outcomes Research Center.

Study 5: Assessing the Relationship between Cancer Care Costs and Reimbursement, being conducted by The Moran Company.

Study 6: Documenting Drug Regimen Costs, being conducted by The Moran Company.

expenses and work values. The Moran Company conducted this study. As part of its research effort, Moran has built a computer model to replicate the CMS reimbursement methodology and analyze the impact of alternative payment methodologies on oncology practices. The study authors are scheduled to meet with CMS policymakers on September 24, 2004 to present the study's first-year findings and recommendations. The CMS meeting was scheduled in advance of the Resource-Based Relative Value Update Committee meeting at the end of September to facilitate a process to provide study findings to inform the RUC's deliberations.

### **C. The Budget Neutrality Exception**

We appreciate CMS's express recognition that "any changes in expenditures in 2005 and 2006 resulting from the CPT Panel/RUC review process are exempt from the budget neutrality requirements" that usually apply to annual fee schedule modifications.

### **D. Limits on the Inclusion of Prompt Payment Discounts in ASP**

In addition to implementing coding and RVU changes to better match reimbursement for drug administration services with resource consumption and administration complexity, we respectfully urge CMS to exercise its complete administrative authority to interpret and implement the "prompt payment discount" component in 42 C.F.R. §414.804(a)(2)(iii) to exclude prompt pay discounts extended by pharmaceutical manufacturers to wholesalers and distributors because those entities do not pass these fees through to their customers.

Requiring manufacturers to subtract the standard 2% prompt payment discount that they extend to wholesalers when ASP is calculated effectively reduces the Medicare reimbursement rate for incident to drugs to ASP+4%. It also undermines the ability of the ASP reimbursement system to achieve its intended goals of covering the above-average acquisition costs borne by many practices as well as the drug-related handling costs that are not adequately accounted for in other physician payment streams.

A regulatory provision that incorporates only those prompt pay discounts provided to providers and suppliers would therefore be consistent with the objectives of MMA. Given the clear intent of Congress, as expressed in pre-passage colloquies and elsewhere, that reimbursement for drugs match prices actually available to providers and reflect the realities of the pharmaceutical marketplace, CMS has the discretionary authority to revise 42 C.F.R. §414.804(a)(2)(iii) to instruct

manufacturers to subtract only those prompt payment discounts given to physicians, hospitals, and pharmacies either (1) directly on purchases shipped to them from the manufacturer without benefit of a wholesaler or (2) indirectly (e.g., because of manufacturer-mandated pass through credits) on purchases delivered to them through the normal distribution channels. Industry standard prompt pay discounts extended to wholesalers or distributors in normal course should not, however, be part of the ASP equation. NPAF concern in this matter remains that of availability of oncology care in the community setting if this provision adversely impacts the level of reimbursement received by the physician.

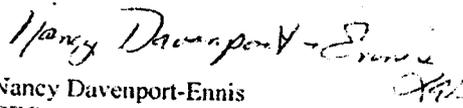
#### **E. Time Is of the Essence**

Third quarter ASP values that manufacturers will report to CMS on October 30, 2004 will set drug reimbursement rates for the first quarter of 2005. We therefore urge CMS to promulgate an ASP Final Rule or issue other guidance that will become effective before the third quarter reporting deadline. Such action should stipulate that only those prompt payment discounts that actually are price concessions to physicians, hospitals, and pharmacies be included in the calculation of ASPs.

### **III. Conclusion**

NPAF would like to thank you again for this opportunity to offer our formal comments for your consideration. We would like to thank CMS for its efforts in implementing MMA legislation, under extremely difficult time constraints, as well as the agency's willingness to engage in dialogue with groups such as ours. NPAF wants to continue to be a constructive voice in this dialogue and we look forward to continuing our work with CMS to implement the prescription drug benefit in a way that beneficiaries will have access to the care they require.

Sincerely,

  
Nancy Davenport-Ennis  
CEO

*Appendix 2:*

***Bios of Advisory Board Members***

**Diana I. Brixner, R.Ph. , Ph.D.**

Diana I. Brixner is currently Associate Professor and Chair of the Department of Pharmacy Practice at the University of Utah College of Pharmacy in Salt Lake City. She is also Executive Director of the Pharmacotherapy Outcomes Research Center, affiliated with the University of Utah Health Sciences Center, where she focuses on the design, conduct, training and communication of pharmaco-economic and outcomes research studies to demonstrate the value of pharmaceutical therapy.

Prior to this appointment Dr. Brixner was the Vice President of Health Care Management for Novartis Pharmaceuticals, based in East Hanover New Jersey, from 1994 to 1999. For the next three years she served as Regional Sales Director and then Executive Director of National Managed Care Accounts.

Previously Dr. Brixner held various positions at SmithKline Beecham, both in the Northwest and at corporate headquarters in Philadelphia, conducting work in pharmaco-economics, outcomes research and disease management in collaboration with managed care organizations. Diana worked for three years at the biotechnology company NeoRx in Seattle, Washington conducting drug discovery research and development of a lecture series for pharmacists entitled "Biotechnology: Impact on Pharmacy".

She received her undergraduate degree in pharmacy in 1982 from the University of Rhode Island and her doctorate in medicinal chemistry in 1987 from the University of Utah. Dr. Brixner previously held an adjunct faculty position at the College of Pharmacy at the University of the Sciences in Philadelphia, Pennsylvania.

**Gary M. Oderda, Pharm.D., M.P.H.**

Gary Oderda received his Pharm.D. degree from the University of California at San Francisco in 1972 and completed an Internship and Residency in Clinical Pharmacy at the University of California Hospital in 1973. Additional education was received at the Johns Hopkins University School of Hygiene and Public Health where he received a Masters in Public Health in 1982.

In 1991 Dr. Oderda moved to the University of Utah where he serves as Professor and Chairman of the Department of Pharmacy Practice from 1991 to 1998. On January 1, 1999 Dr. Oderda began a sabbatical from the University of Utah and started as a Visiting Professor in the Department of Health Care Management at Novartis Pharmaceuticals Corporation in East Hanover, New Jersey. He was active in a variety of Outcomes Research and Disease Management projects. He returned to the University of Utah on January 1, 2000 where he currently is a Professor and Director of the University of Utah Pharmacotherapy Outcomes Research Center.

**James A. Jorgenson, R.Ph., M.S., F.A.S.H.P.**

As Director of the Department of Pharmacy Services, Mr. Jorgenson's responsibilities include the direction and leadership for all pharmacy programs at the University of Utah Health Science Center. Inpatient services provide direct pharmacy care for the 405 bed University Hospital and the 100 bed University Neuropsychiatric Institute and 100 bed Huntsman Cancer Hospital. Ambulatory programs include pharmacy services for on-site clinics and pharmacies as well as eleven retail pharmacies in the University Health Network, the Moran Eye Center and the Huntsman Cancer Institute Infusion Center. Sub acute pharmacy services are provided through a home infusion program. Mr. Jorgenson also holds an appointment at the University of Utah College of Pharmacy as Associate Dean for Clinical Education where he is responsible for experiential teaching site development.

Mr. Jorgenson earned a Bachelor of Science in Pharmacy and a Master of Science in Hospital Pharmacy from the University of Minnesota. He also completed a two year residency in Hospital Pharmacy Administration at United and Children's Hospital in St. Paul, Minnesota. Prior to joining the University of Utah, he was Director of Pharmacy Services at St. Margaret Mercy Healthcare Systems in Indiana and held faculty appointments at both Purdue and Butler's College of Pharmacy. He has served on editorial and advisory boards for Health Care Providers and Industry, on the ASHP Commission on Credentialing and the Councils for Legal and Public Affairs and Administrative Affairs and in numerous state affiliated chapter positions. He also serves as the UU Hospital liaison to the University Health System Consortium and on the ASHP Community Oncology Centers Committee.

**John Ward M.D.**

Dr Ward is the chief of the Oncology Division for the Department of Internal Medicine at the University of Utah School of Medicine since 1998, and Medical Director of the cancer clinics at the Huntsman Cancer Institute since 1999. He has received specialty and subspecialty board certifications in American Board of Internal Medicine, Medical Oncology, and Hematology. He has served on the Board of Directors , Utah Division , American Cancer Society. Dr Ward received his medical education from the University of Utah, and residency and fellowship training at Duke University Medical Center.

**Roy Beveridge M.D.**

Dr Beveridge currently has a clinical appointment at INOVA Fairfax Hospital and is the Co-Director of the Bone Marrow Transplant Program. He is also currently the Director of the National Marrow and Donor Program and serves on committees for the Department of Defense/National Cancer Institute/Red Cross procurement. He was appointed Fellow of American College of Physicians in 1989. He has served on several committees, boards and task forces associated with oncology practice. He served on the Board of Directors for the American Cancer Society. Expert panel participant for BCBS and MDIPA Quality Center for Bone Marrow

and Stem Cell Transplant. He has served as Director of Operations, Stem Cell Transplant for US Oncology in Houston TX from 1998-2003, and was Executive Board Member, and Vice President and President for the National Patient Advocate Foundation between 1998-2003.

He is board certified in Internal Medicine and Medical Oncology. He received his medical education at Cornell University Medical College, residency training at University of Chicago, and fellowship training at John Hopkins Hospital.

**Lee Vermulen M.S. R.Ph.**

Mr. Vermulen currently the Director of the Center for Drug Policy at the University of Wisconsin Hospitals and Clinics. He is a Clinical Associate Professor at the University of Wisconsin Madison School of Pharmacy. He serves on committees for American Society of Health Systems Pharmacy and the American College of Clinical Pharmacy Clinical Affairs.

*Appendix 3:*

***Documenting Cost of Pharmacy Management/Control Services In Community-Based Oncology Practices  
Chemotherapy Regimen Site Survey***

**Chemotherapy:**

Please place an X next to the chemotherapy regimens/agents listed below that you consider to be the top ten utilized regimens/agents at your site. (> 10 patients/month per regime or agent). Please provide # of patient doses/month utilized at your site.

<b>Chemotherapy Regimen/Agent</b>	<b>Please Place X if one of top 10 at your site</b>	<b># of patient doses/month (70kg)</b>
Carboplatin / Paclitaxel (+/- Trastuzumab in metastatic breast cancer)		
Docetaxel		
Gemcitabine (+/- Cisplatin or Carboplatin)		
*FOLFOX 4		
**FOLFIRI (+/- Bevacizumab)		
Rituximab / ***CHOP		
Dose-Dense Doxorubicin/Cyclophosphamide followed by Paclitaxel		
Bortezomib		
Paclitaxel (weekly)		
AC (adriamycin (doxorubicin), cytoxan)		
Gemcitabine		
Gemcitabine/Avastin ( Bevacizumab)		
Topotecan		
Irinotecan		

Chemotherapy Regimen/Agent	Please Place X if one of top 10 at your site	# of patient doses/month (70kg)
Cisplatin		
Velcade (Bortezomib)		

\*FOLFOX = Oxaliplatin, Leucovorin, Fluorouracil bolus, Fluorouracil infusion

\*\*FOLFIRI = Irinotecan, Leucovorin, Fluorouracil infusion

\*\*\*CHOP = Cyclophosphamide, Vincristine, Doxorubicin

Others: Please list

Chemotherapy Regimen/Agent	Please Place X if one of top 10 at your site	# of patient doses/month (70kg)

### Concomitant Therapy:

Please place a X below next to the concomitant agents that you consider are the top ten utilized agents at your site. (> 10 patients/month per regime or agent). Please provide # of doses/month utilized at your site.

Concomitant Agents	Please Place X if one of top 10 at your site	# of doses/month
Zometa (Zoledronic Acid)		
Aredia ( Pamidronate)		
Neulasta (pegfilgastim)		
Procrit (Epoetin alpha)		
Aranesp ( Darbepoetin)		
Anzemet (Dolasetron)		
Zofran (Ondansetron)		

**Others: Please List**

<b>Concomitant Agents</b>	<b>Please Place X if one of top 10 at your site</b>	<b># of doses/month</b>

**Comments:**

Pease email survey back to Keri Fakata PharmD ( [keri.fakata@hsc.utah.edu](mailto:keri.fakata@hsc.utah.edu)) by July 30<sup>th</sup>.

*Appendix 4:*

**Oncology Reimbursement Study Data Collection Survey**

Dear Colleague,

Your clinic site is being asked to complete a four section survey to address the details of payment by Medicare Part B for reimbursement of oncology drug regimens in outpatient settings, including community-based oncology centers and hospital outpatient cancer clinics. There are four participating sites: Universities of Utah and Wisconsin outpatient cancer clinics associated with their respective medical centers, the community cancer centers in Fairfax VA and Montgomery AL. Each site will receive \$15K for the data collection and input on interpretation and the final report; you should have received your subcontracts this week.

The first two sections of the survey are a one- time collection tool of clinic demographics and fixed costs associated with oncology drug management. Please fill this out as completely as possible. There is extra space to fill in site specific information that you feel is important for this study and may not be included on survey. Please fax or email this survey to the contact information provided below.

The second two sections of the survey are the Time in Motion components of the survey. Please read the complete set of instructions at the beginning of each section.

We request that the surveys be faxed daily to 801-587-7923 through the data collection period. Please write your comments clearly so they may be interpreted and recorded properly.

Please feel free to contact me anytime by the information provided below regarding questions or issues that arise in the data collection process.

Keri L. Fakata PharmD  
Research Assistant Professor  
University of Utah  
Pharmacotherapy Outcomes Research Center  
421 Wakara Way Suite 208  
Salt Lake City, UT, 84108  
Office: 801-585-1229  
Pager: 801-339-7061  
Fax: 801-585-6253

**Section I. Oncology Reimbursement Study Data Collection Survey - Cover Sheet**

Please answer the following questions about yourself and your practice setting. Completion of this section is required to compensate your clinic for your time. This information will be held in the strictest confidence, and will not be revealed to the study sponsor.

Name of observer \_\_\_\_\_

Profession \_\_\_\_\_

Address \_\_\_\_\_

Phone # \_\_\_\_\_

**DEMOGRAPHIC INFORMATION:**

1. How many patients does your clinic see in one year?

(Define time frame)

2. What percent is female?

3. Please complete the following 2 tables.

<b>Ethnicity</b>	<b>Percentage of Patients</b>
Hispanic	
Black	
Asian	
Caucasian	
Other	

<b>Payer Mix</b>	<b>Percentage of Patients</b>
Cash	
Private Insurance	
Medicaid	
Medicare	
Indigent	

**Section II. Fixed Cost Data.**

Please answer the following questions regarding fixed cost using your fiscal year. *Complete this section, then move on to Section III.*

4. What defines the fiscal year at your institution? \_\_\_\_\_
5. What is the year of data you will provide? \_\_\_\_\_
6. What is the total number of patient doses of chemotherapy and supportive agents in this year?
  - a. Chemotherapy \_\_\_\_\_
  - b. Supportive \_\_\_\_\_

**SCHEDULING:**

7. What was the actual number of patients scheduled for infusions for the year? *Enter number below.*  
\_\_\_\_\_
8. For the last fiscal year: Please provide labor costs associated with scheduling: *Follow example below*

	<u>Hours worked annually</u>	<u>Hours related to scheduling</u>
Receptionist A	2088	800
Receptionist B	1050	60
Computer support person	2088	1000
Supervisor A	2088	100

*Enter information in table.*

Job classification	Hours worked annually	Hours related to scheduling	Annual cost/hour or salary	% Benefits

9. What are the minor equipment components (computer, telephone, and fax) used for scheduling purposes? *Please provide number below.*

<u>Type/Description</u>	<u>Number</u>
Computer	# _____
Fax	# _____
Phone	# _____

10. Please provide annual telecommunications cost associated with scheduling.  
\_\_\_\_\_

**WASTE MANAGEMENT:**

18. Please indicate estimated or actual uncompensated annual drug waste for your site? (i.e. drug prepared but not given to the patient)

\_\_\_\_\_

19. Please provide annual labor cost associated with waste management.

*Follow the example below and enter in table on next page*

	<u>Hours worked annually</u>	<u>Hours related to scheduling</u>
Janitorial Staff	2064	400
Pharmacist	2088	200
Pharmacy Technician	2088	100

19. *Continued from previous page.*

Job classification	Hours worked annually	Annual cost/hour or salary	Benefits %

**PAYROLL – FTEs**

20. Payroll- For the last fiscal year please provide FTEs for Oncology Pharmacists/ Technicians involved in preparation of chemotherapy including any temporary personnel.  
*Enter in table below.*

	<u>FTEs worked annually</u>
Pharmacist	4.5
Pharmacy Technician	2.5

Job classification	Annual FTE	Cost/hour or salary	Benefits %

**EQUIPMENT:**

21. Chemotherapy hoods. *Enter information below.*

a. Please provide the number of chemotherapy hoods (include model/brand)

\_\_\_\_\_

b. What is the replacement cost for chemotherapy hood(s)?

\_\_\_\_\_

c. What is the installation cost for chemotherapy hoods? (If available for your site)

\_\_\_\_\_

d. What is the space allocation for the clean room? (cost/sq. ft.)

\_\_\_\_\_

e. What is the cost for annualized inspection of chemotherapy hood(s)?

\_\_\_\_\_

f. Please provide cost of any special venting if applicable?

\_\_\_\_\_

g. What is the depreciation period of hood(s)?

\_\_\_\_\_

h. How many ambulatory infusion pumps are utilized? What is the cost or monthly lease?

Use \_\_\_\_\_ Cost \_\_\_\_\_

i. What are your annual costs, specific to oncology practice, for website, subscriptions, drug information service, publications, references?

\_\_\_\_\_

22. What are the minor equipment components (computer, telephone, and fax) used for oncology pharmacy purposes? *Please provide number below.*

	<u>Number</u>	<u>Type/Description</u>
Computer	#	_____
Fax	#	_____
Phone	#	_____

23. Please provide annual telecommunications cost associated with oncology pharmacy site

\_\_\_\_\_

24. **Supplies and Material:** Please check off any supplies utilized during chemotherapy process. Please provide annual use and cost.

Supply	Check if used	Quantity used (bulk) annually	Annual cost
Normal Saline bag			
Dextrose 5% bag			
Phaseal or other venting device			
UV protection bag			
Poly Olefin Bag			
Syringes			
Needles			
Filters			
Tubing			
Gowns			
Gloves			
Booties			
Scrub caps			
Mask			
Chemo mats			
Hand cleansers			
other			

### Section III. Direct Pharmacist Observation Time in Motion Survey

*Continued on next 2 pages.*

#### 25. TIME IN MOTION SURVEY

##### TIME IN MOTION SURVEY: INSTRUCTIONS

Time and motion analysis is intended to accurately measure the time it takes various staff members to perform various tasks by direct observation. The grids attached have been designed to efficiently and accurately measure the length of time required to perform various tasks involved in chemotherapy preparation and management.

Direct observation should be made in a one-on-one fashion with a single observer closely following the movements and activities of a single subject. The major tasks of interest are listed on the data collection form, specific to the type of individual being observed (pharmacist, technician, nurse). Please follow these instructions for data collection.

1. Initiate observation by instructing the subject to go about their activities in as normal a fashion as possible (ask them to ignore the observer unless asked specific questions by the observer).
2. At the start of the observing period, identify the name of the individual being followed and record the date of observation. As multiple pages of data collection will likely be used, carefully number each page consecutively in the space provided.
3. Begin data collection as the subject begins a new task. In the column on the far left of the grid, indicate the start time for that first task, and make a check mark in the grid corresponding to the specific task undertaken at that time by the subject.
4. Continue to observe the subject conducting that task until the subject begins a new task.
5. As soon as the subject changes tasks, mark the time on the next line of the data collection form, and indicate with a check mark what new task the subject has begun. For the purpose of data analysis, the time taken on the previous task will be calculated by subtracting the start time for that task from the start time of the next task.
6. For the purpose of this study, it is essential to note the start time for every task conducted, regardless of whether it is listed as one something essential in this study. If the subject begins a task that is not listed (for example, goes to lunch or on a break), mark the start of that activity in the "other" column and indicate in the comments/drugs handled column what the subject was doing.
7. If the subject is interrupted during a specific task (e.g., with a phone call or question), mark the time of the interruption as a new task, and then document the resumption of the previous task in the next line of the data collection. If the task that is interrupted involves specific drugs, you do not need to re-list the drugs on the line recording the resumption of the interrupted task. Simply refer to the line number of the interrupted task in the resumption line (e.g., "see line 15").
8. If a particular drug or combination of drugs of interest is being handled during the time noted, indicate the drug codes provided by the key on page 11 and the number of dosage forms (syringes, minibags, large volume infusions) handled during the time noted.
9. If a subject is multitasking (e.g., answering a drug information question on the phone while cleaning the hood), continue to document the first task begun and note the start and stop times of the second concurrent task in the comments section.
10. Please print several copies of page 12 of this data collection survey for your observations.
11. Please keep survey pages in order by filling in the page of T&M survey located at the top of the page.

Code Key for Chemotherapy and Supportive Care Agents for Section III

Chemotherapy Agent	CODE	Supportive Care Agent	CODE
Carboplatin	CARBO	<b>5HT-3</b> Dolasetron Ondansetron Granisetron Indicate IV or PO	DOL OND GAN
<b>Taxanes</b> Paclitaxel Docetaxel	TAX DOC	<b>Erythropoietic Agent</b> Aranesp (darbepoetin) Procrit, Epogen (epoetin)	DARBO EPO
Herceptin (Trastuzumab)	HRCPT	<b>Colony stimulating factors</b> Neulasta (pegfilgrastim) Neupogen (filgrastim)	PEG FILG
Gemcitabine	GEM	<b>Bisphosphonates</b> Zometa (zoledronate)Aredia (pamidronate)	ZOL PAM
Cisplatin	CISPLT	Decadron (dexamethasone) Indicate IV or PO	DEX
Rituximab	RITUX		
Cyclophosphamide	CYCLO		
Doxorubicin	DOXO		
Topotecan	TOPO		
Irinotecan	IRONO		
Vincristine	VINCR		
Oxaliplatin	OXAL		
Leucovorin IV or PO	LCV		
Fluorouracil	5FU		

**Section III. Direct Pharmacist Observation Time in Motion Survey**  
*Please observe for one entire 8 hour shift.*

*\*Please Write Clearly\**  
 Date of Observation: \_\_\_\_\_  
 Was this a typical day YES NO (circle one)

Page of T&M \_\_\_\_\_

If atypical day, please repeat survey.

Time	Order Review by RPh	Collect patient data	Evaluate AE	Manage AE	MD consult'n	Other HCP consult'n	Patient comm	Insurer comm	Order entry	Oral premed admin	Product verification	Compoundg	Proce'n check	Drug Information	Patient counseling	CE	Continuity of care	Prod't special hand'g	Other ( )	Interruption	Drug's handled/ Other Comments		
1																							
2																							
3																							
4																							
5																							
6																							
7																							
8																							
9																							
10																							
11																							

**Section IV. Oncology Drug / Regimen Based Time In Motion Survey**

**TIME IN MOTION SURVEY: INSTRUCTIONS**

Please make several copies of this section of the survey. The goal is to observe 10 occurrences of each chemotherapy drug and supportive drug class listed in the drug code table on page 11. Please record actual start and stop time i.e. 10:42.23am to 10:52.52am. A digital watch that shows time with seconds works best for this observation. You may record several stop and start times in an activity box if the process is interrupted for a period of time, or if more than one person is involved in the task. Record only the task you are observing, it is expected that not all tasks will be observed on each observation. If you are aware that a drug occurs less frequently than others at your site and it is on the list please prioritize the low occurrence drugs to make sure that we can achieve the 10 occurrences of that drug within the month. Thank you!

Please print page 11 and keep it for your reference for completion of time in motion surveys.

Section IV. Oncology Drug / Regimen Based Time In Motion Survey

\*Please Write Clearly\* Site \_\_\_\_\_ Observer \_\_\_\_\_ Date \_\_\_\_\_ Page \_\_\_\_\_

Are you observing a regimen Yes or No \_\_\_\_\_  
 if yes, which regimen? \_\_\_\_\_

New Patient? Yes or No \_\_\_\_\_  
 Study Patient? Yes or No \_\_\_\_\_

Regimens represented by drug list include:  
 AC, gemcitabine ± cisplatin or carboplatin, RCHOP, FOLFOX.  
 Provide Codes for drugs observed: \_\_\_\_\_

Were any of the selected drugs produced in Batch? Yes or No \_\_\_\_\_  
 if yes which drug(s)? \_\_\_\_\_  
 Other Drugs Observed: \_\_\_\_\_

Start Time	Stop Time	Order Review by RPh	Collect patient data	Evaluate AE	Manage AE	MD consult'n	Other HCP consult'n	Patient comm	Insurer comm	Order entry	Oral premed admin	Product verification	Compoundg	Proced'n check	Drug Information	Patient counseling	CE	Continuity of care	Prod. Spec. Handlg	PharmD	Pharm Tech	Other Comments
1																						
2																						
3																						
4																						
5																						
6																						
7																						
8																						
9																						

Appendix 5:  
Fixed Costs Per Site

	Alabama		Utah		Virginia		Wisconsin		ALL SITES	
	TOTAL	PER DOSE	TOTAL	AVG PER DOSE						
<b>Storage</b>										
Facilities Cost	\$880.00	\$0.03	\$4,875.00	\$0.82	\$5,167.00	\$0.16	\$5,668.50	\$0.33	\$16,590.50	\$0.20
<b>Total</b>	<b>\$880.00</b>	<b>\$0.03</b>	<b>\$4,875.00</b>	<b>\$0.82</b>	<b>\$5,167.00</b>	<b>\$0.16</b>	<b>\$5,668.50</b>	<b>\$0.33</b>	<b>\$16,590.50</b>	<b>\$0.20</b>
<b>Space Rental</b>										
Annual Cost	\$19,639.77	\$0.70	\$3,857.00	\$0.65	\$28,163.40	\$0.86	\$9,111.25	\$0.53	\$60,771.42	\$0.72
<b>Total</b>	<b>\$19,639.77</b>	<b>\$0.70</b>	<b>\$3,857.00</b>	<b>\$0.65</b>	<b>\$28,163.40</b>	<b>\$0.86</b>	<b>\$9,111.25</b>	<b>\$0.53</b>	<b>\$60,771.42</b>	<b>\$0.72</b>
<b>Inventory Management</b>										
Labor Cost	\$3,878.00	\$1.20	\$8,331.00	\$1.40	\$39,986.00	\$1.23	\$8,853.00	\$0.52	\$91,048.00	\$1.09
Inventory Value	\$106,009.40	\$3.75	\$21,860.51	\$3.66	\$44,509.92	\$1.36	\$30,567.81	\$1.79	\$202,947.64	\$2.42
<b>Total</b>	<b>\$139,887.40</b>	<b>\$4.95</b>	<b>\$30,191.51</b>	<b>\$5.06</b>	<b>\$84,495.92</b>	<b>\$2.59</b>	<b>\$39,420.81</b>	<b>\$2.31</b>	<b>\$293,995.64</b>	<b>\$3.50</b>
<b>Insurance Management</b>										
Labor Cost	\$235,996.00	\$8.36	\$43,050.00	\$7.22	\$289,536.00	\$8.87	\$64,575.00	\$3.78	\$633,157.00	\$7.55
<b>Total</b>	<b>\$235,996.00</b>	<b>\$8.36</b>	<b>\$43,050.00</b>	<b>\$7.22</b>	<b>\$289,536.00</b>	<b>\$8.87</b>	<b>\$64,575.00</b>	<b>\$3.78</b>	<b>\$633,157.00</b>	<b>\$7.55</b>
<b>Waste Management</b>										
Labor Cost	\$3,170.00	\$0.11	\$25,827.00	\$4.33	\$2,059.00	\$0.06	\$18,659.00	\$1.09	\$49,715.00	\$0.59
Annual Drug Waste	\$58,923.00	\$2.09	\$2,500.00	\$0.42	\$35,000.00	\$1.07	\$15,000.00	\$0.88	\$111,423.00	\$1.33
Other Costs	\$38,320.00	\$1.36	\$0.00	\$0.00	\$88,784.00	\$2.72	\$71,253.00	\$4.17	\$198,357.00	\$2.36
<b>Total</b>	<b>\$100,413.00</b>	<b>\$3.56</b>	<b>\$28,327.00</b>	<b>\$4.75</b>	<b>\$125,843.00</b>	<b>\$3.86</b>	<b>\$104,912.00</b>	<b>\$6.15</b>	<b>\$359,495.00</b>	<b>\$4.28</b>
<b>Payroll</b>										
Payroll Cost	\$305,565.00	\$10.82	\$147,172.48	\$24.67	\$351,876.00	\$10.78	\$377,580.00	\$22.12	\$1,182,193.48	\$14.09
<b>Total</b>	<b>\$305,565.00</b>	<b>\$10.82</b>	<b>\$147,172.48</b>	<b>\$24.67</b>	<b>\$351,876.00</b>	<b>\$10.78</b>	<b>\$377,580.00</b>	<b>\$22.12</b>	<b>\$1,182,193.48</b>	<b>\$14.09</b>
<b>Equipment</b>										
Hood Cost	\$3,100.00	\$0.11	\$1,250.00	\$0.21	\$1,200.00	\$0.04	\$1,061.00	\$0.06	\$6,611.00	\$0.08
Venting Cost	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$600.00	\$0.04	\$600.00	\$0.01
Inspections	\$1,200.00	\$0.04	\$350.00	\$0.06	\$1,100.00	\$0.03	\$350.00	\$0.02	\$3,000.00	\$0.04
Computer	\$4,500.00	\$0.16	\$3,000.00	\$0.50	\$3,000.00	\$0.09	\$3,000.00	\$0.18	\$13,500.00	\$0.16
Fax	\$250.00	\$0.01	\$250.00	\$0.04	\$250.00	\$0.01	\$250.00	\$0.01	\$1,000.00	\$0.01
Phone	\$150.00	\$0.01	\$100.00	\$0.02	\$150.00	\$0.00	\$100.00	\$0.01	\$500.00	\$0.01
Dispensing	\$13,452.00	\$0.48	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$13,452.00	\$0.16

Telecom Cost	\$1,800.00	\$0.06	\$1,944.00	\$0.33	\$4,003.00	\$0.12	\$2,330.00	\$0.14	\$10,077.00	\$0.12
Total	\$24,452.00	\$0.87	\$6,894.00	\$1.16	\$9,703.00	\$0.30	\$7,691.00	\$0.45	\$48,740.00	\$0.58

Supplies

Annual Cost	\$98,122.00	\$3.48	\$135,943.00	\$22.79	\$77,382.00	\$2.37	\$40,102.00	\$2.35	\$351,549.00	\$4.19
Total	\$98,122.00	\$3.48	\$135,943.00	\$22.79	\$77,382.00	\$2.37	\$40,102.00	\$2.35	\$351,549.00	\$4.19

Shipping

Annual Cost	\$0.00	\$0.00	\$0.00	\$0.00	\$74,288.00	\$2.28	\$0.00	\$0.00	\$74,288.00	\$0.89
Total	\$0.00	\$0.00	\$0.00	\$0.00	\$74,288.00	\$2.28	\$0.00	\$0.00	\$74,288.00	\$0.89

Info Resources

Annual Cost	\$1,200.00	\$0.04	\$500.00	\$0.08	\$500.00	\$0.02	\$500.00	\$0.03	\$2,700.00	\$0.03
Total	\$1,200.00	\$0.04	\$500.00	\$0.08	\$500.00	\$0.02	\$500.00	\$0.03	\$2,700.00	\$0.03

GRAND TOTAL	\$926,155.17	\$32.80	\$400,809.99	\$67.19	\$1,046,954.32	\$32.08	\$649,560.56	\$38.05	\$3,023,480.04	\$36.02
-------------	--------------	---------	--------------	---------	----------------	---------	--------------	---------	----------------	---------

Appendix 6:

*Observed Chemotherapy Drugs, Regimens, and Supportive Agents*

Chemotherapy Agents	Number of Observations per Agent			
	Alabama	Virginia	Utah	Wisconsin
Carboplatin	12	12	10	15
Cisplatin	12	8	12	19
Cyclophosphamide	13	8	14	25
Docetaxel	3	14	9	10
Doxorubicin	12	10	14	22
Fluorouracil	21	14	15	12
Gemcitabine	10	8	14	14
Herceptin	10	11	7	12
Irinotecan	8	19	11	11
Leucovorin	14	14	15	10
Oxaliplatin	4	12	10	11
Paclitaxel	15	10	11	15
Rituximab	12	12	11	17
Topotecan	3	2	1	9
Vincristine	3	9	8	12
<b>Total Observations</b>	<b>152</b>	<b>163</b>	<b>162</b>	<b>214</b>

Concomitant Agents	Number of Observations per Agent			
	Alabama	Virginia	Utah	Wisconsin
Darbepoetin	20	14	10	12
Decadron	68	3	58	57
Dolasetron	3	8	53	87
Epoetin	0	6	4	8
Filgrastim	0	4	0	5
Granisetron	68	0	8	0
Ondansetron	0	0	3	0
Pamidronate	5	11	0	2
Pegfilgrasim	7	4	6	5
Zoledronate	8	8	11	12
<b>Total Observations</b>	<b>179</b>	<b>58</b>	<b>153</b>	<b>188</b>

Drug Regimens	Number of Observations per Regimen			
	Alabama	Virginia	Utah	Wisconsin
Fluorouracil + Leucovorin	4	3	1	0
Fluorouracil + Leucovorin + Irinotecan	4	0	0	0
Doxorubicin + Cyclophosphamide	7	7	4	11
Carboplatin + Paclitaxel	6	3	1	0
Cyclophosphamide + Vincristine + Doxorubicin	0	0	1	1
Cisplatin + Docetaxel	1	0	0	0
Cisplatin + Paclitaxel	3	0	0	0
Irinotecan + Leucovorin + Fluorouracil infusion	0	4	0	0
Oxaliplatin + Leucovorin + Fluorouracil bolus + Fluorouracil infusion	4	3	4	8

Oxaliplatin + Gemcitabine	0	1	0	0
Gemcitabine + Carboplatin	2	0	0	1
Gemcitabine + Cisplatin	0	0	1	3
Rituximab + Cyclophosphamide + Vincristine + Doxorubicin	1	2	9	11
Regimen Indicated with Nothing Named	1	0	4	1
<b>Total Observations</b>	<b>33</b>	<b>23</b>	<b>25</b>	<b>36</b>

Appendix 7:

Summary of Time-and-Motion Analysis Raw Data

Practice ID	Type	Drug Observation Data			
		Activity	Number of Observations	Sum of Minutes	Sum of Hours
Alabama	Pharm Tech	Compounding	162	364.6	6.1
		Order Entry	6	9.2	0.2
		Product Verification	1	0.7	0.0
		Production Check	3	0.8	0.0
		Collect Patient Data	23	20.1	0.3
	PharmD	Compounding	31	77.7	1.3
		Insurer Communication	1	1.1	0.0
		Manage AE	2	22.7	0.4
		MD Consultation	1	0.9	0.0
		Oral Premed Administration	3	2.1	0.0
		Order Entry	120	191.2	3.2
		Order Review By RPh	122	228.9	3.8
		Other HCP Consultation	22	61.1	1.0
		Product Special Handling	13	32.9	0.5
		Product Verification	18	12.7	0.2
		Production Check	190	106.0	1.8
		Collect Patient Data	4	26.2	0.4
		Compounding	122	1243.6	20.7
		Insurer Communication	1	3.7	0.1
		Oral Premed Administration	3	3.5	0.1
Order Entry	7	20.7	0.3		
Order Review By RPh	3	52.4	0.9		
Other HCP Consultation	3	6.0	0.1		
Utah	Pharm Tech	Patient Communication	2	7.0	0.1
		Product Verification	2	0.4	0.0
		Production Check	1	0.5	0.0
		Collect Patient Data	129	693.5	11.6
		Compounding	1	1.2	0.0
		Drug Information	3	8.5	0.1
		Evaluate AE	1	1.0	0.0
		MD Consultation	11	31.0	0.5
		Oral Premed Administration	92	169.6	2.8
		Order Entry	125	529.2	8.8
	PharmD	Order Entry	125	529.2	8.8

Virginia

Pharm Tech  
PharmD

Order Review By RPh	143	1021.6	17.0
Other HCP Consultation	25	28.6	0.5
Patient Communication	14	54.5	0.9
Product Verification	32	33.7	0.6
Production Check	132	331.5	5.5
Compounding	187	639.9	10.7
Collect Patient Data	3	25.2	0.4
Compounding	3	7.6	0.1
Evaluate AE	2	2.3	0.0
MD Consultation	2	2.3	0.0
Order Entry	117	247.2	4.1
Order Review By RPh	128	255.2	4.3
Other HCP Consultation	15	32.2	0.5
Patient Counseling	10	5.3	0.1
Product Special Handling	141	97.8	1.6
Product Verification	215	117.7	2.0
Production Check	169	106.4	1.8
Compounding	153	764.7	12.7
Product Verification	153	768.9	12.8
Production Check	1	0.8	0.0
Collect Patient Data	134	321.3	5.4
Continuity Of Care	14	70.2	1.2
Drug Information	5	23.7	0.4
Evaluate AE	1	2.7	0.0
Insurer Communication	5	33.1	0.6
Manage AE	1	2.7	0.0
MD Consultation	17	44.9	0.7
Order Entry	157	348.5	5.8
Order Review By RPh	150	351.8	5.9
Other HCP Consultation	12	28.6	0.5
Patient Communication	69	292.2	4.9
Patient Counseling	65	329.5	5.5
Product Verification	1	0.8	0.0
Production Check	149	355.4	5.9

Wisconsin

Pharm Tech  
PharmD

Direct Pharmacist One Day Observation Data			
Activity	Number of Observations	Sum of Minutes	Sum of Hours
Collect Patient Data	4	2.6	0.0
Compounding	21	46.4	0.8
Insurer Communication	1	1.1	0.0
Interruption	14	15.3	0.3

Practice ID  
Alabama

Utah	Order Entry	30	62.5	1.0
	Order Review By RPh	32	62.1	1.0
	Other	45	229.8	3.8
	Other HCP Consultation	25	34.2	0.6
	Patient Communication	1	1.5	0.0
	Product Special Handling	2	2.3	0.0
	Product Verification	20	19.7	0.3
	Production Check	21	26.3	0.4
	CE	1	17.3	0.3
	Collect Patient Data	36	91.2	1.5
	Drug Information	11	47.4	0.8
	Interruption	7	39.2	0.7
	MD Consultation	5	7.2	0.1
	Oral Premed Administration	21	40.1	0.7
Virginia	Order Entry	21	38.9	0.6
	Order Review By RPh	57	134.1	2.2
	Other	21	61.1	1.0
	Other HCP Consultation	34	81	1.4
	Patient Communication	4	11.9	0.2
	Product Verification	19	33.4	0.6
	Production Check	18	49.3	0.8
	CE	3	17.4	0.3
	Collect Patient Data	1	8.4	0.1
	Continuity Of Care	2	8.1	0.1
	Drug Information	7	24.4	0.4
	MD Consultation	12	82	1.4
	Order Entry	33	237.7	4.0
	Order Review By RPh	33	233.9	3.9
Wisconsin	Other	36	183.8	3.1
	Other HCP Consultation	22	99.8	1.7
	Product Special Handling	5	57.3	1.0
	Product Verification	15	149.3	2.5
	Production Check	16	150.1	2.5
	Collect Patient Data	17	33.6	0.6
	Compounding	1	3.4	0.1
	Continuity Of Care	14	43.7	0.7
	Evaluate AE	1	2.8	0.0
	Insurer Communication	4	18.3	0.3
	Interruption	2	0.9	0.0
	Manage AE	1	2.8	0.0
	MD Consultation	11	22.7	0.4

Oral Premed Administration	4	3.7	0.1
Order Entry	45	124.8	2.1
Order Review By RPh	28	58.9	1.0
Other	9	16.1	0.3
Other HCP Consultation	83	167.3	2.8
Patient Communication	23	66.5	1.1
Patient Counseling	12	37.9	0.6
Product Verification	3	3.1	0.1
Production Check	34	75.6	1.3

Appendix 8. Counts of Persons and Infusions by HCPCS Code.

Chemotherapy Procedure Code (HCPCS)	Unweighted Counts		Projection to Population with Medicare and Commercial Supplemental Insurance		Projection to Total Medicare Population	
	Persons	Infusions	Persons	Infusions	Persons	Infusions
C9205-Oxaliplatin	9	30	193	741	583	2,432
J0640-Leucovorin Calcium Injection	787	8,408	12,154	132,415	32,721	351,443
J9000-Doxorubic HCl 10 Mg VI Chemo	589	2,172	9,076	32,850	24,750	90,212
J9001-Doxorubicin HCl Liposome Inj	112	316	1,637	4,504	4,796	13,144
J9045-Carboplatin Injection	1,453	6,415	21,928	97,648	59,389	263,194
J9060-Cisplatin 10 Mg Injection	222	765	3,579	12,518	9,411	31,961
J9062-Cisplatin 50 Mg Injection	215	785	3,281	12,137	8,592	31,416
J9070-Cyclophosphamide 100 Mg Inj	129	460	2,003	7,441	5,318	20,364
J9080-Cyclophosphamide 200 Mg Inj	35	84	484	1,217	1,285	3,273
J9090-Cyclophosphamide 500 Mg Inj	99	320	1,442	4,807	3,836	12,670
J9091-Cyclophosphamide 1.0 Grm Inj	79	254	1,149	3,678	3,108	9,919
J9092-Cyclophosphamide 2.0 Grm Inj	11	20	155	266	394	668
J9093-Cyclophosphamide Lyophilized	329	1,050	4,944	15,706	13,784	43,703
J9094-Cyclophosphamide Lyophilized	141	473	2,204	7,400	6,194	21,248
J9095-Cyclophosphamide Lyophilized	219	683	3,514	11,224	9,921	31,754
J9096-Cyclophosphamide Lyophilized	289	931	4,433	14,298	12,226	40,114
J9097-Cyclophosphamide Lyophilized	52	174	736	2,484	1,976	6,708
J9170-Docetaxel	849	5,040	12,869	76,849	35,333	211,862
J9190-Fluorouracil Injection	1,341	11,998	20,653	187,448	56,202	507,111
J9201-Gemcitabine HCl	872	5,405	13,244	81,693	36,769	226,345
J9206-Irinotecan Injection	398	3,004	6,155	47,212	16,223	123,198

Appendix (continued)

Chemotherapy Procedure Code (HCPCS)	Unweighted Counts		Projection to Population with Medicare and Commercial Supplemental Insurance		Projection to Total Medicare Population	
	Persons	Infusions	Persons	Infusions	Persons	Infusions
J9263-Oxaliplatin	3	3	52	52	141	141
J9265-Paclitaxel Injection	1,070	6,006	16,121	91,360	43,601	245,757
J9310-Rituximab Cancer Treatment	864	4,297	12,791	62,484	35,700	174,878
J9350-Topotecan	126	1,158	1,828	17,171	5,256	49,745
J9355-Trastuzumab	116	1,857	1,692	28,049	4,855	78,178
J9370-Vincristine Sulfate 1 Mg Inj	235	749	3,623	11,610	10,185	32,991
J9375-Vincristine Sulfate 2 Mg Inj	224	684	3,310	10,100	8,997	27,366
J9380-Vincristine Sulfate 5 Mg Inj	1	1	9	9	31	31

## **APPENDIX B**

## PRIALT

(ziconotide intrathecal infusion)

### Full Prescribing Information

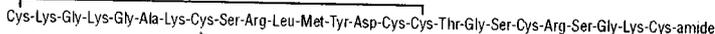
For use only in the Medtronic SynchroMed® EL, SynchroMed® II Infusion System and Simms Deltec Cadd Micro® External Microinfusion Device and Catheter

#### WARNING:

Severe psychiatric symptoms and neurological impairment may occur during treatment with PRIALT. Patients with a pre-existing history of psychosis should not be treated with PRIALT. All patients should be monitored frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. PRIALT therapy can be interrupted or discontinued abruptly without evidence of withdrawal effects in the event of serious neurological or psychiatric signs or symptoms.

#### DESCRIPTION

PRIALT® contains ziconotide, a synthetic equivalent of a naturally occurring conopeptide found in the piscivorous marine snail, *Conus magus*. Ziconotide is a 25 amino acid, polybasic peptide containing three disulfide bridges with a molecular weight of 2639 daltons and a molecular formula of C<sub>102</sub>H<sub>172</sub>N<sub>36</sub>O<sub>32</sub>S<sub>7</sub>. The amino acid sequence and disulfide bridging pattern are given below:



Ziconotide is a hydrophilic molecule that is freely soluble in water and is practically insoluble in methyl t-butyl ether.

PRIALT is formulated as a sterile, preservative-free, isotonic solution for intrathecal (IT) administration using an appropriate microinfusion device (See Dosage and Administration). Each 1, 2, or 5 mL vial of PRIALT (100 mcg/mL) respectively contains 100, 200, or 500 mcg of ziconotide acetate, and the 20 mL vial of PRIALT (25 mcg/mL) contains 500 mcg of ziconotide acetate, with L-methionine and sodium chloride as excipients at pH 4.0–5.0. Each vial is intended for single use only, either undiluted or after dilution to the appropriate concentration with 0.9% Sodium Chloride Injection, USP (preservative free).

#### CLINICAL PHARMACOLOGY

##### Pharmacodynamics

##### Mechanism of Action

Ziconotide binds to N-type calcium channels located on the primary nociceptive (A-δ and C) afferent nerves in the superficial layers (Rexed laminae I and II) of the dorsal horn in the spinal cord. Although the mechanism of action of ziconotide has not been established in humans, results in animals suggest that its binding blocks N-type calcium channels, which leads to a blockade of excitatory neurotransmitter release in the primary afferent nerve terminals and antinociception.

##### Interaction with opioids

Ziconotide does not bind to opioid receptors and its pharmacological effects are not blocked by opioid antagonists. In animal models, IT ziconotide potentiated opioid-induced reduction in gastro-intestinal (GI) motility, but did not potentiate morphine-induced respiratory depression. In rats receiving IT ziconotide, additive analgesic effects were observed with concurrent administration of morphine, baclofen, or clonidine. Concurrent administration of IT ziconotide and morphine did not prevent the development of morphine tolerance in rats.

#### PHARMACOKINETICS

The cerebrospinal fluid (CSF) pharmacokinetics (PK) of ziconotide have been studied after one-hour IT infusions of 1–10 mcg of PRIALT to patients with chronic pain. The plasma PK following intravenous (IV) infusion (0.3–10 mcg/kg/day) have also been studied. Both IT and IV data are shown below (Table 1).

Table 1: PRIALT PK Parameters (Mean ± SD)

Route	Fluid	N	CL (mL/min)	Vd (mL)	T <sub>1/2elim</sub> (hr)
IT	CSF	23	0.38 ± 0.56	155 ± 263	4.6 ± 0.9
IV	Plasma	21	270 ± 44	30460 ± 6366	1.3 ± 0.3

Following one-hour IT administration of 1–10 mcg of PRIALT, both total exposure (AUC; range: 83.6–608 ng•h/mL) and peak exposure (C<sub>max</sub>; range: 16.4–132 ng/mL) values in the CSF were variable and dose-dependent, but appeared approximately dose-proportional. During 5 or 6 days of continuous IT infusions of PRIALT at infusion rates ranging from 0.1–7.0 mcg/hr in patients with chronic pain, plasma ziconotide levels could not be quantified in 56% of patients using an assay with a lower limit of detection of approximately 0.04 ng/mL. Predictably, patients requiring higher IT infusion dose rates were more likely to have quantifiable ziconotide levels in plasma. Plasma ziconotide levels, when detectable, remain constant after many months of IT PRIALT infusion in patients followed for up to 9 months.

#### Distribution

Ziconotide is about 50% bound to human plasma proteins. The mean CSF volume of distribution (Vd) of ziconotide following IT administration approximates the estimated total CSF volume (140 mL).

#### Metabolism

Ziconotide is cleaved by endopeptidases and exopeptidases at multiple sites on the peptide. Following passage from the CSF into the systemic circulation during continuous IT administration, ziconotide is expected to be susceptible to proteolytic cleavage by various ubiquitous peptidases/proteases present in most organs (e.g., kidney, liver, lung muscle, etc.), and thus readily degraded to peptide fragments and their individual constituent free amino acids. Human and animal CSF and blood exhibit minimal hydrolytic activity toward ziconotide *in vitro*. The biological activity of the various expected proteolytic degradation products of ziconotide has not been assessed.

#### Elimination

Minimal amounts of ziconotide (<1%) were recovered in human urine following IV infusion. The terminal half-life of ziconotide in CSF after an IT administration was around 4.6 hours (range 2.9–6.5 hours). Mean CSF clearance (CL) of ziconotide approximates adult human CSF turnover rate (0.3–0.4 mL/min).

#### Special populations

No formal studies were conducted to assess the effect of demographic factors (age, race, gender, and weight), renal or hepatic dysfunction, or to assess the effect of concomitant drugs on the pharmacokinetics of ziconotide due to the low systemic exposure of ziconotide following IT administration.

#### CLINICAL TRIALS

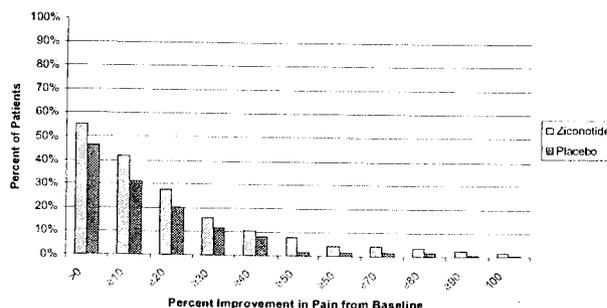
The safety and efficacy of IT PRIALT in the management of severe chronic pain were studied in three double-blind, placebo-controlled, multicenter studies in a total of 457 patients (268 PRIALT, 189 placebo) using two different titration schedules. The slow titration schedule tested dose increases 2–3 times per week with a maximum dose of 19.2 mcg/day (0.8 mcg/hr) at 21 days. The fast titration schedule used daily increases up to a maximum dose of 57.6 mcg/day (2.4 mcg/hr) in 5–6 days. The safety in chronic use was studied in four additional open-label, long-term studies in 977 patients.

A randomized, double-blind, placebo-controlled study was conducted at 39 centers to evaluate the efficacy of IT PRIALT administered using a slow titration schedule in 220 patients with severe chronic pain. Patients were randomized 1:1 between PRIALT (112 patients) and placebo (108 patients). At baseline, 97% of these patients reported that their pain was refractory to treatment including IT morphine, IT bupivacaine (an off-label use for this drug) and/or IT clonidine (an off-label use for this drug) in addition to their systemic analgesics and adjunctive therapy. All IT medications were discontinued over a one to three week period and patients were maintained on a stable regimen of non-IT analgesics including opiates, for at least 7 days prior to randomization. This period was successfully completed by 93% of the patients screened. Dosing with PRIALT was started at 2.4 mcg/day (0.1 mcg/hr) and the dose could be increased by 2.4 mcg/day (0.1 mcg/hr) two to three times/week (minimum titration interval 24 hours) to a maximum dose of 19.2 mcg/day (0.8 mcg/hr). The final mean dose at the end of the trial at 21 days was 6.9 mcg/day (0.29 mcg/hr).

Using a 100 mm Visual Analog Scale of Pain Intensity (VASPI) where 100 mm = worst possible pain, mean baseline pain scores were 81 in both the PRIALT and placebo groups. The primary efficacy variable was the mean percent change in the VASPI score from baseline to day 21. In the intent-to-treat (ITT) efficacy analysis, there was a statistically significant difference between groups in the mean percent change in VASPI score from baseline with the PRIALT group having a 12% mean improvement at Week 3 compared to a 5% mean improvement in the placebo group (p=0.04). The 95% confidence interval for the treatment difference (PRIALT – placebo) was 0.4%, 13%. The effect of IT PRIALT on pain was variable over the time period of treatment for some patients. Some patients had a reduction in VASPI in the first or second week, but did not maintain pain relief by the end of the third week. Other patients, who did not exhibit a reduction in VASPI early in treatment, did have a reduction in VASPI by the third week.

Patients exhibited various degrees of improvement in pain after three weeks of treatment compared with baseline pain assessment. Figure 1 depicts the fraction of patients by their degree of improvement. The figure is cumulative, so that patients whose change from baseline is, for example, 30%, are also included at every level of improvement below 30%. Patients who did not have a VASPI score recorded at Week 3 (Study days 17–23, inclusive) were assigned 0% improvement. The improvement in the proportion of "responders," defined as having a ≥30% improvement from baseline in VASPI, was 16% in the PRIALT group compared to 12% in the placebo group, for a net difference of 4%. The use of non IT opioids decreased by 24% in the PRIALT group and by 17% in the placebo group.

Figure 1: Patients Achieving Various Levels of Pain Relief From Baseline to Week 3



## INDICATIONS AND USAGE

PRIALT (ziconotide intrathecal infusion) is indicated for the management of severe chronic pain in patients for whom intrathecal (IT) therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or IT morphine.

## CONTRAINDICATIONS

PRIALT is contraindicated in patients with a known hyper-sensitivity to ziconotide or any of its formulation components and in patients with any other concomitant treatment or medical condition that would render IT administration hazardous.

Patients with a pre-existing history of psychosis should not be treated with ziconotide. Contraindications to the use of IT analgesia include conditions such as the presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, and spinal canal obstruction that impairs circulation of CSF.

## WARNINGS

**Severe psychiatric symptoms and neurological impairment may occur during treatment with PRIALT. Patients with a pre-existing history of psychosis should not be treated with PRIALT. All patients should be monitored frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. PRIALT therapy can be interrupted or discontinued abruptly without evidence of withdrawal effects in the event of serious neurological or psychiatric signs or symptoms.**

Patients should be cautioned against engaging in hazardous activity requiring complete mental alertness or motor coordination such as operating machinery or driving a motor vehicle during treatment with PRIALT. Patients should also be cautioned about possible combined effects with other CNS-depressant drugs. Dosage adjustments may be necessary when PRIALT is administered with such agents because of the potentially additive effects.

## WITHDRAWAL FROM OPIATES

PRIALT is not an opiate and cannot prevent or relieve the symptoms associated with the withdrawal of opiates. To avoid withdrawal syndrome when opiate withdrawal is necessary, patients must NOT be abruptly withdrawn from opiates. For patients being withdrawn from IT opiates, the IT opiate infusion should be gradually tapered over a few weeks and replaced with a pharmacologically equivalent dose of oral opiates. PRIALT does not interact with opiate receptors and does not potentiate opiate-induced respiratory depression.

## PRECAUTIONS

### General

### MENINGITIS AND OTHER INFECTIONS

Meningitis can occur due to inadvertent contamination of the microinfusion device and other means such as CSF seeding due to hematogenous or direct spread from an infected pump pocket or catheter tract. While meningitis is rare with an internal microinfusion device and surgically-implanted catheter, the incidence increases substantially with external devices. In the 1254 patients in PRIALT clinical trials with an exposure of 662 patient-years, meningitis occurred at 3% (40 cases) in the PRIALT group using either internal or external microinfusion devices and 1% (1 case) in the placebo group with an exposure of only 5 patient-years. The risk of meningitis with external microinfusion devices and catheters was higher with 93% cases (38/41) occurring with external infusion systems (37 PRIALT, 1 placebo).

Patients, caregivers, and healthcare providers must be particularly vigilant for the signs and symptoms of meningitis, including but not limited to fever, headache, stiff neck, altered mental status (e.g., lethargy, confusion, disorientation), nausea or vomiting, and occasionally seizures. Serious infection or meningitis can occur within 24 hours of a breach in sterility such as a disconnected catheter, the most common cause of meningitis with external microinfusion devices. The patient and health care provider should be familiar with the handling of the external microinfusion device and care of the catheter skin exit site at risk of infection. Strict aseptic procedures must be used during the preparation of the PRIALT solution or refilling of the microinfusion device to prevent accidental introduction of any contaminants or other environmental pathogens into the reservoir. In suspected cases (especially in immunocompromised patients) or in confirmed cases of meningitis, CSF cultures must be obtained and appropriate antibiotic therapy must be promptly instituted. Treatment of meningitis usually requires removal of the microinfusion system, catheter, and any other foreign body materials within the IT space and therefore discontinuation of PRIALT therapy.

### COGNITIVE AND NEUROPSYCHIATRIC ADVERSE EVENTS

Use of PRIALT has been associated with CNS-related adverse events, including psychiatric symptoms, cognitive impairment, and decreased alertness/unresponsiveness. For the 1254 patients treated, the following cognitive adverse event rates were reported: confusion (33%), memory impairment (22%), speech disorder (14%), aphasia (12%), thinking abnormal (8%), and amnesia (1%). Cognitive impairment may appear gradually after several weeks of treatment. The PRIALT dose should be reduced or discontinued if signs or symptoms of cognitive impairment develop, but other contributing causes should also be considered. The various cognitive effects of PRIALT are generally reversible within 2 weeks after drug discontinuation. The medians for time to reversal of the individual cognitive effects ranged from 3 to 15 days. The elderly ( $\geq 65$  years of age) are at higher risk for confusion. (See GERIATRIC USE.) In placebo-controlled trials, there was a higher incidence of suicide, suicide attempts

and suicide ideations in PRIALT treated patients (N=3) than in the placebo group (N=1). The incidence was 0.10/patient year for placebo patients and 0.27/patient year for PRIALT patients.

Events of acute psychiatric disturbances such as hallucinations (12%), paranoid reactions (3%), hostility (2%), delirium (2%), psychosis (1%), and manic reactions (0.4%) have been reported in patients treated with PRIALT. Patients with pretreatment psychiatric disorders may be at an increased risk. PRIALT may cause or worsen depression with the risk of suicide in susceptible patients. If appropriate, management of psychiatric complications should include discontinuation of PRIALT, treatment with psychotherapeutic agents if appropriate, and/or short-term hospitalization. Before drug is re-initiated, careful evaluation must be performed on an individual basis.

### REDUCED LEVEL OF CONSCIOUSNESS

Patients have become unresponsive or stuporous while receiving PRIALT. The incidence of unresponsiveness or stupor in clinical trials was 2%. During these episodes, the patient sometimes appears to be conscious and breathing is not depressed. If reduced levels of consciousness occur, PRIALT should be discontinued until the event resolves, and other etiologies (e.g., meningitis) should be considered. There is no known pharmacologic antagonist for this effect. Patients taking concomitant antiepileptics, neuroleptics, sedatives, or diuretics may be at higher risk of depressed levels of consciousness. If altered consciousness occurs, other CNS depressant drugs should also be discontinued as clinically appropriate.

### ELEVATION OF SERUM CREATINE KINASE (CK-MM)

In clinical studies (mostly open label), 40% of patients had serum creatine kinase (CK) levels above the upper limit of normal, and 11% had CK levels that were  $\geq 3 \times$  ULN. In cases where CK was fractionated, only the muscle isoenzyme (MM) was elevated. The time to occurrence was sporadic, but the greatest incidence of CK elevation was during the first two months of treatment. Elevated CKs were more often seen in males, in patients who were being treated with anti-depressants or anti-epileptics, and in patients treated with IT morphine. Most patients who experienced elevations in CK, even for prolonged periods of time, did not have limiting side effects. However, one case of symptomatic myopathy with EMG findings, and two cases of acute renal failure associated with rhabdomyolysis and extreme CK elevations (17,000–27,000 IU/L) have been reported.

Therefore, it is recommended that physicians monitor serum CK in patients undergoing treatment with PRIALT periodically (e.g., every other week for the first month and monthly as appropriate thereafter). Patients should be clinically evaluated and CK measurements obtained in the setting of new neuromuscular symptoms (e.g., myalgias, myasthenia, muscle cramps, asthenia) or a reduction in physical activity. Should these symptoms continue and CK levels remain elevated or continue to rise, it is recommended that the physician consider PRIALT dose reduction or discontinuation.

### INFORMATION FOR PATIENTS

Patients should be cautioned against engaging in hazardous activity requiring complete mental alertness or motor coordination such as operating machinery or driving a motor vehicle during treatment with PRIALT. Patients should also be cautioned about possible combined effects with other CNS-depressant drugs. Dosage adjustments may be necessary when PRIALT is administered with such agents because of the potentially additive effects. The physician should be contacted if the patient experiences new or worsening muscle pain, soreness, weakness with or without darkened urine.

### PATIENTS AND THEIR CAREGIVERS SHOULD BE INSTRUCTED TO CONTACT A PHYSICIAN IMMEDIATELY IF THE PATIENT HAS

- A change in mental status (e.g., lethargy, confusion, disorientation, decreased alertness)
- A change in mood, perception (hallucinations, including unusual tactile sensations in the oral cavity)
- Symptoms of depression or suicidal ideation
- Nausea, vomiting, seizures, fever, headache, and/or stiff neck, as these may be symptoms of developing meningitis

### LABORATORY TESTS

In clinical studies (mostly open label), up to 40% of patients had serum creatine kinase (CK) levels above the upper limit of normal, and 11% had CK levels that were  $\geq 3$ -times the upper limit of normal (see Elevation of Serum Creatine Kinase). Most cases of CK elevation were not associated with muscle weakness, however one case of myopathy with EMG findings, and two cases of acute renal failure associated with rhabdomyolysis and extreme CK elevations (17,000–27,000 IU/L) were reported.

### DRUG INTERACTIONS

Formal PK drug-drug interaction studies have not been performed with PRIALT. As ziconotide is a peptide, it is expected to be completely degraded by endopeptidases and exopeptidases (Phase I hydrolytic enzymes) widely located throughout the body, and not by other Phase I biotransformation processes (including the cytochrome P450 system) or by Phase II conjugation reactions. Thus, IT administration, low plasma ziconotide concentrations and metabolism by ubiquitous peptidases make metabolic interactions of other drugs with ziconotide unlikely. Further, as ziconotide is not highly bound in plasma (approximately 50%) and has low plasma exposure following IT administration, clinically relevant plasma protein displacement reactions involving ziconotide and co-administered medications are unlikely.

Over 90% of patients treated with IT PRIALT used systemic opiates and in the slow titration study, 98% of patients received opioids.

Combination of PRIALT with intrathecal opiates has not been studied in placebo-controlled clinical trials and is not recommended.

#### Interaction with CNS Depressants

Almost all patients in the PRIALT clinical trials received concomitant non-IT medication. Of the 1254 patients treated, most received several concomitant drugs including antidepressants (66%), anxiolytics (52%), antiepileptics (47%), neuroleptics (46%), and sedatives (34%). The use of drugs with CNS depressant activities may be associated with an increased incidence of CNS adverse events such as dizziness and confusion (see PRECAUTIONS).

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity studies have been conducted in animals.

Ziconotide was negative in the *in vitro* bacterial reverse mutation assay, *in vitro* mouse lymphoma assay, *in vivo* mouse micronucleus assay, and in the *in vitro* Syrian hamster embryo (SHE) cell transformation assay.

Ziconotide did not affect male fertility in rats when administered as a continuous intravenous (IV) infusion at a dose of up to 10 mg/kg/day when administered for approximately 8 weeks, including a 28-day pre-mating period, or female fertility at a dose of 3 mg/kg/day when administered for approximately 6 weeks, including a 14-day pre-mating period. Estimated exposures for the male and female rats were approximately 6500-fold and 1700-fold higher, respectively, than the expected exposure resulting from the maximum recommended human daily intrathecal (IT) dose of 0.8 mcg/hr (19.2 mcg/day) based on plasma exposure.

Female fertility in rats was significantly affected following continuous IV infusion at a dose of 10 mg/kg/day. Significant reductions in corpora lutea, implantation sites, and number of live fetuses were observed.

#### Pregnancy

Pregnancy Category C:

Ziconotide was embryolethal in rats when given as a continuous IV infusion during the major period of organogenesis as evidenced by significant increases in post-implantation loss because of an absence or a reduced number of live fetuses. Estimated exposure for embryolethality in the rat was approximately 700-fold above the expected exposure resulting from the maximum recommended human daily intrathecal (IT) dose of 0.8 mcg/hr (19.2 mcg/day). Ziconotide was not teratogenic in female rats when given as a continuous IV infusion at doses up to 30 mg/kg/day or in female rabbits up to 5 mg/kg/day during the major period of organ development. Estimated exposures in the female rat and rabbit were approximately 26,000-fold and 940-fold higher than the expected exposure resulting from the maximum recommended human daily intrathecal (IT) dose of 0.8 mcg/hr (19.2 mcg/day) based on plasma exposure. Maternal toxicity in the rat and rabbit, as evidenced by decreased body weight gain and food consumption, was present at all dose levels. Maternal toxicity in the rat led to reduced fetal weights and transient, delayed ossification of the pubic bones at doses  $\geq 15$  mg/kg/day which is approximately 8900-fold higher than the expected exposure resulting from the maximum recommended human daily IT dose of 0.8 mcg/hr (19.2 mcg/day) based on plasma exposure. The no observable adverse effect level (NOAEL) for embryo-fetal development in rats was 0.5 mg/kg/day and in rabbits was 5 mg/kg/day. Estimated NOAEL exposures in the rat and rabbit were approximately 400-fold and 940-fold higher than the expected exposure resulting from the maximum recommended human daily IT dose of 0.8 mcg/hr (19.2 mcg/day) based on plasma exposure.

In a pre- and post-natal study in rats, ziconotide given as a continuous IV infusion did not affect pup development or reproductive performance up to a dose of 10 mg/kg/day, which is approximately 3800-fold higher than the expected exposure resulting from the maximum recommended human daily intrathecal (IT) dose of 0.8 mcg/hr (19.2 mcg/day) based on plasma exposure. Maternal toxicity as evidenced by clinical observations, and decreases in body weight gain and food consumption were observed at all doses.

No adequate and well-controlled studies have been conducted in pregnant women. Because animal studies are not always predictive of human response, PRIALT should be used during pregnancy only if the potential benefit justifies risk to the fetus.

#### Labor and Delivery

The effect of PRIALT on labor and delivery in humans is not known.

#### Nursing Mothers

It is not known whether PRIALT is excreted in human breast milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from PRIALT, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

#### Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

#### Geriatric Use

Of the total number of subjects in clinical studies of PRIALT, 22% were 65 and over, while 7% were 75 and over. In all trials, there was a higher incidence of confusion in older patients (42% for  $\geq 65$  year old versus 29% for  $< 65$  year old subgroups). Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, the dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

#### Hepatic and Renal Impairment

Formal PK studies were not conducted in patients with hepatic or renal impairment.

#### ADVERSE REACTIONS

The safety of IT PRIALT administered as a continuous infusion has been evaluated in 1254 patients participating in acute and severe chronic pain trials. The duration of treatment has ranged from a one-hour IT infusion to treatment lasting for more than 7.5 years. The mean duration of treatment was 193 days with 173 patients (14%) treated for at least 1 year. The average final dose was 17.6 mcg/day (0.73 mcg/hr). The most frequently reported adverse events ( $\geq 25\%$ ) in the 1254 patients (662 patient years) in clinical trials were dizziness, nausea, confusion, headache, somnolence, nystagmus, asthenia, and pain. Serious adverse events and discontinuation of PRIALT for adverse events are less frequent when the drug is slowly titrated over 21 days, than with a faster titration schedule. (See CLINICAL TRIALS and DOSAGE and ADMINISTRATION.)

Table 2 summarizes the treatment-emergent adverse events with a frequency of 5% or greater in the PRIALT-treated group from the one placebo-controlled trial using the slow titration schedule in patients with severe chronic pain. All events reported during the initial placebo-controlled period of the studies (21 days in the slow titration schedule) are tabulated, regardless of relationship to PRIALT.

**Table 2. Incidence of Treatment-Emergent Adverse Events in Slow Titration Placebo-Controlled Trial by Percent (Events That Occurred in  $\geq 5\%$  of patients and more commonly with PRIALT than with placebo)**

	PRIALT N=112	Placebo N=108
Percentages of Patients		
Any AE	93	82
Body as a Whole	57	42
Asthenia	22	12
Headache	15	12
Pain	11	7
Fever	7	3
Digestive	60	51
Nausea	41	31
Diarrhea	19	17
Vomiting	15	13
Anorexia	10	5
Nervous System	81	51
Dizziness	47	13
Somnolence	22	15
Confusion	18	5
Ataxia	16	2
Abnormal Gait	15	2
Memory Impairment	12	1
Hypertonia	11	5
Anxiety	9	5
Speech Disorder	9	2
Aphasia	8	1
Nystagmus	8	0
Dysesthesia	7	2
Hallucinations	7	0
Nervousness	7	4
Paresthesia	7	3
Vertigo	7	0
Special Senses	20	11
Abnormal Vision	10	4
Urogenital	22	12
Urinary Retention	9	0

The following adverse events assessed as related to PRIALT have been reported in 2% or greater of patients participating in the clinical studies. (COSTART terms, by body system):

**BODY AS A WHOLE:** abdominal pain, accidental injury, asthenia, back pain, catheter complication, catheter site pain, cellulitis, chest pain, chills, fever, flu syndrome, headache, infection, malaise, neck pain, neck rigidity, pain, pump site complication, pump site mass, pump site pain, viral infection. **CARDIOVASCULAR SYSTEM:** hypertension, hypotension, postural hypotension, syncope, tachycardia, vasodilation. **DIGESTIVE SYSTEM:** anorexia, constipation, diarrhea, dyspepsia, gastrointestinal disorder, nausea, nausea and vomiting, vomiting. **HEMIC AND LYMPHATIC SYSTEM:** anemia, ecchymosis. **METABOLIC AND NUTRITIONAL DISORDER:** creatinine phosphokinase increased, dehydration, edema, hypokalemia, peripheral edema, weight loss. **MUSCULOSKELETAL SYSTEM:** arthralgia, arthritis, leg cramps, myalgia, myasthenia. **NERVOUS SYSTEM:** abnormal dreams, abnormal gait, agitation, anxiety, aphasia, ataxia, cerebrospinal fluid abnormal, confusion, depression, difficulty concentrating, dizziness, dry mouth, dysesthesia, emotional lability, hostility, hyperesthesia, hypertonia, incoordination, insomnia, memory impairment, mental slowing, meningitis, nervousness, neuralgia, nystagmus, paranoid reaction, paresthesia, reflexes decreased, somnolence, speech disorder, stupor, thinking abnormal,

tremor, twitching, vertigo. **RESPIRATORY SYSTEM:** bronchitis, cough increased, dyspnea, lung disorder, pharyngitis, pneumonia, rhinitis, sinusitis. **SKIN AND APPENDAGES:** cutaneous surgical complication, dry skin, pruritus, rash, skin disorder, sweating. **SPECIAL SENSES:** abnormal vision, diplopia, photophobia, taste perversion, tinnitus. **UROGENITAL SYSTEM:** dysuria, urinary incontinence, urinary retention, urinary tract infection, urination impaired.

At less than 2%, the following events were assessed by the clinical investigators as related to PRIALT: acute kidney failure, atrial fibrillation, cerebrovascular accident, electrocardiogram abnormal, grand mal convulsion, meningitis, myoclonus, psychosis, respiratory distress, rhabdomyolysis, sepsis, and suicidal ideations. Rare instances of fatal aspiration pneumonia and suicide were reported (<1%).

#### OVERDOSAGE

The maximum recommended IT PRIALT dose is 19.2 mcg/day. The maximum IT dose of PRIALT in clinical trials was 912 mcg/day. In some patients who received IT doses greater than the maximum recommended dose, exaggerated pharmacological effects (e.g., ataxia, nystagmus, dizziness, stupor, unresponsiveness, spinal myoclonus, confusion, sedation, hypotension, word-finding difficulties, garbled speech, nausea, and vomiting) were observed. There was no indication of respiratory depression. Overdoses may occur due to pump programming errors or incorrect drug concentration preparations. In these cases, patients were observed and ziconotide was either temporarily discontinued or permanently withdrawn. Most patients recovered within 24 hours after withdrawal of drug. In the event of an IT overdose, elimination of ziconotide from CSF would be expected to remain constant (CSF  $t_{1/2}$  = 4.6 hours). Therefore within 24 hours of stopping therapy, the ziconotide CSF concentration should be less than 5% of peak levels.

There is no known antidote to ziconotide. General medical supportive measures should be administered to patients who receive an overdose until the exaggerated pharmacological effects of the drug have resolved. Treatment for an overdose is hospitalization, when needed, and symptom related supportive care. Ziconotide does not bind to opiate receptors and its pharmacological effects are not blocked by opioid antagonists.

In the event of an inadvertent intravenous or epidural administration, adverse events could include hypotension, which can be treated with a recumbent posture and blood pressure support as required. The half-life of PRIALT in serum is 1.3 hours.

#### DOSAGE AND ADMINISTRATION

IT PRIALT should be initiated at no more than 2.4 mcg/day (0.1 mcg/hr) and titrated to patient response. Doses may be titrated upward by up to 2.4 mcg/day (0.1 mcg/hr) at intervals of no more than 2-3 times per week, up to a recommended maximum of 19.2 mcg/day (0.8 mcg/hr) by Day 21. Dose increases in increments of less than 2.4 mcg/day (0.1 mcg/hr) and increases in dose less frequently than 2-3 times per week may be used. For each dose titration, assess the dosing requirements and adjust the pump infusion flow rate as required to achieve the new dosing. Controlled studies of pain relief have not been conducted for longer than 3 weeks duration, although 977 patients have been treated with IT PRIALT in long-term open-label trials.

The dose of IT PRIALT should be adjusted according to the patient's severity of pain, their response to therapy and the occurrence of adverse events. The effective dose of PRIALT for analgesia is variable. The average dose level at the end of the 21-day titration used in the slow titration clinical trial (SEE CLINICAL TRIALS) was 6.9 mcg/day (0.29 mcg/hr) and the maximum dose was 19.2 mcg/day (0.8 mcg/hr) on Day 21. Due to the frequency of adverse events, 19.2 mcg/day (0.8 mcg/hr) is the maximum recommended dose.

Because of the lower incidence of serious adverse events and discontinuations for adverse events associated with the slower titration (see ADVERSE REACTIONS), a faster titration schedule should only be used if there is an urgent need for analgesia that outweighs the risk to patient safety.

In clinical trials, no rebound or other adverse events related to discontinuation of PRIALT were noted, although treatment was almost always discontinued abruptly. Vials of PRIALT should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

#### Administration

PRIALT should be administered intrathecally (IT) by or under the direction of a physician experienced in the technique of IT administration and who is familiar with the drug and device labeling. PRIALT is not intended for intravenous administration. PRIALT is intended for IT delivery using a programmable implanted variable-rate microinfusion device or an external microinfusion device and catheter (see PRECAUTIONS-Meningitis and Other Infections). Refer to the manufacturer's manual for specific instructions and precautions for programming the microinfusion device and/or refilling the reservoir.

PRIALT is used for therapy undiluted (25 mcg/mL in 20 mL vial) or diluted (100 mcg/mL in 1, 2 or 5 mL vials). Diluted PRIALT is prepared with 0.9% Sodium Chloride Injection, USP (preservative free) using aseptic procedures to the desired concentration prior to placement in the microinfusion pump. The 100 mcg/mL formulation may be administered undiluted once an appropriate dose has been established. SALINE SOLUTIONS CONTAINING PRESERVATIVES ARE NOT APPROPRIATE FOR IT DRUG ADMINISTRATION AND SHOULD NOT BE USED. Refrigerate but do not freeze all PRIALT solutions after preparation and begin infusion within 24 hours. Discard any PRIALT solution with observed particulate matter or discoloration and any unused portion left in the vial.

#### Medtronic SynchroMed EL or SynchroMed II Infusion System (SEE PRECAUTIONS-Meningitis and Other Infections)

Refer to the manufacturer's manuals for specific instructions and precautions for performing a reservoir rinse, initial filling, refilling the reservoir, and programming.

#### Instructions for Use of PRIALT with Pump

1. Naive Pump Priming (i.e., first time use with PRIALT)  
Only the undiluted 25 mcg/mL formulation should be used for naive pump priming. Rinse the internal surfaces of the pump with 2 mL of PRIALT at 25 mcg/mL. Repeat twice for a total of three rinses.

#### 2. Initial Pump Fill

Only the undiluted 25 mcg/mL formulation should be used for initial pump fill. Fill the naive pump after priming as above with the appropriate volume of PRIALT at 25 mcg/mL. Begin dosing at a delivery rate no higher than 2.4 mcg/day (0.1 mcg/hr). In a naive pump, PRIALT is lost due to two factors that do not occur upon subsequent refills: adsorption on internal device surfaces, such as the titanium, and by dilution in the residual space of the device. Consequently, the pump reservoir should be refilled with PRIALT within 14 days of the initial fill to ensure appropriate dose administration.

#### 3. Pump Refills

For subsequent pump refills, fill the pump at least every 40 days if PRIALT is used diluted. For undiluted PRIALT, fill the pump at least every 60 days. To ensure aseptic transfer of PRIALT into the device, it is recommended that the Medtronic refill kit be used. The pump contents should be emptied prior to refill with PRIALT.

If the internal infusion system must be surgically replaced while the person is receiving PRIALT, the replacement pump should be rinsed with PRIALT (No. 1 above), and this initial fill solution must be replaced within 14 days (No. 2 above). Subsequent refills should be done at least every 60 days if PRIALT is used undiluted or at least every 40 days if PRIALT is used diluted.

PRIALT (ziconotide intrathecal infusion)	Initial Fill Expiry	Refill Expiry
25 mcg/mL, undiluted	14 Days	60 Days
100 mcg/mL, undiluted	N/A	60 Days
100 mcg/mL, diluted	N/A	40 Days

#### Simms Deltac Cadd Micro External Microinfusion Device and Catheter (See PRECAUTIONS-Meningitis and Other Infections)

Refer to the manufacturer's manuals for specific instructions and precautions for performing the initial filling, refilling of the reservoir or replacement of the drug cartridge, and operation. The appropriate external microinfusion device is filled for the first time with PRIALT solution at a concentration of 5 mcg/mL. This solution is prepared by diluting PRIALT with 0.9% Sodium Chloride, USP (preservative free). The flow rate for the external microinfusion device usually starts at 0.02 mL/hr to deliver the initial dose rate of 2.4 mcg/day (0.1 mcg/hr) of PRIALT. Changes in dose rate are made by adjusting the flow rate of the infusion system and/or the concentration of PRIALT solution.

#### HOW SUPPLIED

PRIALT is supplied as a 25 mcg/mL solution in a single-use 20 mL glass vial and as a 100 mcg/mL solution in single-use glass vials containing 1 mL, 2 mL, or 5 mL of solution. One vial is packaged per carton.

#### Presentation (NDC)

25 mcg/mL: 20 mL vial (59075-723-10). Only the undiluted 25 mcg/mL formulation should be used for PRIALT naive pump priming.

100 mcg/mL: 1 mL (59075-720-10)

2 mL (59075-721-10)

5 mL (59075-722-10)

#### STORAGE

- Refrigerate PRIALT during transit.
- Store PRIALT at 2°C–8°C (36°F–46°F).
- PRIALT, once diluted aseptically with saline, may be stored at 2°C–8°C for 24 hours.
- Do NOT freeze PRIALT.
- Protect from light.

U.S. Patent Nos. 5,364,842, 5,795,864, and 5,859,186

Distributed by:

Elan Pharmaceuticals, Inc.

San Diego, CA 92121

© 2005 Elan Pharmaceuticals, Inc.

PRIALT® is a trademark of Elan Pharmaceuticals, Inc.

SynchroMed® EL and SynchroMed® II are registered trademarks of Medtronic, Inc.

Simms Deltac Cadd Micro® is a registered trademark of Arduus Medical, Inc.

Rx

6000323-A

Rev. 12/04



Advancing Transfusion and Cellular Therapies Worldwide

113

ERP  
P...  
R...

Gustaf  
K...  
...  
...  
...  
...  
Bazell

September 14, 2005

The Honorable Mark McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Room 445-G  
Washington, DC 20201

Re: CMS-1501-P – Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

AABB appreciates the opportunity to comment regarding the proposed rule for Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. AABB's members are responsible for virtually all of the blood collected and over 70 percent of the blood transfused in the United States.

AABB requests that CMS carefully consider our comments regarding the following transfusion and cellular therapy related issues:

- Payments for Blood and Blood Products;
- APC 0112, Apheresis and Photopheresis; and
- Code 38230, Bone Marrow Harvesting for Transplantation.

**Payments For Blood Products**

AABB commends CMS for acknowledging the need to protect beneficiaries' access to a safe blood supply and paying special attention to blood-related ambulatory payment classifications (APCs). However, AABB has significant concerns regarding CMS' unrealistically low payments for many blood-related products under its hospital outpatient prospective payment system. In particular, AABB is troubled by the proposed reductions in APC rates in 2006 for several blood products.

Neither the current 2005 nor proposed 2006 APC rates for blood products accurately reflect the increasing cost of these products resulting from blood safety advances. As AABB and others in the transfusion medicine community have explained to CMS in the past, blood is an ever changing biologic. The transfusion medicine community is constantly taking steps to respond to emerging threats to the blood supply and make blood as safe as possible. In recent years, the community worked together to speed the introduction of a new blood screening test that was successful in preventing well over 1,000 individual transfusion recipients from being infected with the potentially deadly West Nile virus. More recently, blood centers and hospitals have invested in additional technologies and methodologies to detect bacteria in blood components. These blood safety advances clearly save patients' lives. They also, necessarily, add to the cost of each unit of blood.

CMS' existing CY 2005 APC rates for several blood components already fall notably below hospitals' actual acquisition costs for blood. Most of CMS' proposed payments for blood products in 2006 offer hospitals little relief, and the agency's proposed reductions in payments for some components threaten hospitals' abilities to afford needed blood products even more than in past years. Notably, for 2006, CMS proposes to pay only \$161.71 for a unit of leukocyte reduced red blood cells (RBCs) (APC 0954), the most commonly transfused blood product. Last year, AABB, the American Red Cross and America's Blood Centers surveyed blood centers nationally to determine the number of units of each major blood product sold to each hospital between September 2003 and December 2003 and the price per unit. The median hospital acquisition cost for leukoreduced red blood cells in this 2003 time period was \$198 and the mean was \$199. Since that time, with the introduction of additional blood safety measures, the cost of leukocyte reduced RBCs has continued to increase. Therefore, CMS' proposed payment in 2006 is clearly inadequate.

CMS itself acknowledges that "possible errors in hospital billing or coding for blood products in CY 2004 may have contributed to . . . decreases in medians." AABB notes CMS' recent efforts to address the hospitals' difficulties in understanding complex blood billing issues by issuing guidance in Program Transmittal 496. AABB appreciates these efforts and looks forward to continuing to work with CMS to ensure that its guidance materials provide hospitals with the clearest possible directions for coding and billing blood products and services. However, it will take significant time for hospitals to fully understand the complexities of such coding and billing, and, in the meantime, CMS will not have accurate claims data on which to base its APC rates for blood and blood products.

Although AABB appreciates CMS' effort to limit cuts in payments for blood products with severe decreases in simulated medians, we believe that the alternative payment proposed by the agency – limiting the payment reduction to 10 percent below the 2005 APC rate – would still result in substantial underpayments to hospitals for life-saving blood products. **Therefore, in order to more appropriately limit underpayments and better ensure patient access to the highest quality blood products, AABB requests that CMS use its CY 2005 APC payment rates as a floor for all blood and blood**

**products in 2006. In other words, we urge the agency to consider basing median costs for blood and blood products in CY 2006 on the greater of: (1) the simulated medians calculated using CY 2004 claims data; or (2) the CY 2005 APC payment medians for such products.**

On August 18, 2005, the Advisory Panel on Ambulatory Payment Classifications Groups endorsed, by unanimous vote, the above recommendation. AABB believes that this change in outpatient reimbursement for blood products is necessary to ensure patients have access to the best possible blood products. Hospitals will still not be reimbursed for their full acquisition costs. But at least their damages would be limited under this reasonable approach.

### **APC 0112, Apheresis and Photopheresis**

AABB commends CMS for moving Code 36515, Therapeutic Apheresis with Extracorporeal Immunoabsorption and Plasma Reinfusion, from APC 0111 back to 0112. This is a very costly procedure and it fits better both clinically and in terms of resource requirements in APC 0112. However, the proposed decrease in payment level for APC 0112 would result in grossly inadequate reimbursement and could have a severe impact on the ability of hospitals to provide these services.

There are three procedure codes assigned to APC 0112. Code 36515, Therapeutic Apheresis with Extracorporeal Immunoabsorption and Plasma Reinfusion, is used to treat patients with immune thrombocytopenic purpura (287.3) refractory to conventional steroid therapy and advanced rheumatoid arthritis (714.0) unresponsive to at least two conventional disease-modifying anti-rheumatic drugs. Code 36516, Therapeutic Apheresis with Extracorporeal Selective Adsorption or Selective Filtration and Plasma Reinfusion, is used to treat patients with hypercholesterolemia (272.x) who are not successfully managed with diet or maximum lipid-lowering drug therapy and who are at high risk for adverse cardiovascular events. Code 36522, Photopheresis, Extracorporeal, is used to treat patients with cutaneous T-cell lymphoma of various types (202.1, 202.2) and increasingly to treat graft versus host disease in bone marrow transplant patients and to prevent solid organ transplant rejection. All of these procedures are performed using sophisticated and costly technology.

CMS has proposed to reduce its payment for these services, by more than 25 percent, from \$2,127 to \$1,583. This payment will not cover the costs of performing these services. For example, the disposable supplies alone for Code 36516 cost approximately as much money as the total APC payment. Additional costs relating to clinical labor, equipment and overhead associated with a procedure that can take five hours to perform must also be included. Similar supply cost issues exist with respect to Code 36515.

Recognizing that the proposed rate is derived from estimated median costs converted from hospital charges attributed to this APC, AABB suspects that there may be significant problems in the data. It is very likely that some hospitals did not fully reflect the costs of the expensive disposables such as the Prosorba® column or the lipid

apheresis disposables in their charges for the procedure. AABB believes that hospitals that charge separately for the disposables are apt to charge more accurately for the procedure than hospitals that bundle the entire costs of the disposable supplies in their charge for the procedure. It is AABB's understanding that if the rates were derived only from claims which included separate charges for supplies with the claim for the procedure, the average charges would be substantially higher. Therefore, AABB urges CMS to consider basing the rate only on claims where separate charges for supplies have been identified. AABB also requests CMS to reexamine the calculation of the median costs due to what appear to be peculiarities in the data.

AABB is concerned that unless the payment level for APC 0112 is adjusted appropriately, beneficiaries may not have access to promising new applications of the apheresis technology. AABB would welcome the opportunity to work with CMS and other interested parties to develop more reliable data reflecting the actual costs of providing these services in the hospital outpatient setting. AABB will also seek to educate our hospital members that provide these specialized services to improve the accuracy of claims submitted for these services. In order to clarify this issue for hospitals, AABB recommends that CMS consider requiring the separate reporting of the very costly disposable supplies for this APC, as it does for the "device dependent" APCs.

**In sum, for 2006, AABB asks CMS to (1) reexamine the calculation of the median costs of this APC as discussed above and/or (2) consider basing the rate only on claims that have separate charges for supplies. If these approaches are impractical or do not resolve the current problem of median costs, AABB would then urge CMS to freeze the current APC rate or, at a minimum, provide a floor on a reduction similar to the proposal for device dependent APCs.**

#### **Code 38230, Bone Marrow Harvesting for Transplantation**

Having inadequate cost data, CMS proposes to pay only \$732 for Code 38230, Bone Marrow Harvesting for Transplantation, which is assigned to APC 0111 (Blood Product Exchange). Unfortunately, CMS has very limited data regarding this code. With many of these services performed for much younger patients and/or in cancer exempt hospitals, CMS had only nine claims for this code. The cost range varied enormously, from \$140 to \$66,770, with a median of \$1,209 and a mean of \$10,740.

This is an extremely costly procedure with actual cost probably five to ten times the median cost indicated. The typical bone marrow harvest procedure takes approximately two hours of operation room time, including time to administer and recover from general anesthesia. The proposed \$732 payment for APC 011 appears greatly inadequate when compared to payments for other procedures requiring similar amounts of time and general anesthesia.

**Until improved cost data are available, AABB strongly urges CMS to move this code from the current APC to APC 0123, Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant, which has a proposed payment rate of \$1,364. This**

rate would better reflect the costs of the service and would also result in a more clinically homogeneous APC grouping. In fact, the title of APC 0123 seems to apply specifically to this procedure code.

AABB hopes that CMS will act on the above recommendations aimed at ensuring Medicare beneficiaries have access to quality blood products and transfusion and cellular therapies. If you have questions or require additional information, please contact Theresa Wiegmann, director of public policy, at 301-215-6554 or [Theresa 1@aabb.org](mailto:Theresa1@aabb.org).

Sincerely,



Karen Shoos Lipton, JD  
Chief Executive Officer

THAD COCHRAN, MISSISSIPPI, CHAIRMAN

TED STEVENSON, ALASKA  
ARLEN SPECTER, PENNSYLVANIA  
PETE V. DOMENICI, NEW MEXICO  
CHRISTOPHER S. BOND, MISSOURI  
MITCH MCCONNELL, KENTUCKY  
CONRAD BURNS, MONTANA  
RICHARD C. SHELBY, ALABAMA  
JUDD GREGG, NEW HAMPSHIRE  
ROBERT F. BENNETT, UTAH  
LARRY CRAIG, IDAHO  
KAY BAILEY MITCHISON, TEXAS  
MIKE DEWINE, OHIO  
SAM BROWNBACK, KANSAS  
WAYNE ALLARD, COLORADO

ROBERT C. BYRD, WEST VIRGINIA  
DANIEL K. INOUE, HAWAII  
PATRICK J. LEAHY, VERMONT  
TOM HARKIN, IOWA  
BARBARA A. MIKULSKI, MARYLAND  
BARRY REID, NEVADA  
HERB KOHL, WISCONSIN  
PATTY MURRAY, WASHINGTON  
BYRON L. DORGAN, NORTH DAKOTA  
DIANNE FEINSTEIN, CALIFORNIA  
RICHARD J. DURBIN, ILLINOIS  
TIM JOHNSON, SOUTH DAKOTA  
MARY L. LANDRIEU, LOUISIANA

J. KEITH KENNEDY, STAFF DIRECTOR  
TERRENCE E. SAUVAIN, MINORITY STAFF DIRECTOR

SR  
NTIAPC

10F66 114-0

(on behalf of 66 Constituents)

# United States Senate

COMMITTEE ON APPROPRIATIONS  
WASHINGTON, DC 20510-6025  
<http://appropriations.senate.gov>

Hariter  
Spolter  
Hostettler  
Kane  
Sanow  
Hart  
Bazell

September 14, 2005

CMS 1501-P  
Re: Gamma Stereotactic Radiosurgery

The Honorable Mark McClellan  
Administrator  
Centers for Medicare and Medicaid Services  
Washington, D.C. 20202

Dear Mr. McClellan:

I am writing to follow up on the issue of gamma stereotactic radiosurgery. Over the past eight years, I have corresponded with your office to encourage the proper coding and designation for these types of procedures. At my request, a meeting was held on June 3, 2005. Representatives from CMS and industry groups representing hospital facilities that provide radiosurgery treatments were in attendance. I appreciate your making staff available to discuss the issues surrounding medical procedures and the equitable coding and placement of their use.

On July 25, 2005, your agency released the proposed Medicare regulations for hospital outpatient services. I am told that the proposed regulations would provide a partial solution to the problem. However, I understand that the proposed regulation may have a detrimental affect on an already beleaguered hospital claims system.

Groups representing industry, including physicians and hospitals, have made several suggestions to the proposed regulation. I am passing these suggestions on to you and would appreciate you giving them every consideration.

1. Designate a single full CPT code that is within the 6XXXXX series of surgical codes. Another temporary code will only place additional stress on the hospitals providing this procedure. Insurers consider this a surgical procedure conducted by a neurosurgeon.
2. Immediately place the new surgical code into an APC designation that is perceived as surgical. A placement within a New Technology APC or an accepted radiation APC is not acceptable and will result in further problems.
3. Use CMS data collected over the last two years to correctly reimburse the new surgical code. It is my understanding that since 2000, this procedure has seen its reimbursement decrease by over 50%. Data collected over the last two

years show that it should increase by a minimum of the same percentage if properly coded and placed within a surgical APC by itself.

4. CMS should use a correct and accepted definition for the procedure. The Nuclear Regulatory Commission, the Food and Drug Administration and all commercial insurers call this procedure "Gamma Stereotactic Radiosurgery." By definition it is surgeon-based and those words should be added to the descriptor to alleviate confusion and problems with other dissimilar treatment claims submissions. CMS should not continue to describe this procedure as if it were a radiation therapy procedure, but should look back to its original definition before it was changed by CMS.
5. Hospital representatives and physicians have stated that commercial payers reimburse according to brain lesion with a significant reduction in reimbursement for each additional tumor. Reimbursing in such a manner should result in tremendous savings as multiple procedures are avoided and all tumors are addressed in one surgical procedure.
6. New coding would mirror the following:
  - o New APC 210, 211, or 219, Titled: Surgeon-Based Gamma Stereotactic Radiosurgery
  - o New CPT code 61794 or 6XXXX described as: Surgeon-Based Gamma Stereotactic Radiosurgery, complete course one procedure, per lesion. (Status = T)
  - o Reimbursement would use the combined data from the current codes of G0242 and G0243 which is around \$10,100 per procedure.

I continue to remain very concerned about the reimbursement rates for the small group of hospitals that provide surgeon-based gamma stereotactic radiosurgery and look forward to your prompt reply.

My Best.

Sincerely,



Arlen Specter  
Chairman  
Subcommittee on Labor, Health and  
Human Services, Education and  
Related Agencies

115

NT/APC



Hunter  
Spolter  
Hostetter,  
Kane  
Sanson  
Hart  
Briest

September 15, 2006

The Honorable Mark McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Re: Proposed Changes to the OPPS Payment System and 2006 Payment Rates

Issue: New Technology APC

Dear Dr. McClellan:

Calypso Medical Technologies is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

We would like to thank CMS for the opportunity to make recommendations regarding the proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

**New Technology APCs**

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

Calypso Medical Technologies is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization, utilizing closed processes that are not subject to procedural protections typically required for public policy. AMA meetings are closed to the public and the bases for decisions are not available to the public, including hospitals and physicians. The AMA CPT Editorial Panel allows no participation or representation from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

The Honorable Mark McClellan  
Page 2  
September 15, 2005

Clearly, the requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions.

The requirement to submit New Technology APC applications together with CPT code applications presents an inherent conflict of purpose. By definition, category I CPT codes are assigned to procedures that have become an accepted standard of care and are in widespread use. This conflicts with and, in fact, defeats the purpose of creating a special coding vehicle (new technology APCs) to facilitate adoption and dissemination of new technology and the collection of clinical data. If manufacturers are forced to apply for a CPT code before widespread use or extensive information about the technology is available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code. This often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries and many commercial payers thus denying Medicare patients access to technology. The end result of the proposed rule would be a disincentive for manufacturers, particularly smaller ones, to innovate and market novel and beneficial medical technologies.

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives from manufacturers on the decision making panel and offer additional concerned parties the opportunity to participate, comment, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiary's full access to the same high quality care in the hospital outpatient setting realized by patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me either via email at [emeier@calypsomedical.com](mailto:emeier@calypsomedical.com) or telephonically at (206) 774-4205.

Sincerely,



Eric R. Meier  
President and CEO

**mms**

116

Pynt Pates  
APC weights  
APC/6en

Heygster  
Burley  
Kane  
Sanow  
Hart  
Bazell

September 16, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

**VIA FED EX**

Re: CMS-1501-P -- Comments on the Hospital Outpatient Prospective Payment System Proposed Rule for Calendar Year 2006

**I. INTRODUCTION**

These comments are submitted on behalf of MMS, Inc. ("MMS"). MMS appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") concerning the hospital outpatient prospective payment system ("OPPS") proposed rule for calendar year 2006 (the "Proposed Rule").<sup>1</sup> Specifically, we wish to comment on the Proposed Rule's treatment of three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation ("3D-CAMPS") technology, which is reported using G0288, "Reconstruction, computed tomographic angiography of aorta for preoperative planning and evaluation post vascular surgery," and is assigned to APC 417, "Computerized Reconstruction."

"3D-CAMPS" is a generic term that refers to a specific and unique health information technology that enables vascular surgeons to deliver the safest and most effective treatment for abdominal aortic aneurysms ("AAAs") and thoracic aortic aneurysms ("TAAs"). Endovascular implantation of stent grafts has rapidly become the standard of care for treating AAAs and TAAs, and 3D-CAMPS delivers precise anatomical measurements and three-dimensional modeling that greatly improve the ability of vascular surgeons to plan this intervention (including in terms of patient and graft selection) and to monitor outcomes of the surgery. 3D-

<sup>1</sup> See Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule, 70 Fed. Reg. 42,674 (July 25, 2005).

CAMPS has been endorsed by the Society for Vascular Surgery ("SVS") as the standard of care for surgical planning and follow-up in connection with endovascular repair of AAAs and TAAs, and it has been recognized by the Food and Drug Administration as adequate for postmarketing surveillance of stent grafts.

In summary, we propose the following:

- (1) CMS should mandate the use of an appropriate revenue code for G0288 to eliminate hospital's confusion as evidenced by the use of 17 different revenue codes for G0288 in the 2004 claims data. A suggested revenue code is 0780 (Telemedicine), because the overwhelming majority (84%) of the services billed with G0288 in 2004 were performed remotely by MMS with data transmitted via the internet. If this revenue code is unavailable then the default aggregate hospital CCR could be used. Uniform and appropriate revenue coding should help alleviate the effects of providers not billing charges high enough to result in cost findings near acquisition cost.
- (2) CMS should use the aggregate hospital CCRs to calculate median cost for 3D-CAMPS, which would result in a median cost of approximately \$415.
- (3) As a fallback measure, if the preceding recommendations cannot be implemented, CMS at a minimum should establish the 2006 payment rate for 3D-CAMPS at the 2005 payment level, adjusted upward in accordance with the 2006 conversion factor update, to yield a 2006 payment of approximately \$275. In light of the successive and substantial payment reductions for this service over the past few years resulting in rates well below demonstrated acquisition costs, stabilizing the payment rate would be an appropriate measure to ensure continued access to this technology for vascular surgeons and their patients.
- (4) CMS should revise the descriptor for G0228 to read "Three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation in accordance with measurements and modeling specifications of the Society for Vascular Surgery." This will ensure that the code is used only for true 3D-CAMPS technologies that provide the functionality endorsed by SVS as the standard of care for endovascular repair of AAAs and TAAs.

## **II. BACKGROUND ON 3D-CAMPS**

Before the development of 3D-CAMPS technology, the primary tool for surgical planning and post-procedure monitoring for AAAs and TAAs was an angiogram, which is a costly, invasive procedure that presents significant health risks to Medicare patients. 3D-CAMPS provides physicians with precise anatomic measurements and a far more accurate portrayal of a patient's condition compared to angiograms, at significantly less cost to the health care system and with less risk to the patient. 3D-CAMPS's measurements, along with its highly accurate multi-model object planning tool, are the basis for physicians to execute AAA and TAA surgical planning and post-operative evaluation.

The development of 3D-CAMPS was driven largely by FDA's concerns with serious complications reported with stent grafts.<sup>2</sup> Shortly after issuing a public notification on these devices in 2001, FDA began consultations with representatives from the Society for Vascular Surgery ("SVS"), MMS, and stent graft manufacturers to develop a system that would enable post-surgical monitoring of AAA patients. Through this collaborative process, a suite of anatomical measurements was developed that was deemed by SVS to be the standard of care for post-operative monitoring of stent graft implantation, including to assess the need to correct graft migration or loss of exclusion of aortic pressure from the aneurysm sac. This suite of measurements, along with other functionality specifications (including the ability to perform multi-object three-dimensional modeling), became the basis of 3D-CAMPS technology, which was first developed by MMS in the form of its Preview product.<sup>3</sup> FDA recognized 3D-CAMPS as being an appropriate mechanism to monitor for postmarketing surveillance of stent grafts.

In addition to its central role in AAA and TAA postmarketing surveillance, 3D-CAMPS also has been endorsed by SVS as the standard of care for pre-surgical treatment planning for endovascular repair of aortic aneurysms, and as the most effective means of meeting the stent graft labeling requirements for pre-operative measurement. The precise measurements provided by 3D-CAMPS greatly enhance a surgeon's ability to plan the intervention, and thereby minimize the incidence of complications attributable to improper patient or graft selection and incorrect graft placement.

### **III. PROBLEMS WITH PROPOSED RULE AND RECOMMENDATIONS**

#### **A. Payment for 3D-CAMPS**

CMS has had difficulty over the past several years establishing an appropriate payment for 3D-CAMPS (G0288) based on OPPS claims data. Upon its introduction into the outpatient setting in 2001 and through 2002, 3D-CAMPS was paid under the OPPS at \$625.00, based on actual acquisition cost data provided by MMS. For both 2003 and 2004, CMS proposed to reduce the OPPS payment for 3D-CAMPS by more than half to \$250.00 and \$260.65,

<sup>2</sup> On April 27, 2001, FDA issued a Public Health Notification expressing concerns with reports of serious adverse events with stent grafts thought to be associated with sub-optimal graft placement, endoleak, graft migration, problems with device integrity, and aneurysm anatomy. See Food and Drug Administration, "FDA Public Health Notification: Problems with Endovascular Grafts for Treatment of Abdominal Aortic Aneurysm (AAA)" (April 27, 2001); see also Food and Drug Administration, "FDA Public Health Notification: Updated Data on Mortality Associated with Medtronic AVE AneuRx® Stent Graft System" (December 17, 2003). In the notification, FDA said it is "critical that physicians who evaluate and treat AAA patients have the information needed to make informed decisions on patient selection, device selection, and follow-up management." FDA said it would work with manufacturers to "obtain relevant data that will help us understand how these problems affect the overall risk/benefit assessment of this product."

<sup>3</sup> Because of the expense of establishing an information technology infrastructure capable of performing 3D-CAMPS, most physicians currently obtain this service on a contract basis with MMS. Nevertheless, a small (and we expect increasing) number of larger institutions are capable of providing genuine 3D-CAMPS services in-house, and it is a distinct possibility that another entity will emerge to compete with MMS in providing 3D-CAMPS on a contract basis.

respectively, based on the “median cost” of this service as derived from OPPS claims data. In response to each of these proposals, MMS provided the agency with actual acquisition cost data demonstrating that the proposed payment levels were less than half of the actual cost of this service to hospitals. CMS maintained the \$625.00 payment level for 2003, but for 2004, the agency blended MMS’s actual cost data (which demonstrated a median cost of \$625.00) with the OPPS claims data to arrive at a payment level of \$450.00,<sup>4</sup> a reduction of 28 percent that was not subject to any dampening measures. In 2005, CMS instituted another significant reduction in payment to \$267 (a 41% reduction from the 2004 payment of \$450) for 3D-CAMPS based on OPPS claims data that grossly understate the actual cost of this service to hospitals.

For 2006, CMS has once again proposed a further reduction in the payment for 3D-CAMPS based on OPPS claims data that grossly understate the actual cost of this service to hospitals. Specifically, the agency proposes to pay for 3D-CAMPS at \$240.76, a reduction of 10 percent from the already inadequate 2005 payment of \$267. MMS’s sales data for 2004 indicate an average price of \$476.22 for MMS’s Preview service coded with G0288. The 2004 hospital outpatient claims data and MMS sales data show that Preview accounts for approximately 84 percent of the 2004 claims for 3D-CAMPS in the OPPS database. Table 1 summarizes these findings.<sup>5</sup> Moreover, the mean cost and charges between the MMS and non-MMS customers are less than 5% different and therefore, the contention that “market forces” (i.e., newer low cost providers of similar services) may be driving the cost finding down is unsubstantiated by this data. In summary, the overwhelming majority of hospitals are paying an average of \$476 for 3D-CAMPS but stand to receive approximately \$241 if the proposed 2006 payment is adopted.

Table 1. Comparison of 2004 HOPD Data for MMS and non-MMS customers

	Number of Unique Providers	Total Claim Count	Weighted Mean Charge	Weighted Mean Cost
MMS	125	4266	\$ 1,130	\$ 272
Not MMS	30	829	\$ 1,068	\$ 273
MMS % of Total	81%	84%		
% Difference			5%	0%

THE MORAN COMPANY

It is difficult to determine precisely why the OPPS claims data continue to generate cost estimates for this procedure that are almost half of the actual acquisition cost. An analysis of the 2004 claims data by The Moran Company<sup>6</sup>, however, indicates several potential sources of error, including the use of a confusing array of revenue codes by hospitals and providers not adequately marking up charges to result in a cost finding near acquisition.

<sup>4</sup> See Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates; Final Rule, 68 Fed. Reg. 63,398. 63,415-16. (Nov. 7, 2003).

<sup>5</sup> The Moran Company submitted a list of providers who submitted claims for G0288 to MMS and MMS identified those providers who had used their service in 2004; these providers were determined to be MMS providers and the remaining were “non-MMS” providers.

<sup>6</sup> See attached power point presentation, Attachment A, “The Moran Company, “Findings from an Analysis of G0288 (APC 417) in the 2004 HOPPS Claims Prepared for Medical Metrx Solutions” (August 30, 2005).

## 1. Revenue Code Confusion

According to the Moran Company analysis of G0288 (APC 0417) in the 2004 OPSS claims database, for the G0288 single claims, there were 17 different revenue codes used.<sup>7</sup> In fact, some hospitals use more than one revenue code to describe G0288. Such variation in revenue codes results in the haphazard application of various cost to charge ratios for G0288 and therefore inaccurate estimates of the median cost associated with G0288.

To ameliorate the revenue code confusion surrounding G0288, CMS should mandate the use of an appropriate revenue code for G0288 to eliminate hospital's confusion as evidenced by the use of 17 different revenue codes for G0288 in the 2004 claims data. The Moran Company analysis substituted the aggregate hospital CCR in lieu of the 17 different CCRs that were used by hospitals to code G0288.<sup>8</sup> The result was a median cost of \$418.34. This analysis demonstrates that applying a consistent and more appropriate CCR results in a median cost that more accurately reflects the acquisition cost of the service. A suggested revenue code is 0780 (Telemedicine), because the overwhelming majority of the services billed with G0288 are performed remotely by MMS with image data transmitted via the internet from hospitals. If this revenue code is unavailable then the default aggregate hospital CCR should be used. Uniform and appropriate revenue coding should also help alleviate the effects of inadequate charge mark-ups on accurate median cost determination.

## 2. Inadequate Charge Mark-ups

While most hospitals are charging more than acquisition cost for 3D-CAMPS, the markup for this service appears to be far less than what is reflected in relevant cost-to-charge ratios. This occurrence is not surprising, because for most hospitals 3D-CAMPS is essentially a "pass-through" service that is obtained on a contract basis from MMS with relatively little additional input from the hospital. Furthermore, in 2004 the payment rate for G0288 was \$450 and hospitals were being reimbursed an amount closer to acquisition cost of MMS's 3D-CAMPS service, and therefore hospitals may not have fully appreciated that the charges would be inadequate once the CCR was applied to calculate the cost. Consequently, charges reduced to cost for this service are well below actual acquisition cost.<sup>9</sup>

The inadequate charge markup problem can be partially ameliorated by appropriate revenue coding, as discussed above. Given the clinical importance of 3D-CAMPS in treating aortic aneurysms (as evidenced by SVS's endorsement of this technology as the standard of care for treatment planning and follow-up), we believe it is imperative that CMS take appropriate measures to ensure that inadequate OPSS payment does not hinder adoption of this technology in the outpatient setting. Accordingly, we recommend that CMS increase the OPSS payment for 3D-CAMPS to \$415 to approximate the median cost of \$418.34 for G0288 calculated by the Moran Company using the aggregate hospital CCRs.

---

<sup>7</sup> Id.

<sup>8</sup> Id.

<sup>9</sup> Id.

### 3. Fallback Measure to Stabilize 2006 Payment

As a fallback measure, if the preceding recommendations cannot be implemented, CMS at a minimum should establish the 2006 payment rate for 3D-CAMPS at the 2005 payment level, adjusted upward in accordance with the 3.2 percent OPPS conversion factor update for 2006. This would yield a 2006 payment of approximately \$275.

While this payment rate still would be substantially less than the actual acquisition cost of the service, using this alternative approach nevertheless would prevent the negative financial effect that another significant payment reduction would have on hospitals that utilize this technology. Indeed, in light of the successive and substantial payment reductions for this service over the past few years that have resulted in payments far below hospitals' demonstrated acquisition cost, we believe stabilizing the payment rate in 2006 would be an appropriate measure to ensure continued access to this technology for vascular surgeons and their patients.

#### **B. Descriptor for G0288**

Since 2003, 3D-CAMPS has been reported using G0288, "Reconstruction, computed tomographic angiography of aorta for preoperative planning and evaluation post vascular surgery."<sup>10</sup> The descriptor for this code should be amended so that it describes 3D-CAMPS technology more accurately and with adequate specificity.

First, we believe the generalized language in this descriptor may cause confusion as to the services that should be billed with G0288, and may result in certain "home brew" technologies being reported under this code that are far less sophisticated and clinically valuable (though perhaps less costly) than 3D-CAMPS. This could exacerbate the extent to which the OPPS median cost data understate the actual cost of 3D-CAMPS to providers. Therefore, the descriptor for G0288 should specify that it may be used only for 3D-CAMPS technologies capable of generating the measurements and modeling deemed essential by SVS.

In addition, the code descriptor should not be limited to services that use computed tomography angiography (CTA). Many hospitals do not perform CTA on-site, and some patients who must undergo vascular surgery of the aorta cannot tolerate the contrast material used to generate a CTA. Under such circumstances, 3D-CAMPS can process data from computed tomography (CT) or magnetic resonance (MR) images.

Accordingly, CMS should revise the descriptor so that it reads as follows:

"Three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation in accordance with

---

<sup>10</sup> Upon its introduction, the code was described as "Reconstruction, computed tomographic angiography of aorta for surgical planning for vascular surgery." In response to comments by MMS, CMS subsequently changed the descriptor to encompass use of the code for post-operative monitoring.

Mark B. McClellan, M.D., Ph.D.  
Centers for Medicare & Medicaid Services  
September 16, 2005

MMS Comments on CY2006  
OPPS Proposed Rule

7

measurements and modeling specifications of the Society for  
Vascular Surgery.”

\* \* \*

We appreciate the opportunity to provide these comments and are eager to work with CMS to ensure that physicians and patients continue to realize the clinical benefits offered by 3D-CAMPS. Please let me know if I can be of further assistance.

Sincerely,

*M. Weston Chapman (J&M)*

M. Weston Chapman  
Chairman and Chief Executive Officer

## Attachment A

### Findings from an Analysis of CPT G0288 (APC 0417) in the 2004 HOPPS Claims

Prepared for MMS  
Presented to CMS  
August 30, 2005  
Revised September 14, 2005

THE MORAN COMPANY

1

### Background

- In 2003, service was billed using HCPCS C9708 which mapped to new tech APC (0975 – Level VI) and was paid a rate of \$650 – external data was submitted and used to set this rate.
- In 2004, a new code is introduced (G0288) which mapped to a new technology APC (1506 – Level VI) both claims and external invoice data were used to set a payment rate of \$450.
- In 2005, CMS proposes a payment rate of \$266.72 which is based on claims data alone

THE MORAN COMPANY

2

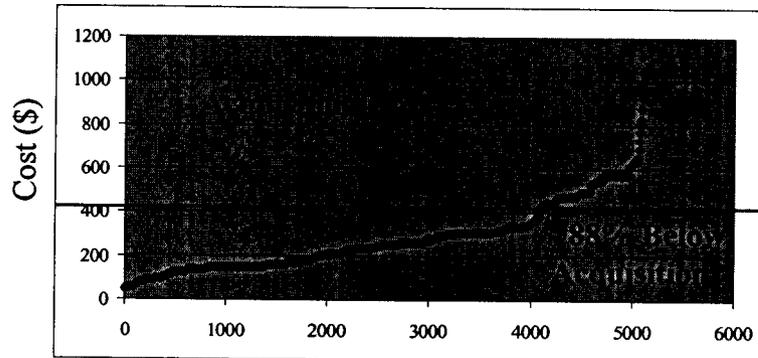
**The proposed payment rate for APC 0417 is below acquisition cost...**

- Most providers are not billing charges that produce a cost finding near the actual acquisition cost.

THE MORAN COMPANY

3

### Distribution of Cost Findings



Median Cost =  
\$246.44

Count of Single Claims

THE MORAN COMPANY

4

## Possible Explanations

- Confusing array of revenue codes from which to choose.
  - For the single claims, this procedure was billed with 17 different revenue codes.
  - Some providers using more than one revenue code.
- The departmental charge structures may not be designed to capture this kind of “outsourced” clinical service.
- In 2004, payment rate was \$450.00 and thus, providers are being adequately reimbursed for the service in the data year used for setting CY 2006 rates and may not yet realize charges do not reflect acquisition cost.

THE MORAN COMPANY

5

## Distribution of Revenue Codes

Revenue Code	Revenue Code Description	Number of Single Claims
0350	Computed tomographic (CT) scan-general classification	2,245
0409	Other imaging services-other	1,065
0352	CT scan-body scan	992
0320	Radiology diagnostic-general classification	383
0359	CT scan-other CT scans	251
0400	Other imaging services-general classification	38
0361	Operating room services-minor surgery	32
0272	Medical/surgical supplies-sterile supply	20
0330	Radiology therapeutic-general classification	20
0351	CT scan-head scan	14
0333	Radiology therapeutic-radiation therapy	11
0360	Operating room services-general classification	9
0490	Ambulatory surgical care-general classification	9
0270	Medical/surgical supplies-general classification	5
0921	Other diagnostic services-peripheral vascular lab	4
0420	Physical therapy-general classification	2
0402	Other imaging services-ultrasound	1

THE MORAN COMPANY

6

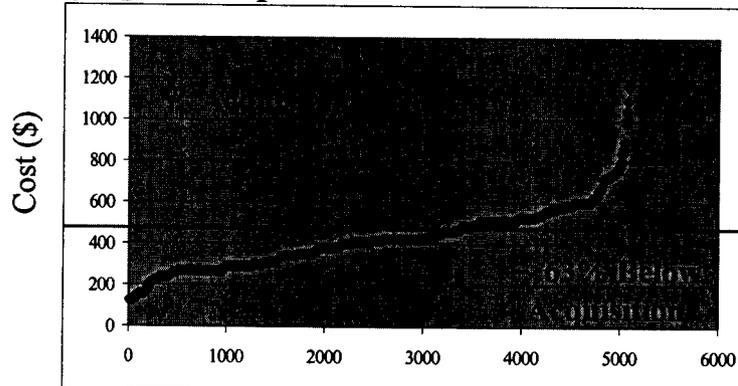
## Possible Technical Options?

- If CMS believes these concerns warrant an exception, a potential technical option would be use the aggregate hospital CCRs in lieu of departments.
  - Advantages of this approach:
    - There is precedent: similar to method used for brachytherapy sources
    - Resulting cost findings are closer to acquisition cost.

THE MORAN COMPANY

7

## Distribution of Cost Findings with Aggregate Hospital CCRs



Median Cost =  
\$418.34

Count of Single Claims

THE MORAN COMPANY

8

117



**American Association of Physicists in Medicine**

One Physics Ellipse  
College Park, MD 20740-3846  
(301) 209-3350  
Fax (301) 209-0862  
<http://www.aapm.org>

Levi  
Huygster  
Hunder  
Burley  
Spolter  
Nostetler  
Kane  
SAROW  
HART  
Bazell

B-Therapy  
APC weights  
PBT  
S/T  
Imaging  
NT/APC

September 15, 2005

The Honorable Mark McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P

Dear Dr. McClellan:

The American Association of Physicists in Medicine (AAPM) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule, published in the July 25, 2005 *Federal Register*.

AAPM's mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the Nuclear Regulatory Commission and various State Health Departments. AAPM represents over 5,000 medical physicists.

We would like to thank CMS for significant positive changes in radiation oncology payment policy since the inception of HOPPS, however, we recognize that further refinements are essential to ensure appropriate payment to hospitals and meaningful access to high quality cancer treatment care for Medicare beneficiaries.

## **Brachytherapy**

All radiation oncology procedure codes (CPT codes 77xxx) have proposed increases in 2006 under HOPPS except brachytherapy APCs 312, 313 and 651 (see Table 1).

**Table 1 Comparison of 2005 vs. Proposed 2006 HOPPS Payment Rates for Brachytherapy APCs**

APC	CPT Codes	2005 Payment	2006 Proposed Payment	Percentage Change from 2005 to 2006
312 Radioelement Applications	77761, 77762, 77763, 77776, 77777	\$317.87	\$296.90	-6.6%
313 Brachytherapy	77781, 77782, 77783, 77784, 77779	\$790.75	\$763.48	-3.4%
651 Complex Interstitial Radiation Source Application	77778	\$1,248.93	\$720.71	-42.3%

Historically, CMS has used only "correctly coded" claims to determine brachytherapy payment rates and we recommend that they do so for 2006. According to data analysis, 86% of the 11,963 claims contained procedure code 77778 and at least one unit of a brachytherapy source device "C" code. However, the 2006 proposed payment rate for APC 651 is based on 342 claims or approximately 2.8% of the total outpatient claims from 2004. The extremely low volume of claims used for rate-setting is troubling. Based upon the data, we are disappointed that CMS did not rely on the use of "correctly coded" claims to set the 2006 proposed rates for APC 651, which includes CPT 77778.

AAPM recommends that CMS use only "correctly coded" claims for brachytherapy APCs 312, 313, and 651 to determine the final 2006 HOPPS payment rates. "Correctly coded" claims are defined as an outpatient claim that contains a brachytherapy procedure code and at least one brachytherapy source device "C" code (see Table 2).

**Table 2 "Correctly Coded" Brachytherapy Claims (Based on 2004 Outpatient Claims Data)**

APC	CPT Codes	Brachytherapy Device "C" Codes	2006 Proposed Median Cost	2006 Estimated Median Cost based on "Correctly Coded" Claims
312 Radioelement Applications	77761, 77762, 77763, 77776, or 77777	C1716, C1718, C1719, C1720, C2616, C2632, or C 2633	\$301.91	\$403
313 Brachytherapy	77781, 77782, 77783, 77784, or 77779	C1717 only	\$776.35	\$849.39
651 Complex Interstitial Radiation Source Application	77778	C1716, C1718, C1719, C1720, C2616, C2632, or C 2633	\$732.86	\$864.54

Claims that had both the brachytherapy procedure and a brachytherapy source "C" code had median costs that were approximately 9 percent to 34 percent higher than the average all single-procedure claims for the APC. This suggests that a correct coding screen, similar in concept to the screens CMS applied in the past to "device-dependent" APCs, may result in more appropriate and accurate payment rates for brachytherapy APCs.

The proposed fluctuation in payment for APC 651 is significant, and this contributes to an ongoing concern that significant problems exist with the accuracy and/or interpretation of CMS's data for brachytherapy procedures. These issues could result in part from the challenges faced by hospitals in learning new codes and policies, given that significant changes have occurred on nearly an annual basis since 2000 in the coding of prostate brachytherapy services and related medical devices. Further, we believe that the problem is compounded by Medicare's single claims methodology (see discussion on APC Relative Weights below).

In the 2006 proposed rule, CMS acknowledges that a payment reduction of more than 15% from the 2005 HOPPS payment rate might be problematic for hospitals that provide these services. Brachytherapy APC 651 has a proposed reduction of 42.3% and we are concerned that this may effect access to this minimally invasive cancer therapy, which has a lower incidence of serious complications, such as impotence and urinary incontinence. In addition, AAPM is concerned about the accuracy of CMS's brachytherapy related hospital claims data and are troubled by the small number of claims used to determine payment for brachytherapy APCs.

**AAPM recommends that CMS use only "correctly coded" claims for brachytherapy APCs 312, 313, and 651 to determine the final 2006 HOPPS payment rates where each brachytherapy procedure claim must contain an appropriate brachytherapy source device "C" code(s). Further, CMS should provide more education to hospitals regarding the importance of accurate coding, including brachytherapy sources and related devices.**

### **APC Relative Weights**

AAPM appreciates the agency's efforts to include multiple procedure claims data to calculate relative payment weights by using the "same date of service" and an expanded list of "bypass" codes in order to provide more single and "pseudo" single claims, however, additional revisions to the current methodology must be explored in order to ensure that CMS is basing payment on a substantial number of accurate hospital claims.

Significant reductions in proposed 2006 payment rates for a number of device-related APCs, including APC 651, are a direct result of the inaccurate capture of costs estimated from CMS's single and "pseudo" single procedure claim rate-setting methodology. This is particularly problematic for procedures routinely performed in conjunction with other procedures (e.g., radiation oncology) whose costs, by definition, would always be reported on multiple procedure claims, but under single claims methodology are not being captured. APC 651 *Complex interstitial radiation source application* contains one procedure code CPT 77778, which had a total of 11,963 claims, however, CMS utilized less than 3% for rate-setting purposes.

**AAPM recommends that CMS develop alternative methodologies to capture both single and multiple procedure claims. Additional data will increase the likelihood of stable APC payments in the future.**

### **Proton Beam Therapy**

**AAPM supports the CMS proposal to move Proton Beam Codes 77523 and 77525 from New Technology APC 1510 to clinical APC 667 Level II Proton Beam Radiation Therapy.**

We commend the agency for recognizing the distinction between simple and intermediate/complex proton beam therapy.

### **Stereotactic Radiosurgery**

For 2006, CMS is not proposing any changes to the APC assignment for stereotactic radiosurgery treatment delivery codes G0173, G0243, G0251, G0039 and G0340. Further, CMS proposes to discontinue HCPCS code G0242 and G0338 for reporting the charges for stereotactic radiosurgery planning under HOPPS, and to instruct hospitals to bill charges for stereotactic radiosurgery planning using all of the available CPT codes that most accurately reflect the services provided.

**AAPM believes that stereotactic radiosurgery treatment planning is already well described by CPT codes 77295 3D simulation and 77301 IMRT planning. AAPM supports the elimination of the "G" codes for stereotactic radiosurgery treatment planning.**

### **Multiple Diagnostic Imaging Procedures**

Currently under HOPPS, hospitals receive the full APC payment for each diagnostic imaging procedure for each service on a claim, regardless of how many procedures are performed using a single modality and whether or not contiguous areas of the body are reviewed. CMS proposes that whenever two or more procedures in the same family are performed in the same session, the first procedure will be paid at the full reimbursement level and the second at a discount of 50%.

AAPM agrees with the CMS position that, when some of the procedures identified by CMS are performed in the same session, some of the resource costs are not incurred twice. However, we have concerns that CMS has used external rather than internal data and methodology to analyze this position. CMS utilized the Medicare Physician Fee Schedule methodology and data, rather than that of the HOPPS process in developing this policy. Further, we believe that the hospital's cost-to-charge ratios and related cost reporting methodology already takes into account reductions for multiple imaging procedures. Since the HOPPS methodology already accounts for the cost efficiencies of multiple procedures in the same session, an additional 50% reduction, as described in the proposed rule, would contradict this methodology and systematically disadvantage hospitals relative to other imaging facilities.

**AAPM supports the American College of Radiology's comments and the APC Advisory Panel's recommendation that CMS delay implementation of the multiple diagnostic imaging procedure reduction for one year to allow additional time to study this proposal.**

### **New Technology APCs**

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review.

AAPM supports the proposal but recognizes that this added requirement may delay access to new technologies for Medicare beneficiaries. We request that CMS recognize the potential for delay by this additional step and expedite the CMS review of New Technology APC applications to compensate.

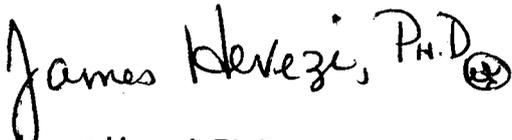
**AAPM supports the CMS proposal to require the submission of CPT application to the AMA CPT Editorial Panel prior to submitting a New Technology APC application.**

### **Conclusion**

Appropriate payment for radiation oncology procedures and medical physics services is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in the hospital outpatient setting.

We hope that CMS will take these issues under consideration during the development of the 2006 Hospital Outpatient Final Rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (703) 534-7979.

Sincerely,

Handwritten signature of James Hevezi, Ph.D. in cursive script, including a small circular emblem at the end.

James Hevezi, Ph.D.  
Chair, AAPM Professional Economics Committee

September 14, 2005

B-Therapy

Levi  
Kane  
Snow  
Hart  
Bazell

The Honorable Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Room 443-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

**Re: (CMS-1501-P) Medicare Program; Proposed Changes to the Hospital  
Outpatient Prospective Payment System and Calendar Year 2006 Payment  
Rates; Proposed Rule**

Dear Dr. McClellan:

On behalf of Theragenics Corporation<sup>®</sup>, I submit these comments regarding Medicare's policies for prostate brachytherapy under the hospital outpatient prospective payment system (HOPPS). These comments respond to the recent proposed rule published by the Centers for Medicare and Medicaid Services (CMS) at 70 *Federal Register* 42674 on July 25, 2005.<sup>1</sup>

Theragenics Corporation<sup>®</sup>, located in Buford, Georgia, received FDA approval in 1986 for TheraSeed<sup>®</sup>, a radioactive medical device made with Palladium-103 and used to treat solid, localized cancerous tumors. TheraSeed<sup>®</sup> is the only Palladium-103 brachytherapy source that is 100% made in the U.S.A.

Brachytherapy is an important treatment for patients with localized prostate cancer that provides outstanding clinical outcomes, low complication rates and overall cost-effectiveness. However, since the HOPPS began in 2000, access to prostate brachytherapy has been threatened by a series of challenges and problems arising from Medicare's claims data for prostate brachytherapy and CMS' interpretation of this data. In 2003, Congress enacted a provision on brachytherapy under the Medicare Modernization Act to safeguard beneficiary access to brachytherapy in response to such concerns.

The issues highlighted in this letter reflect the fact that these challenges and problems remain. In the proposed rule for 2006, CMS used less than 3 percent of the HOPPS claims for prostate brachytherapy as the basis for proposing a reduction of 42 percent for one of the core procedures required for prostate brachytherapy (APC 651). The small sample of claims used by CMS includes a significant portion that are either erroneous or non-representative. Certainly, such

<sup>1</sup> Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule, 70 Fed. Reg. 42674 (Jul. 25, 2005) (to be codified at 42 C.F.R. pts 419, 485).



**Corporate Offices**

5 2 0 3 B R I S T O L I N D U S T R I A L W A Y , B U F O R D , G A 3 0 5 1 8  
p h o n e 7 7 0 . 2 7 1 . 0 2 3 3 f a x 6 7 8 . 4 8 2 . 4 9 0 9

claims should not provide sufficient rationale for such a significant reduction in reimbursement from one year to another.

To ensure against problems with patient access or other undesirable outcomes under Medicare, we urge CMS to consider the following points when finalizing the HOPPS rule for 2006.

- Maintaining meaningful access to prostate brachytherapy is important to both Medicare beneficiaries and the Medicare program.
- As the APC Advisory Panel recommended recently, CMS should only use “correctly coded” claims in establishing reimbursement for APC 651 in 2006.
- Especially given the longstanding concerns regarding CMS’ data for prostate brachytherapy, CMS should limit the percentage decrease for APC 651 to avoid potential adverse impacts on beneficiary access.
- For the future, CMS should develop better data and methodologies for establishing reimbursement rates for prostate brachytherapy procedures and sources.

These points are discussed in detail below.

\* \* \* \*

**I. Maintaining Meaningful Access to Prostate Brachytherapy is Important to Both Medicare Beneficiaries and the Medicare Program.**

Prostate cancer strikes approximately 200,000 men each year in the United States. This includes many elderly men who rely on Medicare for their health care coverage. As a result, it is critical that Medicare provide ongoing and meaningful access to brachytherapy to treat prostate cancer.

The procedure typically takes only about forty-five minutes in the hospital outpatient setting. Prostate brachytherapy consists of the implantation of radioactive sources or “seeds” in and around the cancerous prostate. Men are usually able to return to their normal activities within two to three days after the procedure.

There are a number of reasons why maintaining access to prostate brachytherapy is especially important:

- **Outstanding Clinical Results.** Brachytherapy treats early-stage prostate cancer as well as or better than the most common clinical alternative of radical prostatectomy (surgical excision of the prostate), a more invasive in-patient procedure. Brachytherapy for prostate cancer is supported by over 17 years of data, and the TheraSeed® device alone has been used to treat over 100,000 men.



- **Lower Complication Rates.** Prostate brachytherapy results in significantly lower rates of complications in treating prostate cancer than radical prostatectomy, including: lower risks of erectile dysfunction (also known as impotence); lower risks of urinary incontinence; and lower risks of other significant complications such as surgical mortality.
- **Cost-Effectiveness.** Prostate brachytherapy offers not only a *clinically effective* treatment, but also a *cost-effective* treatment. Studies involving Medicare data show that brachytherapy offers a lower direct treatment cost than radical prostatectomy, as well as lower indirect costs for the treatment and mitigation of serious complications.

As a result, we urge CMS to ensure that Medicare beneficiaries are protected from changes in policy that could threaten access to prostate brachytherapy.

## II. As the APC Advisory Panel Recommended Recently, CMS Should Only Use “Correctly Coded” Claims in Establishing Reimbursement for APC 651 for 2006.

APC 651 is used to code for prostate brachytherapy, a high volume cancer therapy, as well as other complex interstitial brachytherapy procedures using more than 10 brachytherapy sources per procedure. For 2006, CMS proposed a payment level for APC 651 of \$720.71. This is a 42.3 percent reduction from the current (2005) payment of \$1,248.93.

The longstanding problems with CMS’ brachytherapy data are compounded by Medicare’s single claim methodology, which resulted in the use of only a small fraction of the nearly 12,000 claims for CPT 77778. In the 2004 database used by CMS to establish reimbursement levels for calendar year 2006, there were 11,963 claims containing CPT code 77778. However, CMS opted to base the 2006 proposed reimbursement level for APC 651 on just 342 claims. This is only 2.8 percent of the total number of claims for this procedure, and use of the small fraction of claims is problematic.

In August 2005, the APC Advisory Panel recommended that CMS recalculate the 2006 payment rate for APC 651 using only “correctly coded” claims. Specifically, the Panel endorsed the following written recommendation:

For APC 651, *The Panel recommends* that CMS evaluate the analysis proposed by the Coalition for the Advancement of Brachytherapy, using only the subset of claims that include brachytherapy source C codes to calculate median costs, in advance of finalizing the proposed rule.<sup>2</sup>

---

<sup>2</sup> APC Panel Biannual Meeting – August 2005, Panel Recommendations. <http://www.cms.hhs.gov/faca/apc/panel-recommendations.pdf>



In this context, the term “correctly coded” refers to outpatient claims containing a brachytherapy procedure code and at least one brachytherapy source device “C” code

CMS’s coding screen for “device-dependent” APCs provides a model for examining these brachytherapy claims. CMS found that claims submitted without reporting the device tended to underreport charges and costs when compared to claims with the device reported. CMS removed these unrepresentative claims for “device-dependent” APCs prior to calculating the rates. Similar screening is necessary to ensure more appropriate and accurate payment rates for brachytherapy APCs.

Because the typical radiation oncology encounter involves multiple services, CMS’ use of single claims means that CMS based its proposed payment rate for APC 651 on atypical encounters. The data from single encounter claims is so low that it must represent services performed in small, relatively non-busy centers with low technological complexity and similarly inappropriately low costs and charges. The overwhelming majority of brachytherapy procedures are done with other procedures, as evidenced by the small number of single claims captured in CMS’s updated data.

If CMS had used claims that contained CPT 77778 and at least one brachytherapy device “C” code, the median cost would be approximately 18 percent higher — totaling \$864.54.

Given these ongoing concerns and the significant change in payment that is proposed for APC 651, Theragenics recommends that CMS review the 2004 claims data for APC 651 *Complex Interstitial Radiation Source Application* to ensure that the brachytherapy sources are included on each hospital claim that contains CPT procedure code 77778. This will ensure the use of the more accurate claims data. We urge CMS to revise the final payment rate for 2006 to reflect more accurately the cost of complex interstitial brachytherapy procedures.

**III. Especially Given the Longstanding Concerns regarding CMS’ Data for Prostate Brachytherapy, CMS Should Limit the Percentage Decrease for APC 651 to Avoid Potential Adverse Impacts on Beneficiary Access.**

If using only “correctly coded” claims to determine the 2006 median for APC 651 results in a 15 percent or greater reduction than the current 2005 payment, Theragenics requests that CMS apply the “device-dependent” or a similar adjustment factor to APC 651 to adjust the reimbursement rate to no less than 85 percent of the payment rate in 2005. Complex interstitial brachytherapy always requires the use of 10 or more brachytherapy sources, which are defined as medical devices.

The 42.3 percent payment reduction proposed for APC 651 is very significant. As CMS notes in the proposed rule, reductions in excess of 15 percent “may be problematic for hospitals that



provide the services contained in this APC,” and may affect beneficiary access to this important treatment for prostate cancer. A recent market analysis conducted for Theragenics concluded that the continual whipsawing of reimbursement levels and coding has left prostate brachytherapy providers confused. There is a lag time of up to several years for physicians and purchasing agents to modify internal processes and coding, and the prior CMS changes to reimbursement are just now being fully implemented. Another dramatic shift in the form of a 42% reduction will result in even more provider confusion and have a negative effect on beneficiary access.

Theragenics recommends that CMS apply a “dampening” adjustment to all device-related APCs, including APC 651, and limit the reduction in payment from 2005 to 2006 rates.

If inadequate reimbursement prevents hospital outpatient departments from providing brachytherapy as a treatment option for prostate cancer, Medicare beneficiaries may be forced to choose more costly and invasive alternative treatment options. Using only “correctly coded” claims and applying an adjustment factor to APC 651 will help address potential barriers in the short-term.

**IV. For the Future, CMS Should Develop Better Data and Methodologies for Establishing Reimbursement Rates for APC 651 and Other Prostate Brachytherapy Procedures and Sources.**

We urge CMS to create new APC payment rates using both single and multiple procedure claims. The use of additional data should increase the likelihood of accurate APC payments in the future.

Theragenics also recommends that CMS consider the best external data available in constructing APC rates, including proprietary or confidential data, to determine median cost calculations whenever the single claims methodology yields an insignificant number of claims. This will help set payment rates and avoid over-reliance on skewed data. CMS should re-consider its stringent criteria and parameters for submitting external data, considering all external data based on its merits, including confidential proprietary data. CMS should expand the use of confidential, proprietary external data to calculate future payment rates whenever such data is needed and proven reliable.

\* \* \* \* \*

We urge CMS to implement these straightforward solutions to ensure ongoing access for prostate brachytherapy. Please do not hesitate to contact us if we may provide any further information. You may contact Janet Zeman or me at (770) 271-0233.



The Honorable Mark B. McClellan  
September 16, 2005  
Page 6

Respectfully submitted,



M. Christine Jacobs  
President & CEO  
Theragenics Corporation®

cc: Janet Zeman, Theragenics

::ODMA\PCDOCS\WSH\364242\1



P41P

Asplen  
KANE  
SANDW

119



Hart  
Bazell  
www.southbaymentalhealth.com  
50 Aldrin Road • Plymouth, MA 02360  
508-830-0004 • Fax 508-830-0295

**Administration**  
Brockton

**Mental Health and  
Substance Abuse  
Treatment**  
Attleboro  
Brockton  
Fall River  
Lawrence  
Lowell  
Plymouth  
S. Yarmouth  
Weymouth  
Worcester

**Mental Health  
Outreach**  
New Bedford

**Adult Day Services**  
Fall River  
Holbrook  
Plymouth  
S. Yarmouth  
Worcester

**Children's and  
Adolescent Day  
Services**  
Fall River  
Lowell

**Early Intervention**  
Brockton  
Fall River  
Lowell

September 15, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
Mail Stop C4-26-05  
7500 Security Blvd.  
Baltimore, Md. 21244-1850

**Re: Partial Hospitalization Service Proposed Changes to the Hospital  
Outpatient PPS-CMS-1501-P**

South Bay Mental Health, Inc. is a freestanding Community Mental Health Center in Massachusetts. We have been providing Partial Hospitalization services since 1995. Our initial response regarding CMS-1501-P and a 15% rate reduction for CY2006 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction.

It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A \$40/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of \$289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, transportation, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas. A daily per diem of \$241.57 cannot be justified with these expenses.
2. CMS identified the Median cost of group therapy at \$82.31. Our program offers 5 services per day at a minimum. This summarizes to a median cost of \$329.24. A per diem of \$241.57 cannot be justified with these expenses.



www.southbaymentalhealth.com  
50 Aldrin Road • Plymouth, MA 02360  
508-830-0004 • Fax 508-830-0295

**Administration**  
Brockton

**Mental Health and  
Substance Abuse  
Treatment**

Attleboro  
Brockton  
Fall River  
Lawrence  
Lowell  
Plymouth  
S. Yarmouth  
Weymouth  
Worcester

**Mental Health  
Outreach**  
New Bedford

**Adult Day Services**  
Fall River  
Holbrook  
Plymouth  
S. Yarmouth  
Worcester

**Children's and  
Adolescent Day  
Services**  
Fall River  
Lowell

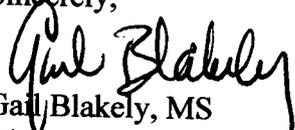
**Early Intervention**  
Brockton  
Fall River  
Lowell

3. Many of our patients have both Medicaid and Medicare. Medicaid cuts are strongly threatened here in Massachusetts. If the 20% co-pay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to \$193.26 ( $\$241.57 \times .80$ ). A daily per diem of \$241.57 cannot be justified with this situation.
4. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.
5. Based on the above issues, South Bay Mental Health, Inc. asks that CMS leave the per diem unchanged from the CY 2005 rate of \$281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had over one hundred admissions so far in CY 2005, and every one would be a high risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

  
Gail Blakely, MS  
Director of Day Services

Cc: Peter Scanlon, CEO

120



RIVERVEST

7733 Forsyth Boulevard, Suite 1650  
St. Louis, MO 63105

Phone: 314.726.6700  
Fax: 314.726.6715

NT/APC

Hunter  
Spolter  
Hostetler  
Kane  
Sarnow  
Hart  
P

September 15, 2005

The Honorable Mark McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Re: Proposed Changes to the OPSS Payment System and 2006 Payment Rates

Issue: New Technology APC

Dear Dr. McClellan:

RiverVest Venture Partners is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

We would like to thank CMS for the opportunity to make recommendations regarding the proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

**New Technology APCs**

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

RiverVest Venture Partners is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization, utilizing closed processes, that are not subject to procedural protections typically required for public policy. AMA meetings are closed to the public and the bases for decisions are not available to the public, including hospitals and

physicians. The AMA CPT Editorial Panel allows no participation or representation from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

Clearly, the requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions.

The requirement to submit New Technology APC applications together with CPT code applications presents an inherent conflict of purpose. By definition, category I CPT codes are assigned to procedures that have become an accepted standard of care and are in widespread use. This conflicts with and, in fact, defeats the purpose of creating a special coding vehicle (new technology APCs) to facilitate adoption and dissemination of new technology and the collection of clinical data. If manufacturers are forced to apply for a CPT code before widespread use or extensive information about the technology is available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code. This often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries and many commercial payers thus denying Medicare patients access to technology. The end result of the proposed rule would be a disincentive for manufacturers, particularly smaller ones, to innovate and market novel and beneficial medical technologies.

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives from manufacturers on the decision making panel and offer additional concerned parties the opportunity to participate, comment, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiaries full access to the same high quality care in the hospital outpatient setting realized by patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me.

Sincerely,



Jay W. Schmelter  
Managing Director  
314-726-6700  
7733 Forysth Blvd., Suite 1650  
Clayton, MO 63105  
jschmelter@rivervest.com

16. Continued from previous page.

Job classification	Hour worked annually	Hours related to inventory management	Annual cost/hour or salary	% Benefits

17. For the last fiscal year provide your labor costs associated with communication with insurance providers to obtain prior authorization or reimbursement information for chemotherapy or supportive agents?

*Follow example below and enter in table.*

Hours worked annually      Hours related to insurance  
communications

Patient account rep	2064	800
Business office personnel	2088	400
Supervisor	2080	200
Coding specialist	2080	2000

Job classification	Hour worked annually	Hours related to inventory management	Annual cost/hour or salary	% Benefits