

DEPARTMENT OF DEFENSE**Office of the Secretary**

[DOD-2007-HA-0048; RIN 0720-AB19]

32 CFR Part 199**TRICARE; Outpatient Hospital Prospective Payment System (OPPS)****AGENCY:** Office of the Secretary, DoD.**ACTION:** Proposed rule.

SUMMARY: This proposed rule implements a prospective payment system for hospital outpatient services similar to that furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Social Security Act. The rule also recognizes applicable statutory requirements and changes arising from Medicare's continuing experience with this system including certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Department is publishing this rule to implement an existing statutory requirement for adoption of Medicare payment methods for institutional care which will ultimately provide incentives for hospitals to furnish outpatient services in an efficient and effective manner.

DATES: Written comments received at the address indicated below by June 2, 2008 will be accepted.

ADDRESSES: You may submit comments, identified by docket number and or Regulatory Information Number (RIN) number and title, by either of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301-1160.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Introduction and Background**

The OPPS evolved out of Congressional mandates for replacement

of Medicare's cost-based payment methodology with a prospective payment system (PPS). Medicare implemented OPPS for services furnished on or after August 1, 2000, with temporary transitional provisions to buffer the financial impact of the new prospective payment system (e.g., incorporating transitional pass-through adjustments and proportional reductions in beneficiary cost-sharing to lessen potential payment reductions experienced under the new OPPS).

Congress likewise established enabling legislation under section 707 of the National Defense Authorization Act of Fiscal Year 2002 (NDAA-02), Public Law 107-107 (December 28, 2001) changing the statutory authorization [in 10 U.S.C. 1079(j)(2)] that TRICARE payment methods for institutional care shall be determined, to the extent practicable, in accordance with the same reimbursement rules used by Medicare. Similarly, under 10 U.S.C. 1079(h), the amount to be paid to health care professional and other non-institutional health care providers "shall be equal to an amount determined to be appropriate, to the extent practicable, in accordance with the same reimbursement rules used by Medicare". Based on these statutory mandates, TRICARE is adopting Medicare's prospective payment system for reimbursement of hospital outpatient services currently in effect for the Medicare program as required under the Balanced Budget Act of 1997 (BBA 1997), (Pub. L. 105-33) which added section 1833(t) of the Social Security Act providing comprehensive provisions for establishment of a Medicare hospital OPPS. The Act required development of a classification system for covered outpatient services that consisted of groups arranged so that the services within each group were comparable clinically and with respect to the use of resources. The Act also described the method for determining the Medicare payment amount and beneficiary coinsurance amount for services covered under the outpatient PPS. This included the formula for calculating the conversion factor and data requirements for establishing relative payment weights.

Centers for Medicare & Medicaid Services (CMS) published a proposed rule in the **Federal Register** on September 8, 1998 (63 FR 47552) setting forth the proposed PPS for hospital outpatient services. On June 30, 1999, a correction notice was published (64 FR 35258) to correct a number of technical and typographical errors contained in the September 8, 1998 proposed rule.

Subsequent to publication of the proposed rule, the Medicare, Medicaid, and State Child Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (BBRA 1999) (Pub. L. 106-133) enacted on November 29, 1999, made major changes that affected the proposed Medicare OPPS. The following BBRA 1999 provisions were implemented in a final rule (65 FR 18434) published on April 7, 2000.

- Made adjustments for covered services whose costs exceed a given threshold (*i.e.*, an outlier payment).
- Established transitional pass-through payments for certain medical devices, drugs, and biologicals.
- Placed limitations on judicial review for determining outlier payments and the determination of additional payments for certain medical devices, drugs, and biologicals.
- Included as covered outpatient services implantable prosthetics and durable medical equipment and diagnostic x-ray, laboratory, and other tests associated with those implantable items.
- Limited the variation of costs of services within each payment classification group.
- Required at least annual review of the groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, the addition of new services, new cost data, and other relevant information or factors.
- Established transitional corridors that would limit payment reductions under the hospital outpatient PPS.
- Established hold harmless provisions for rural and cancer hospitals.
- Provided that the coinsurance amount for a procedure performed in a year could not exceed the hospital inpatient deductible for the year.

Section 1833(t) of the Social Security Act was subsequently amended by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106-554) and the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108-173) making additional changes in the OPPS.

As a prelude to implementation of the OPPS, Congress enacted the Omnibus Budget Reconciliation Act of 1986 (OBRA) (Pub. L. 99-509) which paved the way for development of a PPS for hospital outpatient services by prohibiting payment for non-physician services furnished to hospital patients (inpatients and outpatients), unless the services were furnished either directly or under arrangement with the hospital, except for services of physician

assistants, nurse practitioners and clinical nurse specialists. Exceptions were also made for clinical diagnostic procedures, the payment of which may only be made to the person or entity that performed, or supervised the performance of, the test; and for exceptionally intensive hospital outpatient services provided to Skilled Nursing Facility (SNF) residents that lie well beyond the scope of the care that SNFs would ordinarily furnish, and thus beyond the ordinary scope of the SNF care plan. Consolidated billing facilitated the payment of services included within the scope of each ambulatory payment classification (APC). The OBRA also mandated hospitals to report claims for services under the Healthcare Common Procedure Coding System (HCPCS) which enabled the identification of specific procedures and services used in the development of outpatient PPS rates.

Ongoing changes and refinement to the OPSS have been accomplished through annual proposed and final rulemaking, along with interim transmittals and program memoranda taking into consideration changes in medical practice, addition of new services, new cost data, and other relevant information and factors. TRICARE will recognize to the extent practicable all applicable statutory requirements and changes arising from Medicare's continuing experience with this prospective payment system, including changes to the amounts and factors used to determine the payment rates for hospital outpatient services paid under the prospective payment system [e.g., annual recalibration (updating) of group weights and conversion factors and adjustments for area wage differences (wage index updates)]. The agency will adopt all of Medicare's CY 2008 OPSS changes published in the **Federal Register** on November 27, 2007, (72 FR 66580); e.g., extending the current packaging to include guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, contrast agents, and observation services; and reduction of payments in cases where a hospital receives a substantial partial credit from the manufacturer toward the cost of a replacement device implanted in a procedure.

While TRICARE intends to remain as true as possible to Medicare's basic OPSS methodology (i.e., adoption and updating of the Medicare data elements used to calculate the prospective payment amounts), there will be some

deviations required to accommodate the uniqueness of the TRICARE program. These deviations have been designed to accommodate existing TRICARE benefit structure and claims processing procedures/systems implemented under the TRICARE Next Generation Contracts (T-NEX), while at the same time eliminating any undue financial burden to TRICARE Prime, Extra, and Standard beneficiary populations. Following is a brief discussion of each of these deviations:

- *Outpatient Code Editor (OCE)*—The Medicare Outpatient Code Editor with APC program edits data to help identify possible errors in coding and assigns Ambulatory Payment Classification numbers based on HCPCS codes for payment under the OPSS. The OPSS APC is an outpatient equivalent of the inpatient Diagnosis Related Group (DRG)-based PPS. Like the inpatient system based on DRGs, each APC has a pre-established prospective payment amount associated with it. However, unlike the inpatient system that assigns a patient to a single DRG, multiple APCs can be assigned to one outpatient claim. If a patient has multiple outpatient services during a single visit, the total payment for the visit is computed as the sum of the individual payments for each service. Medicare provides updated versions of the OCE, along with installation and user manuals, to its fiscal intermediaries on a quarterly basis. The updated OCE reflects all new coding and editing changes during that quarter.

It was found upon initial testing of the OCE that it could not be used in its present form given the fact that the extensive editing embedded in its software program was specific to Medicare's benefit structure and internal claims processing requirements. As a result, the Agency has developed a TRICARE-specific OCE which will better accommodate the benefit structure and claims processing systems currently in place under the T-NEX contracts. This modified software package will edit claims data for errors and indicate actions to be taken and reasons why the actions are necessary. This expanded functionality will facilitate the linkage between the action being taken, the reasons for the action, and the information on the claim that caused the action. The edits will be specific for TRICARE, ensuring compliance with current claims processing criteria. The OCE will also assign an APC number for each service covered under the OPSS and return information to be used as input to the TRICARE PRICER program.

Like Medicare's OCE, the TRICARE-specific OCE will be updated on a quarterly basis incorporating, to the extent practicable, all Medicare changes/updates (i.e., those changes initiated through rulemaking and transmittals/program memoranda). Periodic updating of the TRICARE-specific OCE will ensure consistency and accuracy of claims processing and payment under the OPSS.

- *Deductible and Cost-Sharing*—Medicare's OPSS coinsurance was initially frozen at 20 percent of the national median charge for the services within each APC (wage adjusted for the provider's geographic area) or 20 percent of the APC payment rate, whichever was greater (i.e., the coinsurance for an APC could not fall below 20 percent of the APC payment rate). This was designed so that, as the total payment to the provider increased each year based on market basket updates, the present or frozen coinsurance amount would become a smaller portion of the total payment until the coinsurance represented 20 percent of the total. Once the coinsurance became 20 percent of the payment amount, annual updates would be applied to the coinsurance so that it would continue to account for 20 percent of the total charge. Wage adjusted coinsurance amounts were further limited by the Medicare inpatient deductible. Subsequent legislation has accelerated the reduction of beneficiary copayment amounts by imposing prescribed percentage limitations off of the APC payment rate. For example, for all services paid under the OPSS in CY 2005, the national unadjusted copayment amount cannot exceed 45 percent of the APC rate. Accelerated reductions were imposed specifically for those APC groups for which coinsurance represented a relatively high proportion of the total payment.

A program payment percentage is calculated for each APC by subtracting the unadjusted national coinsurance amount for the APC from the unadjusted payment rate and dividing the result by the unadjusted payment rate. The payment rate for each APC group is the basis for determining the total payment (subject to wage-index adjustment) that a hospital will receive from the beneficiary and the Medicare program.

Since imposition of Medicare's unadjusted national coinsurance amounts would have an adverse financial impact on TRICARE beneficiaries (i.e., imposition of significantly higher cost-sharing for Prime beneficiaries), the Agency has opted to use the following hospital

outpatient deductible and cost-sharing/ copayments currently being applied in Tables 1 and 2 below for Prime, Extra, and Standard TRICARE programs for hospital outpatient services:

TABLE 1.—HOSPITAL OUTPATIENT DEDUCTIBLES

TRICARE programs	Active duty family members		Retirees, their family members & survivors
	E1–E4	E5 & above	
Prime	None	None	None.
Extra	\$50 per Individual	\$150 per Individual	\$150 per Individual.
	\$100 Maximum per family	\$300 Maximum per family	\$300 Maximum per family.
Standard	\$50 per Individual	\$150 per Individual	\$150 per Individual.
	\$100 Maximum per family	\$300 Maximum per family	\$300 Maximum per family.

TABLE 2.—HOSPITAL OUTPATIENT COPAYMENTS/COST-SHARING

Type of service	TRICARE prime program			TRICARE extra program	TRICARE standard program
	Active duty family member		Retirees, their family members & survivors		
	E1–E4	E5 & above			
Hospital Outpatient Departments: Clinic visits; therapy visits; treatment rooms, etc.	\$0 copayment per visit.	\$0 copayment per visit.	\$12 copayment per visit.	Active Duty Family Members: Cost-share—15% of fee negotiated by contractor	Active Duty Family Members: Cost-share—20% of the allowable charge.
Emergency Services: Emergency and urgently needed care obtained in hospital emergency room	\$0 copayment per visit.	\$0 copayment per visit.	\$30 copayment per emergency room visit.	Retirees, Their Family Members & Survivors: Cost-share—20% of the fee negotiated by the contractor	Retirees, Their Family Members & Survivors: Cost-share—25% of the allowable charge.
Ambulatory Surgery (same day): Hospital-based ambulatory surgical center.	\$0 copayment per visit.	\$0 copayment per visit.	\$25 copayment No separate copayment/cost-share for separately billed professional charges.	ADFM's: Cost-share—\$25 Retirees, Their Family Members & Survivors: Cost-share—20% of the institutional fee negotiated by the contractor.	ADFM's: Cost-share—\$25. Retirees, Their Family Members & Survivors: Lesser of 25% of group rate or 25% of billed charge.
Birthing Centers Prenatal care, outpatient delivery, and postnatal care provided in hospital-based birthing center	\$0 copayment per visit.	\$0 copayment per visit.	\$25 copayment		
Partial Hospitalization Programs (PHPs): Mental health services provided in authorized hospital-based PHP.	\$0 copayment per visit.	\$0 copayment per visit.	40 per diem charge No separate copayment/cost-share for separately billed professional charges	ADFM's: \$20 per diem charge Retirees, Their Family Members & Survivors: Cost-share—20% of the TRICARE allowed amount	ADFM's: \$20 per diem charge. Retirees, Their Family Members & Survivors: Cost-share—25% of the TRICARE allowed amount.

○ *Hold-Harmless Protection*—Since the inception of the Medicare OPPS, providers have been eligible to receive additional transitional outpatient payments (TOPs) if the payments they received under the OPPS were less than the payments they could have received for the same services under the payment system in effect before the OPPS. Prior to January 1, 2004, most hospitals that realized lower payments under OPPS received transitional corridor payments based on a percent of the decreased payments, with the exception of cancer

hospitals, children's hospitals and rural hospitals having 100 or fewer beds which were held harmless under this provision and paid the full amount of the decrease in payment under the OPPS. Since transitional corridor payments were intended to be temporary payments to ease the provider's transition from a prior cost-based payment system to a prospective payments system, they were terminated as of January 1, 2004, with the exception of cancer and children's hospitals which were held harmless permanently under

transitional corridor provisions of the statute (section 1833(t)(7) of the Social Security Act). The authority for making transitional corridor payments under section 1833(t)(7)(D)(i) of the Act, as amended by section 411 Public Law 108–173, expired for rural hospitals having 100 or fewer beds, and sole community hospitals (SCHs) located in rural areas as of December 31, 2005. However, subsequent legislation (Section 5105 of Pub. L. 109–171) reinstated the hold-harmless transitional outpatient payments (TOPs)

for covered OPD services furnished on or after January 1, 2006, and before January 1, 2009, for rural hospitals having 100 or fewer beds that are not SCHs. This provision provided an increased payment for such hospitals for outpatient services if the OPSS payment they received was less than the pre-BBA payment amount (i.e., the amount that was received prior to implementation of OPSS) that they would have received for the same covered service. When the OPSS payment is less than the payment the provider would have received prior to OPSS implementation, the amount of payment is increased by 90 percent of the amount of that difference for CY 2007, and by 85 percent of the amount of the difference for CY 2008. The amount of payment under section 1833(t)(13)(B) of the Act, as amended by section 411 of Public Law 108–73, also provided a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPSS, excluding drugs, biologicals, brachytherapy seeds and services paid under pass-through payments effective January 1, 2006, if justified by a study of the difference in costs for rural SCHs, which include Medicare essential access community hospitals or EACHs.

While the Agency adopted the hold-harmless TOPs for rural hospitals having 100 or fewer beds and SCHs, it opted to totally exempt cancer and children's hospitals from the OPSS in lieu of imposing the hold-harmless provision, given the administrative complexity of capturing the data required for payment of monthly interim TOP amounts. TOPs would require a comparison of what would have been paid [i.e., billed charges and CHAMPUS Maximum Allowable Charge (CMAC) amounts] prior to implementation of the OPSS for hospital outpatient services to those amounts actually paid under the OPSS for the same services. A TOP would be allowed in addition to the OPSS amount if payment to a cancer or children's hospital was lower than the amount that would have been paid prior to implementation of the OPSS. Since transitional corridor payments were specifically designed to supplement the losses experienced under the OPSS (i.e., to pay for services at the full amount that would have been allowed prior to implementation of the OPSS), and most, if not all, outpatient services paid at a billed or CMAC would exceed the OPSS amount, the program cannot justify the administrative burden/expense of maintaining the hold-harmless provisions for cancer and children's hospitals. As a result, TRICARE will

continue to reimburse cancer and children's hospitals on a fee-for-services basis using billed charges and CMAC rates; i.e., they will be excluded altogether from the OPSS.

Adoption of the Medicare OPSS has also highlighted other policy considerations which must be addressed in order to accommodate preexisting authorization criteria and reimbursement systems. Following are these identified policy considerations and prescribed resolutions:

○ *Partial Hospitalization Programs (PHP)*—Currently, TRICARE coverage extends to both full- and half-day psychiatric partial hospitalization services furnished by TRICARE-authorized partial psychiatric hospitalization programs and authorized mental health providers for the active treatment of a mental disorder. Each psychiatric partial hospitalization program must be either a distinct part of an otherwise authorized institutional provider or a freestanding program certified pursuant to TRICARE certification standards; i.e., the facility must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) under the current edition of the Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services and meet all other requirements as prescribed under 32 CFR 199.6(b)(4)(xii)(A) through (D). These authorized and participating partial hospitalization programs are paid a percentage off of the average inpatient per diem amount per case to both high- and low-volume psychiatric hospitals. Full-day partial hospitalization programs (minimum of 6 hours) receive 40 percent of the average inpatient per diem, while partial hospitalization programs with less than 6 hours (with a minimum of three hours) will be paid a per diem of 75 percent of the rate for full-day partial hospitalization programs.

Although the prescribed payment methodology for PHP under OPSS is similar to that currently being used (i.e., payment under a per diem recognizing the provider's overhead costs and support staff), there are subtle differences in that OPSS' all-inclusive per diems represent actual median costs of furnishing a day of partial hospitalization while per diems under the existing TRICARE system as prescribed under 32 CFR 199.14(a)(2)(ix) are extrapolated from inpatient costs based on the intensity of the program (i.e., dependent on whether it is classified as a full- or half-day program). Another notable difference

between the two programs is the continuation of reimbursement of half-day PHPs (≥ 3 hrs. but < 6 hrs.) under TRICARE which are currently not recognized for payment under the Medicare OPSS (i.e., Medicare has not established a separate APC for half-day PHPs which can be used for reimbursement under the TRICARE OPSS). This deviation from the Medicare PHP required the establishment of an additional APC, the per diem of which was set at 75 percent of the unadjusted full-day PHP APC amount (i.e., 75 percent of the APC 0033 amount of \$234.73, equaling \$176.05 for CY 2007). This will ensure continued coverage of a well established mental health treatment modality (half-day PHP) which has been in place under TRICARE for over a decade. The above-established per diems reflect the structure and scheduling of PHPs, and the composition of the PHP APC consists of the cost of all services provided each day. Although there is a requirement that each PHP day include a psychotherapy service, there is no specification regarding the specific mix of other services furnished within the day.

The TRICARE criteria under which PHP services may be rendered are different than Medicare's—both with regard to the need for PHP services and facility requirements. Currently, Medicare OPSS partial hospitalization services may be provided to patients in lieu of inpatient psychiatric care in hospital outpatient departments or Medicare-certified community mental health centers (CMHCs). The Agency has opted to retain the existing mental health review criteria under 32 CFR 199.4(b)(10) in order to ensure the continued level and quality of mental health care afforded under the basic program. Following are the TRICARE review criteria for determining the medical necessity of psychiatric partial hospitalization services:

- The patient is suffering significant impairment from a mental disorder (as defined in § 199.2) which interferes with age appropriate functioning.
- The patient is unable to maintain himself or herself in the community, with appropriate support, at a sufficient level of functioning to permit an adequate course of therapy exclusively on an outpatient basis (but is able, with appropriate support, to maintain a basic level of functioning to permit partial hospitalization services and presents no substantial imminent risk of harm to self or others).
- The patient is in need of crisis stabilization, treatment of partially stabilized mental health disorders, or

services as a transition from an inpatient program.

- The admission into the partial hospitalization program is based on the development of an individualized diagnosis and treatment plan expected to be effective for the patient and permit treatment at a less intensive level.

Based on existing mental health review criteria under 32 CFR 199.4(b)(10) and certification requirements prescribed under 32 CFR 199.6(b)(4)(xii)(A), including accreditation by the JCAHO, under the current edition of the Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation/ Developmental Disabilities Services, not all hospital-based PHPs will be assured of receiving payment under the OPSS unless they meet the above prescribed certification requirements and enter into a participation agreement with TRICARE. CMHC PHPs have been excluded from payment under the TRICARE OPSS since CMHCs are not recognized as authorized providers under the TRICARE program.

While the authorization standards under 32 CFR 199.6(b)(4)(xii)(A) through (D) will be retained/applied for both hospital-based and freestanding PHPs currently recognized under the Program, including the requirement for a written participation agreement with TRICARE, freestanding PHPs will be exempt from OPSS and will continue to be reimbursed under the old TRICARE PHP per diem system as prescribed under 32 CFR 199.14(a)(2)(ix), subject to their own unique mental health copayment/cost-sharing provisions.

- *Ambulatory Surgery Procedures*—Currently, ambulatory surgery procedures provided in both freestanding ambulatory surgery centers (ASCs) and hospital outpatient departments or emergency rooms are paid using prospectively determined rates established on a cost basis and divided into eleven groups as prescribed under 32 CFR 199.14(d). These payment groups are further adjusted for area labor costs based on Metropolitan Statistical Areas (MSAs). The payment rates established under this system apply only to facility charges for ambulatory surgery (e.g., standard overhead amounts that include, but are not limited to, nursing and technician services, use of the facility and supplies and equipment directly related to the surgical procedure) and do not include such items as physician's fees, laboratory, X-rays or diagnostic procedures (other than those directly related to the performance of the surgical procedure), prosthetics and durable medical equipment for use in

the patient's home. Ambulatory surgery procedures (both provided in hospital-based and freestanding ambulatory surgery centers) are subject to their own unique copayment/cost-sharing provisions under the current TRICARE ambulatory surgery benefit.

With implementation of the OPSS, hospital-based ambulatory surgery procedures will no longer be reimbursed under the original eleven tier payment system, but will instead be paid on a rate-per-service basis that varies according to the APC group to which the surgical procedure is assigned. The relative weight of the APC group will represent the median hospital cost of the services included in the APC relative to the median cost of services included in APC 0606, Level 3 Clinic Visit. The prospective payment rate for each APC will be calculated by multiplying the APC's relative weight by a nationally established conversion factor and adjusting it for geographic wage differences. The APC payment will be subject to the deductible and cost-sharing/copayment amounts currently being applied under Prime, Extra, and Standard TRICARE programs for hospital outpatient services. Denial of Medicare inpatient procedures will also be adhered to under the OPSS (i.e., denial of inpatient surgical procedures performed in a hospital outpatient setting) except for those inpatient procedures, which upon medical review, could be safely and efficaciously rendered in an outpatient setting due to TRICARE's younger, healthier beneficiary population. Exceptions to Medicare's inpatient surgical procedure listing were based in major part to standardized utilization management review criteria, (i.e., Interqual and Milliman), used by TRICARE Managed Care Support Contractors' medical review staff. TRICARE-specific APCs will be developed for these designated inpatient procedures based on median costs from the most recent 12 months of claims history. OPSS reimbursement will also be extended for an inpatient procedure performed to resuscitate or stabilize a patient with an emergent, life-threatening condition who dies before being admitted as a patient, which in this case, will be paid under a new technology APC.

Freestanding ASCs will be exempt from OPSS and will continue to be paid under the existing eleven tier payment system. ASC procedures will be placed into one of ten groups by their median per procedure cost, starting with \$0 to \$299 for Group 1, and ending with \$1,000 to \$1,299 for Group 9 and \$1,300 and above for Group 10, subject to their own unique copayment/cost-sharing

provisions under the TRICARE freestanding ambulatory surgery benefit. The eleventh payment tier/group was added to the ASC reimbursement system as of November 1, 1998, for extracorporeal shock wave lithotripsy, with a rate established off of the inpatient Diagnostic Related Group (DRG) 323 which is currently \$3,289.

- *Birthing Centers*—As described in 32 CFR 199.6(b)(4)(xi), a birthing center is a freestanding or institution-affiliated outpatient maternity care program which principally provides a planned course of outpatient prenatal care and outpatient childbirth services limited to low-risk pregnancies. These all-inclusive maternity and childbirth services are currently being reimbursed in accordance with 32 CFR 199.14(e) at the lower of the TRICARE established all-inclusive rate or the billed charge. The all-inclusive rate includes laboratory studies, prenatal management, labor management, delivery, post-partum management, newborn care, birth assistant, certified nurse-midwife professional services, physician professional services, and the use of the facility to the extent that they are usually associated with a normal pregnancy and childbirth. Since institutional-affiliated maternity centers will continue to be reimbursed under the TRICARE maximum allowable birthing center all-inclusive rate methodology as prescribed under 32 CFR 199.14(e), payment will be equal to the sum of the Class 3 CMAC for total obstetrical care for a normal pregnancy and delivery (CPT code 59400) and the TMA supplied non-professional component amount, which includes both the technical and professional components of tests usually associated with a normal pregnancy and childbirth. As a result, hospital-based birthing centers will continue to be reimbursed the same as freestanding birthing centers except that updating of the hospital-based all inclusive rate, consisting of the CMAC for procedure code 59400 (Birthing Center, all-inclusive charge, complete) and the state specific non-professional component, will lag two months behind the freestanding birthing center all-inclusive update; i.e., the freestanding birthing center all-inclusive rate components will usually be updated on February 1 of each year to coincide with the annual CMAC file update, followed by the hospital-based birthing center all-inclusive rate component updates on April 1 of the same year.

- *Observation Stays*—Observation Services are those services furnished on a hospital's premises, including the use of a bed and periodic monitoring by a

hospital's staff, which are reasonable and necessary to evaluate an outpatient's condition or to determine the need for a possible admission to the hospital as an inpatient. Under Medicare, prior to CY 2008, a hospital may receive separate APC payments for observation services for patients having diagnoses of chest pain, asthma, or congestive heart failure, when billed in conjunction with an evaluation and management visit for a minimum of 8 hours. Since these qualifying diagnoses would greatly restrict separate payment of observation stays currently being reimbursed based solely on medical necessity, they are being expanded to accommodate the special needs of unique TRICARE beneficiary populations (e.g., separate payment for maternity observations stays). Separate payment of maternity observation stays required the modification of the existing conditional criteria for separate payment of observation stays associated with pain, asthma or congestive heart failure. Under the TRICARE OPSS, additional hospital services (e.g., separate emergency room visit or clinic visit) will not be required on a claim with a maternity diagnosis in order to receive separate payment for an observation stay. The minimum time requirements have also been reduced from 8 to 4 hours to ensure maximum coverage of medically necessary maternity observation stays.

○ *End-State Renal Disease (ESRD) Dialysis Services*—In accordance with sections 1881(b)(2) and (b)(7) of the Social Security Act, a facility that furnishes dialysis services to Medicare patients with ESRD is paid a prospectively determined rate for each dialysis treatment furnished. The rate is a composite that includes all costs associated with furnishing dialysis services except for the costs of physician services and certain laboratory tests and drugs that are billed separately. CMS has exercised the authority granted under section 1833(t)(1)(B)(i) to exclude from the outpatient PPS those services for patients with ESRD that are paid under the ESRD composite rate. Since TRICARE does not have a comparable composite rate in effect for payment of ESRD services, they will be reimbursed under TRICARE's OPSS.

II. Treatment Settings Subject to Outpatient Prospective Payment System

The outpatient prospective payment system is applicable to any hospital participating in the Medicare program except for Critical Access Hospitals (CAHs), Indian Health Service hospitals, certain hospitals in Maryland that

qualify for payment under the state's cost containment waiver, and hospitals located outside one of the 50 states, the District of Columbia and Puerto Rico and specialty care providers which include: (1) Cancer and children's hospitals; (2) freestanding ASCs; (3) freestanding Partial Hospitalization Programs (PHPs); (4) freestanding psychiatric and Substance Use Disorder Rehabilitation Facilities (SUDRFs); (5) Comprehensive Outpatient Rehabilitation Facilities (CORFs); (6) Home Health Agencies (HHAs); (7) hospice programs; (8) other corporate services providers (e.g., freestanding cardiac catheterization centers, freestanding sleep diagnostic centers, and freestanding hyperbaric oxygen treatment centers); (9) freestanding birthing centers; (10) VA hospitals; and (11) freestanding ESRD centers. Due to their inability to meet the more stringent requirements imposed for hospital-based and freestanding PHPs under the Program, CMHCs have also been excluded from payment under OPSS for partial hospitalization program (PHP) services since they are not recognized as authorized providers under the TRICARE program.

An outpatient department, remote location hospital, satellite facility, or other provider-based entity must also be either created by, or acquired by, a main provider (hospital qualifying for payment under OPSS) for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial administrative control of the main provider, in accordance with the following requirements under 42 CFR § 413.65 (Medicare Regulation) in order to qualify for payment under the OPSS:

- *Licensure*—The outpatient department, remote location hospital, or the satellite facility and the main hospital are operated under the same license, except in areas where the State requires a separate license for the department of the provider.

- *Clinical integration*—Professional staff of the outpatient department, remote location hospital or satellite facility are monitored by, and have clinical privileges at the main hospital. The medical director of the outpatient facility must also maintain a reporting relationship with the chief medical officer at the main hospital that has the same frequency, intensity and level of accountability that exists in the relationship between other departmental medical directors and the chief medical officer of the main hospital. Medical records for patients treated in the facility or organization

must be integrated into a unified retrieval system (or cross reference) of the main hospital and there must be full access to all services provided at the main hospital for patients treated in the outpatient facility requiring further care.

- *Financial integration*. The financial operation of the outpatient facility must be fully integrated within the financial system of the main hospital, as evidenced by shared income and expenses between the main hospital and outpatient facility.

- *Public awareness*. The outpatient department, remote location hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the outpatient facility they are aware that they are entering the main provider and are billed accordingly.

Having clear criteria for provider-based status is important because this designation can result in additional TRICARE payments for services at the provider-based facility (i.e., the incorporation of additional facility costs for covered outpatient services/procedures). TRICARE will accept the providers' determination on whether they meet the regulatory criteria for provider-based status for purposes of seeking reimbursement under the TRICARE OPSS.

III. Application of Ambulatory Payment Classification (APC) Model

Payment for services under the OPSS is based on grouping outpatient services into APC groups in accordance with provisions outlined in section 1833(t) of the Social Security Act and its implementing regulation 42 CFR Part 419. This grouping is accommodated through the reporting of HCPCS codes and descriptors that are used to group homogenous services (both clinically and in terms of resource consumption) into their respective APC groups.

During the development of the hospital OPSS it was recognized that certain hospital outpatient services were being paid based on fee schedules or other prospectively determined rates that were being applied across other ambulatory care settings. As a result, the following services were excluded from the OPSS in order to achieve consistency of payment across different service delivery sites: (1) Physician services; (2) nurse practitioner and clinical nurse specialist services; (3) physician assistant services; (4) certified nurse-midwife services; (5) services of a qualified psychologist; (6) clinical social worker services, except under half- and full-day partial hospitalization programs in which the services are included within the per diem payment amount;

(7) services of an anesthetist; (8) screening and diagnostic mammographies; (9) clinical diagnostic services; (10) non-implantable DME, orthotics, prosthetics, and prosthetic devices and supplies; (11) hospital outpatient services furnished to SNF inpatients as part of their comprehensive care plan; (12) physical therapy; (13) speech-language pathology; (14) occupational therapy; (15) influenza and pneumococcal pneumonia vaccines; (16) take-home surgical dressings; (17) services and procedures designated as requiring inpatient care; and (18) ambulance services. These services will continue to be reimbursed under the current CMAC fee schedule or other TRICARE-recognized allowable charge methodology (e.g., statewide prevalings).

The remaining outpatient procedures which were not being paid under current fee schedules or other prospectively determined rates were grouped under an APC based on the following criteria:

- *Resource Homogeneity*—The amount and type of facility resources (for example, operating room, medical supplies, and equipment) that are used to furnish or perform the individual procedures or services within each APC group should be homogeneous. That is, the resources used are relatively constant across all procedures or services even though resources used may vary somewhat among individual patients.

- *Clinical Homogeneity*—The definition of each APC should be “clinically meaningful.” That is, the procedures or services included within the APC group relate generally to a common organ system or etiology, have the same degree of extensiveness, and utilize the same method of treatment.

- *Provider Concentration*—The degree of provider concentration associated with the individual services that comprise the APC is considered. If a particular service is offered only in a limited number of hospitals, then the impact of payment for the services is concentrated in a subset of hospitals. Therefore, it is important to have an accurate payment level for services with a high degree of provider concentration. Conversely, the accuracy of payment levels for services that are routinely offered by most hospitals does not bias the payment system against any subset of hospitals.

- *Frequency of Service*—Unless there is a high degree of provider concentration, creating separate APC groups for services that are infrequently performed is avoided. Since it is

difficult to establish reliable payment rates for low-volume groups, HCPCS codes are assigned to an APC that is most similar in terms of resource use and clinical coherence.

- *Minimal Opportunities for Upcoding and Code Fragmentation*—The APC system is intended to discourage using a code in a higher paying group to define the care. That is, putting two related codes such as the codes for excising a lesion for 1.1 cm and one of 1.0 cm, in different APC groups may create an incentive to exaggerate the size of the lesions in order to justify the incrementally higher payment. APC groups based on subtle distinctions would be susceptible to this kind of coding. Therefore, APC groups were kept as broad and inclusive as possible without sacrificing resource or clinical homogeneity.

These procedures, along with their specific HCPCS coding and descriptors, were used to identify and group services within each established APC group. They included: (1) Surgical procedures (including hospital-based ASC procedures currently being paid under the eleven tier ASC payment methodology); (2) radiology, including radiation therapy; (3) clinic visits; (4) emergency department visits; (5) diagnostic services and other diagnostic tests; (6) partial hospitalization for the mentally ill; (7) surgical pathology; (8) cancer therapy; (9) implantable medical items (e.g., prosthetic implants, implantable DME and implantable items used in performing diagnostic x-rays and laboratory tests); (10) specific hospital outpatient services furnished to a beneficiary who is admitted to a SNF, but in which case the services are beyond the scope of SNF comprehensive care plans; (11) certain preventive services, such as colorectal cancer screening; (12) acute dialysis (e.g., dialysis for poisoning); and (13) ESRD services. These hospital outpatient procedures will be paid on a rate-per-service basis that varies according to the APC group to which they are assigned.

In accordance with section 1833(t)(2) of the Social Security Act, services and items within an APC group cannot be considered comparable with respect to the use of resources in the APC group if the highest median cost is more than 2 times the lowest median cost for an item or service within the same group (referred to as the “2 times rule”). Exceptions may be granted in unusual cases, such as low-volume items and services.

IV. Packaging and Special Payment Provisions Under OPPTS

The prospective payment system establishes a national payment rate, standardized by geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis, which has ultimately resulted in the establishment of distinct groups of surgical, diagnostic, and partial hospitalization services, as well as medical visits. No separate payment is made for packaged services, because the cost of these items is included in the APC payment for the service of which they are an integral part. These costs include, but are not limited to: (1) Use of operating suite; (2) use of procedure room or treatment room; (3) use of recovery room or area; (4) use of an observation bed; (5) anesthesia, along with supplies and equipment for administering and monitoring anesthesia or sedation; (6) certain drugs, biologicals, and other pharmaceuticals; (7) medical and surgical supplies; (8) surgical dressings; (9) devices used for external reduction of fractures and dislocations; (10) intraocular lenses (IOLs); (11) capital related costs; (12) costs incurred to procure donor tissue other than corneal tissue; (13) incidental services such as venipuncture; (14) implantable items used in connection with diagnostic laboratory tests, and other diagnostics; and (15) implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices.

Payments for packaged services under the OPPTS are bundled into the payment providers receive for separately payable services provided on the same day and are identified by the status indicator (SI) “N” (unconditionally packaged) or SI “Q” (conditionally packaged). Hospitals include charges for packaged services on their claims, and the costs associated with these packaged services are bundled into the costs for separately payable procedures in calculating their payment rates. The following criteria are used in determining whether procedures should be packaged: (1) Whether the service is normally provided separately or in conjunction with other services; (2) how likely it is for the costs of the packaged code to be appropriately mapped to the separately payable codes with which it was performed; (3) whether the APC payment to which the services were packaged will offset the hospital’s actual

costs; and (4) whether the expected cost of the service is relatively low.

Special logic has also been programmed into the OCE which will have the OPSS PRICER automatically assign payment for a special packaged service reported on a claim if there were no other services separately payable under the OPSS claim for the same date. A new status indicator "Q" will be assigned to these special packaged codes to indicate that they are usually packaged, except for special circumstances when they are separately payable.

Based on the above packaging criteria, it was determined that certain other expensive items and services which were otherwise considered an integral part of another procedure should not be packaged within that procedure's APC payment rate, since the resulting payment would not offset the costs of those items and services. This could have a potentially negative impact, thereby jeopardizing access to these items and services in a hospital outpatient setting. As a result, the costs associated with these items and services were not packaged within the APC of the primary procedure with which they were normally associated. Instead, separate APCs were developed for payment of these items and services under the following payment provisions:

- *Transitional Pass-Through for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals.* Although the costs of drugs, biologicals and pharmaceuticals are generally packaged into the APC payment rate for the primary procedure or treatment with which the drugs are usually furnished, there are special temporary additional payments or "transitional pass-through payments" available under section 1833(t)(6) of the Social Security Act for at least two years, but not more than three years for the following drugs and biologicals: (1) Current orphan drugs, as designated under section 526 of the Federal Food, Drugs, and Cosmetics Act; (2) current drugs and biological agents used for treatment of cancer; (3) current radiopharmaceutical drugs and biological products; and (4) new drugs and biologic agents in instances where the item was not being paid as a hospital outpatient service as of December 31, 1996, and where the cost of the item is "not insignificant" in relation to the hospital OPSS payment amount.

Section 1833(t)(6)(D)(i) of the Social Security Act sets the payment rate for pass-through eligible drugs as amounts determined under section 1842(o) of the Act. Section 1847A of the Act

establishes the use of average sales price (ASP) methodology (i.e., 106 percent of the ASP which is the rate equivalent to the payment that would be received in a physician office setting) as the basis for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act. Section 1883(t)(6)(D)(i) also states if a drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the payment rate is equal to the average price for the drug or biologicals for all competitive acquisition areas. Thus, drugs and biologicals with pass-through status in CY 2007 will receive payment consistent with the provision of section 1842(o) of the Act, at a rate that is equivalent to the payment they would receive in a physician office setting (106 percent of the ASP) or the rate that would be paid under the competitive acquisitions program, while pass-through radiopharmaceuticals will be paid the hospital's charge for the radiopharmaceutical adjusted to the cost using the hospital's overall cost-to-charge ratio (CCR).

- *Packaging and Payment for Drugs, Biologicals and Radiopharmaceuticals Without Pass-Through Status.* Drugs, biologicals, and radiopharmaceuticals that do not have pass-through status are paid in one of two ways: either packaged into the APC payment rate for the procedure or treatment with which the products are usually furnished, or separately based on a packaging threshold which has been set at \$55 for CY 2007. Therefore, for CY 2007 and beyond, drugs, biologicals and radiopharmaceuticals that are not new and do not have pass-through status will be packaged if their calculated per-day cost is less than \$55 for CY 2007 or less than the updated threshold (i.e., the packaging threshold inflated annually by the Producer Price Index (PPI) for prescription drugs), with the exception of 5HT3 antiemetics which will continue to be paid separately regardless of their calculated per-day cost.

Section 1833(t)(14) of the Act requires special classification of certain separately payable drugs, biologicals and radiopharmaceuticals and mandates payment under section 1833(t)(14)(A)(iii) of the Act for specified covered outpatient drugs in CY 2006 and subsequent years to be equal to the average acquisition cost for the drug subject to any adjustment for overhead costs, which for CY 2007 is a combined rate of 106 percent of the ASP. Separately payable drugs and biologicals without ASP-based data will be paid at their mean cost calculated from Medicare CY 2005 hospital claims

data. The preadmission-related services associated with intravenous immune globulin (IVIG) will continue to be paid under a New Technology APC with a rate of \$75. Also, payment for blood clotting factors in the outpatient setting will be set at 106 percent of the ASP, plus the updated furnishing fee of \$0.15. The temporary policy of paying radiopharmaceuticals at charges reduced to costs is also being extended for one additional year since it is still considered the best proxy for radiopharmaceutical acquisition and overhead costs. However, separate payment will only apply to those radiopharmaceuticals with per-day costs greater than \$55.

- *Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes, But Without OPSS Claims Data.* For CY 2007, hospitals will receive payment for nonpass-through radiopharmaceuticals without hospital claims data that have been assigned HCPCS codes as of January 1, 2007, at the hospital's charge for the radiopharmaceutical adjusted to cost using the hospital's overall cost-to-charge ratio, which will be the same methodology used in the payment for pass-through radiopharmaceuticals. For new drugs without pass-through status or hospitals claims data, payment will be made at the lesser of the ASP or competitive acquisition contract price (Part B CAP). In rare instances where a drug does not have a Part B drug CAP rate or data available for use for ASP methodology, payment will be made at 95 percent of the product's most recent AWP. Established drugs without hospital claims data that have been classified as separately payable in CY 2007 will be paid per the ASP-based methodology at a rate of 106 percent of the ASP.

New drugs, biologicals and devices which qualify for separate payment under OPSS, but have not yet been assigned to a transitional APC (i.e., assigned to a temporary APC for separate payment of an expensive drug or device) will be reimbursed under the TRICARE standard allowable charge methodology. This allowable charge payment will continue until a transitional APC has been assigned (i.e., until CMS has had the opportunity to assign the new drug, biological or device to a temporary APC for separate payment).

- *Drug Administration Coding and Payment.* For CY 2007, hospitals will be expected to report the full set of CPT drug administration codes in a manner consistent with their descriptors, CPT instructions and correct coding

principles. They will no longer be able to report the alphanumeric HCPCS codes (C8950, C8951, C8952, C8954, and C8955) that were recognized prior to January 1, 2007. These newly recognized CPT codes will be assigned to six new drug administration APCs, with payment rates based on median costs for the APCs as calculated from Medicare's CY 2005 claims data.

○ *Payment for Blood and Blood Products.* Since Medicare's implementation of the OPSS in August 1, 2000, separate payments have been made for blood and blood products through APCs rather than packaging them into the procedures with which they were administered. Hospital payment for the costs of blood and blood products, as well as the costs of collecting, processing, and storing blood products, are made through the OPSS payments for specific blood product APCs. For CY 2007, these blood product payments will be based on the unadjusted, simulated median costs for blood and blood products that are derived from CY 2005 Medicare claims data, with the exception of the seven products for which there will be a payment adjustment to smooth their transition to full claims-based payments in the future.

○ *Other Procedure or Service Costs Not Packaged in APC Payment.* Costs for casting, splinting and strapping services, immunosuppressive drugs for patients following organ transplant, and certain other high-cost drugs that are infrequently administered are not packaged into the costs of the primary procedures with which they are normally associated. Instead, new APC groups have been created for these items and services, which will allow separate payment.

○ *Corneal Tissue Acquisition Costs.* Corneal tissue acquisition costs will not be packaged with the APC payment for corneal transplant surgical procedures. Instead, separate payment will be made based on the hospital's reasonable costs incurred to acquire corneal tissue. Corneal acquisition costs must be submitted using HCPCS code V2785 (Processing, Preserving and Transporting Corneal Tissue), indicating the actual cost of the acquisition rather than the hospital's charge on the bill.

○ *Transitional Pass-Through Payment for Devices.* Transitional payments will only apply to new and innovative medical devices meeting the following criteria: (1) Were not recognized for payment as a hospital outpatient service prior to 1997 (i.e., payment was not being made as of December 31, 1996) or treated as meeting the time constraints under

special prescribed conditions; (2) have been approved/cleared for use by the Food and Drug Administration (FDA); (3) are determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part; (4) are an integral and subordinated part of the procedure performed; (5) are used for one patient only (except for reprocessed single-use devices meeting FDA's most recent regulatory criteria on single-use devices); (6) are surgically implanted or inserted via a natural or surgically created orifice on incision and remain with the patient after the patient is released from the hospital outpatient department; (7) are not equipment, instruments, apparatus, implements, or such items for which depreciation and financing expenses are recovered as depreciable assets; (8) are not materials and supplies such as sutures, clips or customized surgical kits furnished incidental to a service or procedure; (9) are not material such as biologicals or synthetics that are used to replace human skin; (10) no existing or previously existing device category is appropriated for the device; (11) associated cost is not insignificant in relation to the APC payment for the service in which the innovative medical equipment is packaged; and (12) it has been demonstrated that utilization of the device provides substantial clinical improvement for beneficiaries compared with currently available treatments, including procedures utilizing devices in existing or previously existing device categories.

The duration of transitional pass-through payments for devices is for at least two, but not more than three years. This period begins with the first date on which a transitional pass-through payment is made for any medical device that is described by the new medical category. The costs of the devices will be packaged into the costs of the procedures with which they are normally billed once they are no longer eligible for pass-through payment.

Device pass-through payments (those procedures designated with a SI "H") are calculated by applying the statewide cost-to-charge ratio (CCR), which is based on the geographical CBSA (2 digit = rural, 5 digit = urban), to the hospital's charges on the claims and subtracting any appropriate pass-through offset. The offset adjustment only applies when a pass-through device is billed in addition to the primary procedure with which it is normally associated.

Provisions are also in place in accordance with 1833(t)(6)(D)(ii) of the Social Security Act for reducing transitional pass-through payments by

the estimated portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments. Offsets are calculated by comparing the median APC cost without device packaging to the median APC cost (including device packaging), developed from claims with device codes, to determine the percentage of median APC costs attributable to the associated pass-through device. These percentages are then applied to the APC payment amounts in order to determine the applicable amounts to be deducted from the pass-through payments, known as the "offset" amounts. Offset amounts are only applied when it can be determined that an APC contained cost is actually associated with the device. Currently, there is only one transitional pass-through payment offset in effect for device category C1820 (generator, neurostimulator (implantable), with rechargeable battery and charging system) with an amount of \$8,668.94, which represents 77.65 percent of the CY 2007 payment rate for APC 0222.

Two new device categories have been established for pass-through payment starting in 2007: (1) L8690—auditory osseointegrated device, external sound processor, replacement; and (2) C1821—interspinous process distraction device (implantable). The offset amounts for both of these new device categories were set to \$0 for CY 2007, since there were no identifiable device-related costs associated with their procedure APCs (i.e., APC 0256 for L8690 and APC 0050 for C1821). The pass-through status of this rechargeable neurostimulator device (C1820) is scheduled to expire on January 1, 2008.

○ *Payment When Devices are Replaced Without Cost or Where Credit for a Replacement Device is Furnished to the Hospital.* Payments will be reduced for selected APCs in cases in which an implanted device is replaced without cost to the hospital or with full credit for the removed device in accordance with 42 CFR 419.45. The amount of the reduction to the APC rate will be calculated in the same manner as the offset amount that would be applied if the implanted device assigned to the APC had pass-through status as defined under 42 CFR 419.66. OPSS payments would be contingent on section 1833(t)(2)(E) of the Social Security Act, which permits equitable adjustments to the OPSS payments contingent on meeting all of the following criteria: (1) All procedures assigned to the selected APCs must require implantable devices that would be reported if device replacement procedures were performed; (2) the

required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedures, at least temporarily; and (3) the offset percent for the APC (i.e., the median cost of the APC *without* device costs divided by the median cost of the APC *with* device costs) must be significant—significant offset percent is defined as exceeding 40 percent.

The presence of the modifier “FB” [“Item Provided Without Cost to Provider, Supplier, or Practitioner or Credit Received for Replacement (examples include, but are not limited to: devices covered under warranty, replaced due to defect, or provided as free samples)”] would trigger the adjustment in payment if the procedure code to which the modifier “FB” was amended appeared in Table 3 and was also assigned to one of the APCs listed in Table 4 below.

TABLE 3.—DEVICES FOR WHICH THE FB MODIFIER MUST BE REPORTED WITH THE PROCEDURE WHEN FURNISHED WITHOUT COST OR AT FULL CREDIT FOR A REPLACEMENT DEVICE

Device	Description
C1721 ..	AICD, dual chamber.
C1722 ..	AICD, single chamber.
C1764 ..	Event recorder, cardiac.
C1767 ..	Generator, neurostim, imp.
C1771 ..	Rep dev, urinary, w/sling.
C1772 ..	Infusion pump, programmable.
C1776 ..	Joint device (implantable).
C1777 ..	Lead, AICD, endo single coil.
C1778 ..	Lead, neurostimulator.
C1779 ..	Lead, pmkr, transvenous VDD.
C1785 ..	Pmkr, dual, rate- resp.
C1786 ..	Pmkr, single, rate- resp.
C1813 ..	Prostheses, penile, inflatab.
C1815 ..	Pros, urinary sph, imp.
C1820 ..	Generator, neuro, rechg bat sys.
C1882 ..	AICD, other than sing/dual.

TABLE 3.—DEVICES FOR WHICH THE FB MODIFIER MUST BE REPORTED WITH THE PROCEDURE WHEN FURNISHED WITHOUT COST OR AT FULL CREDIT FOR A REPLACEMENT DEVICE—Continued

Device	Description
C1891 ..	Infusion pump, non-prog, perm.
C1895 ..	Lead, AICD, endo dual coil.
C1896 ..	Lead, AICD, non sing/dual
C1897 ..	Lead, neurostim, test kit.
C1898 ..	Lead, pmkr, other than trans.
C1899 ..	Lead, pmkr/ACID combination.
C1900 ..	Lead coronary venous.
C2619 ..	Pmkr, dual, non rate- resp.
C2620 ..	Pmkr, single, non rate- resp.
C2621 ..	Pmkr, other than sing/dual.
C2622 ..	Prosthesis, penile, non- inf.
C2626 ..	Infusion pump, non-prog, temp.
C2631 ..	Rep dev, urinary, w/o sling.
L8614 ..	Cochlear device/system.

TABLE 4.—ADJUSTMENTS TO APCs IN CASES OF DEVICES REPORTED WITHOUT COST OR FOR WHICH FULL CREDIT IS RECEIVED

APC	SI	APC group title	CY 2007 offset amt. (percent)
0039	S	Level I Implantation of Neurostimulator	78.85
0040	S	Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve	54.06
0061	S	Laminectomy or Incision for Implantation of Neurostimulator Electrodes, Excluded	60.06
0089	T	Insertion/Replacement of Permanent Pacemaker and Electrodes	77.11
0090	T	Insertion/Replacement of Pacemaker Pulse Generator	74.74
0106	T	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	41.88
0107	T	Insertion of Cardioverter-Defibrillator	90.44
0108	T	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	77.75
0222	T	Implantation of Neurological Device	77.65
0225	S	Implantation of Neurostimulator Electrodes, Cranial	79.04
0227	T	Implantation of Drug Infusion Devices	80.27
0229	T	Transcatheter Placement of Intravascular Shunts	46.17
0259	T	Level IV ENT Procedures	84.61
0315	T	Level II Implantation of Neurostimulator	76.03
0385	S	Level I Prosthetic Urological Procedures	83.19
0386	S	Level II Prosthetic Urological Procedures	61.16
0418	T	Insertion of Left Ventricular Pacing Elect.	87.32
0654	T	Insertion/Replacement of a Permanent Dual Chamber Pacemaker	77.35
0655	T	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker	76.59
0680	S	Insertion of Patient Activated Event Recorders	76.40
0681	T	Knee Arthroplasty	73.37

If the device code (i.e., one of the codes in Table 3 above) is assigned to one of the APCs listed in Table 4 above, the unadjusted payment rate for the procedure APC will be reduced by an amount equal to the percent in Table 4 times the unadjusted payment rate. The actual adjustments can be viewed on the following CMS Web site: <http://www.cms.hhs.gov/HospitalOutpatientPPS/>

In cases in which the device is being replaced without cost, the hospital will report a token device charge. However, if the device is being inserted as an upgrade, the hospital will report the

difference between its usual charge for the device being replaced and the credit for the replacement device. Multiple procedure reductions would also continue to apply even after the APC payment adjustment to remove payment for the device cost, because there would still be the expected efficiencies in performing the procedure if it was provided in the same operative session as another surgical procedure. Similarly, if the procedure was interrupted before administration of anesthesia (i.e., there was a modifier 52 or 73 on the same line as the procedure), a 50 percent

reduction would be taken from the adjusted amount.

○ *Coding and Payment of Emergency Department Visits.* The following five Type B emergency department G-codes have been established for emergency departments meeting the definition of a dedicated emergency department (DED) under the Emergency Medical Treatment and Labor Act (EMTALA) regulations in 42 CFR 489.24, but which are not Type A emergency departments (i.e., they may meet the DED definition but are not available 24 hours a day, 7 days a week).

TABLE 5.—CY 2007 FINAL HCPCS CODES TO BE USED TO REPORT EMERGENCY DEPARTMENT VISITS PROVIDED IN TYPE B EMERGENCY DEPARTMENTS

HCPCS code	Short descriptor	Long descriptor
G0380	Level 1 hosp. type B visit.	Level 1 hospital emergency department visit provided in a Type B emergency department. (The ED must meet at least one of the following requirements: (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.)
G0381	Level 2 hosp. type B visit.	Level 2 hospital emergency department visit provided in a Type B emergency department. (The ED must meet at least one of the following requirements: (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.)
G0382	Level 3 hosp. type B visit.	Level 3 hospital emergency department visit provided in a Type B emergency department. (The ED must meet at least one of the following requirements: (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.)
G0384	Level 4 hosp. type B visit.	Level 4 hospital emergency department visit provided in a Type B emergency department. (The ED must meet at least one of the following requirements: (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.)
G0385	Level 5 hosp. type B visit.	Level 5 hospital emergency department visit provided in a Type B emergency department. (The ED must meet at least one of the following requirements: (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.)

The use of these G-codes, along with the following redefinition of a Type A emergency department, will serve as a vehicle to capture median cost and resource differences among visits to Type A emergency departments, Type B emergency departments and clinics:

Type A Emergency Department—A type A emergency department is a hospital-based facility or department that must be open 24 hours a day, 7 days a week and meet at least one of the following requirements: (1) It is licensed by the State in which it is located under applicable State laws as an emergency department; or (2) It is held out to the

public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

A new G-code (G0390—Trauma response team activation associated with hospital critical care services) was also created (effective January 1, 2007) to be used in addition to CPT codes 99291 and 99292 to address the meaningful cost difference between critical care when billed with and without trauma activation. If critical care is provided without trauma

activation, the hospital will bill with either CPT 99291 or 99292, receiving payment for APC 0617 with a median cost of \$402.67. However, if trauma activation occurs, the hospital would be allowed to bill one unit of G-code (G0390), reported with revenue code 68x on the same date of service, thereby receiving \$491.66 under APC 0618. Hospitals will continue to bill CPT codes for both clinic and Type A Emergency department visits until national guidelines have been established.

The above CPT E/M codes and other HCPCS codes currently assigned to the

clinic visit APCs have been mapped in Table 6 to eleven new APCs; five for

clinic visits; five for emergency department visits; and one for critical

care services, based on median costs and clinical consideration.

TABLE 6.—ASSIGNMENT OF CPT E/M CODES AND OTHER HCPCS CODES TO NEW VISIT APCs FOR CY 2007

CY 2007 APC title	CY 2007 APC	HCPCS	Short descriptor
Level 1 Hospital Clinic Visits	0604	92012	Eye exam, established pat.
		99201	Office/outpatient visit, new (Level 1).
		99211	Office/outpatient visit, est (Level 1).
		G0101	CA screen; pelvic/breast exam.
		G0245	Initial foot exam pt lops.
		G0241	Office consultation (Level 1).
		G0271	Confirmatory consultation (Level 1).
		G0264	Assmt otr CHF, CP, asthma.
		92002	Eye exam, new patient.
		92014	Eye exam and treatment.
		99202	Office/outpatient visit, new (Level 2).
Level 2 Hospital Clinic Visits	0605	99212	Office/outpatient visit, est (Level 2).
		99213	Office/outpatient visit, est (Level 3).
		99243	Office consultation (Level 3).
		99242	Office consultation (Level 2).
		99273	Confirmatory consultation (Level 3).
		99272	Confirmatory consultation (Level 2).
		99431	Initial care, normal newborn.
		G0246	Follow-up eval of foot pt lop.
		G0344	Initial preventive exam.
		92004	Eye exam, new patient.
		99203	Office/outpatient visit, new (Level 3).
Level 3 Hospital Clinic Visits	0606	99214	Office/outpatient visit, est (Level 4).
		99274	Confirmatory consultation (Level 4).
		99244	Office consultation (Level 4).
		99204	Confirmatory consultation (Level 1).
Level 4 Hospital Clinic Visits	0607	99215	Office/outpatient visit, est (Level 5).
		99245	Office consultation (Level 5).
		99275	Confirmatory consultation (Level 5).
Level 5 Hospital Clinic Visits	0608	99205	Office/outpatient visit, new (Level 5).
		G0175	OPPS service, sched team conf.
Level 1 Type A Emergency Visits	0609	99281	Emergency department visit.
Level 2 Type A Emergency Visits	0613	99282	Emergency department visit.
Level 3 Type A Emergency Visits	0614	99283	Emergency department visit.
Level 4 Type A Emergency Visits	0615	99284	Emergency department visit.
Level 5 Type A Emergency Visits	0616	99285	Emergency department visit.
Critical Care	0617	99291	Critical care, first hour.

○ *Inpatient Only Procedures.* The inpatient list on TMA's OPPS Web site at <http://www.tricare.mil/opps> specifies those services that are only paid when provided in an inpatient setting because of the nature of the procedure, the need for at least 20 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the underlying physical condition of the patient. The following criteria will be used when reviewing procedures to determine whether or not they should be moved from the inpatient list and assigned to an APC group for payment under OPPS: (1) The simplest procedure described by the code may be performed in most outpatient departments; (2) the procedure is related to codes that have already been removed from the inpatient list; (3) the procedure is being performed in numerous hospitals on an outpatient basis; and (4) the procedure can be appropriately and safely performed in an ASC. While it is anticipated that TRICARE will be

following the Medicare inpatient listing fairly closely, there may be occasions where, upon medical review, it is found that a particular inpatient procedure can be provided safely in an outpatient setting due to TRICARE's younger, healthier beneficiary population. These procedures will be removed from the TRICARE inpatient listing and will be assigned to either an existing or new APC group based on their median costs.

If a patient was not admitted as an inpatient, and the procedure designated as an inpatient-only procedure (by OPPS payment status indicator "C") was performed to resuscitate or stabilize a patient with an emergency, life-threatening condition and the patient dies before being admitted as an inpatient, the hospital would bill for payment under the OPPS for the services that were furnished on that date and included modifier—"CA" on the line with the HCPCS code for the inpatient procedure. Payment for all services other than the inpatient

procedure designated under OPPS by status indicator "C", furnished on the same date, would be bundled into a single payment under APC 0375 (Ancillary Outpatient Services the Patient Expires) whose CY 2007 median cost is \$3,539.

○ *Partial Hospitalization Services.* Partial hospitalization services are those services furnished by TRICARE-authorized partial hospitalization programs and authorized mental health providers for the active treatment of a mental disorder. All services must follow a medical model and patient care must be under the general direction of a licensed psychiatrist employed by the partial hospitalization program to ensure medication and physical needs of all the patients are considered. The OPPS established per diem payment for both half- and full-day partial hospitalization represents the hospital's costs for overhead, support staff and the services of clinical social workers (CSWs) and occupational therapists

(OTs). For Substance Use Disorder Rehabilitation Facilities (SUDRFs), the cost of alcohol and addiction counselor services would also be included in the PHP per diem. However, the OPPS does not include the cost of services for physicians, clinical psychologists, and psychiatric nurse practitioners (NPs), which will continue to be billed separately for covered mental health services. In order to receive payment under OPPS, the hospital must use specific HCPCS and revenue codes and report partial hospitalization services under bill type 13X, along with condition code 41 on the UB-04 (HCFA 1450 claim form). The claim must also include a mental health diagnosis and an authorization on file for each day of service, along with a designated H-code (i.e., either H0035 for half-day PHP or H0037 for full-day PHP) and its accompanying revenue code, prior to assigning a half- or full-day partial hospitalization APC. Specific therapy codes (e.g., coding for family, group and individual psychotherapy) will be reported in addition to the designated partial hospitalization codes H0035 and H0037 and will be packaged into a single PHP code for the same date of service, with the exception of electroconvulsive therapy (ECT). Claims that do not meet the above criteria (e.g., claims filed without condition code 41, appropriate H-coding—H0035 or H0037, and/or revenue code) will undergo further payment review to ensure that outpatient mental health procedures do not exceed the full-day partial hospitalization per diem amount; i.e., the sum of the individual mental health APC amounts on any particular day does not exceed the full-day partial hospitalization per diem amount. The half-day PHP per diem (APC T0001) will be priced at 75 percent of the full-day APC (0033) amount of \$233.37 for CY 2007. Free-standing psychiatric partial hospitalization services will continue to be reimbursed the all-inclusive PHP per diem rates as established under 32 CFR 199.14(a)(2)(ix), subject to their own unique mental health copayment/cost-sharing provisions.

○ *Separate Payment for Observation Stays.* Observation care is a well-defined

set of specific, clinically appropriate services that include short-term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients, or if they are able to be discharged from the hospital. The determination of whether or not observation services are separately payable under APC 0339 (observation) has been shifted from the hospital billing department to the OPPS claims processing logic using two HCPCS codes (i.e., G0378—Hospital observation services per hour, and G0379—Direct admission of patient for hospital observation care). These HCPCS codes will be assigned status indicator “Q” (package service subject to separate payment based on criteria) that will trigger the OCE logic during the processing of the claim to determine if the observation service or direct admission service is packaged with the other separately payable hospital services provided, or if a separate APC payment for observation services or direct admission to observation is appropriate. Following are the criteria that must be met in order to receive separate payment under APC 0039: (1) The beneficiary must have one of four medical conditions—congestive heart failure, chest pain, asthma, or maternity—as documented by specific ICD-9-CM diagnosis codes; (2) the number of units reported with HCPCS code G0378 must be equal to or exceed 8 hours for observation stays with diagnoses of chest pain, asthma or congestive heart failure and a minimum of 4 hours for maternity observation services; (3) an emergency department visit, clinic visit, critical care visit, or direct admission to observation services using HCPCS code G037 must be provided on the same day as, or the day before the observation except for maternity observation stays; (4) ongoing physician evaluation must be provided. The FY 2007 median cost for the observation APC 0339 is \$442.81.

Direct admissions to observation will continue to be paid at a rate equal to that of a Level 1 Clinic Visit (APC 0604) with a CY 2007 median cost of \$50.37 when a beneficiary is seen by a physician in the community and then is

directly admitted into a hospital outpatient department for observation care that does not qualify for separate payment under APC 0039, or under T0002. In order to receive separate payment for a direct admission into observation (APC 0604), the claim must show: 1) Both HCPCS codes G0378 (Hourly Observation) and G0379 (Direct Admit to Observation) with the same date of service; 2) that there are no services with status indicator “T” or “V” (clinic or emergency department visit) or critical care (APC 0620) provided on the same day of service as HCPCS code G0379; and 3) that the observation care does not qualify for separate payment under APC 0339.

If the period of observation spans more than one calendar day, hospitals should include all of the hours for the entire period of observation on a single line and enter as the date of service for that line the date the patient is admitted to observation. Also, if there are multiple maternity observation stays on the same day without condition code G0 or 27 to indicate that the visits were distinct and independent of each other, the first listed observation stay will be paid and the rest will be denied.

○ *Payment for Brachytherapy Sources.* In accordance with section 1833(t)(2)(H) of the Social Security Act, brachytherapy sources are being paid separately under their own service groups (APCs) reflecting the number, isotope, and radioactive intensity of the devices of brachytherapy furnished, including separate groups for palladium-103 and iodine-125 devices. The payment for devices of brachytherapy based on hospitals’ charges, adjusted to costs as prescribed under section 1833(t)(16)(C) of the Social Security Act, has been extended under the Tax Relief and Health Care Act of 2006 to January 1, 2008. As a result, brachytherapy sources will continue to be assigned to status indicator “H” and will not be eligible for outlier payments in CY 2007. The codes for the CY 2007 separately paid sources, long descriptors and APCs are listed in Table 7 below:

TABLE 7.—SEPARATELY PAID BRACHYTHERAPY SOURCES WITH LONG DESCRIPTORS AND ASSIGNED APCS

CPT/ HCPCS	Long descriptor	SI	APC
A9527	Iodine 1-125, sodium iodide solution, therapeutic, per millicurie	H	2632
C1716	Brachytherapy source, Gold 198, per source	H	1716
C1717	Brachytherapy source, High Dose Rate Iridium 192, per source	H	1717
C1718	Brachytherapy source, Iodine 125, per source	H	1718
C1719	Brachytherapy source, Non-High Dose Rate Iridium 192, per source	H	1719
C1720	Brachytherapy source, Palladium 103, per source	H	1720

TABLE 7.—SEPARATELY PAID BRACHYTHERAPY SOURCES WITH LONG DESCRIPTORS AND ASSIGNED APCs—Continued

CPT/ HCPCS	Long descriptor	SI	APC
C2616	Brachytherapy source, Yttrium-90, per source	H	2616
C2632	(See note below)	D
C2633	Brachytherapy source, Cesium-131, per source	H	2633
C2634	Brachytherapy source, High Activity, Iodine-125, greater than 1.01 mCi (NIST), per source	H	2634
C2635	Brachytherapy source, High Activity, Palladium-103, greater than 2.2 mCi (NIST), per source	H	2635
C2636	Brachytherapy linear source, Palladium-103, per 1 MM	H	2636
C2637	Brachytherapy source, Ytterbium-169, per source	H	2637

Note: C2632 has been deleted and replaced by A9527, effective January 1, 2007.

- *APC for Vaginal Hysterectomy.* When billing for vaginal hysterectomies, hospitals must use procedure 58260, which will be assigned to APC 0202.

- *New Technology APCs.* A process has also been developed that will recognize new technologies that do not otherwise meet the definition of current orphan drugs, or current cancer therapy drugs and biologicals and brachytherapy, or current radiopharmaceutical drugs and biological products, and which are considered a covered benefit under TRICARE. In contrast to the other APC groups, the new technology APC groups do not take into account clinical aspects of the services they are to contain, but only their costs. This process, along with transitional pass-throughs, will provide additional payment for a significant share of new technologies. New items and services will be assigned to new technology APCs when it is determined that they cannot appropriately be placed into existing APC groups. The new technology APC groups have established payment rates based on the midpoint of ranges of possible costs providing a mechanism for initiating payment at an appropriate level within a relatively short timeframe. The cost bands for New Technology APCs range from: \$0 to \$50, in increments of \$10; \$50 to \$100, in increments of \$50; \$100 to \$2,000, in increments of \$100; and \$2,000 to \$6,000, in increments of \$500. These increments which are in two parallel sets of New Technology APCs—one with status indicator “S” and the other with “T”—allow assignment to the same APC group procedures that are appropriately subject to a multiple procedure payment reduction (T) with those that should not be discounted (S).

- *Coding Requirement for Reimbursement Under TRICARE OPPTS.* To receive TRICARE reimbursement under OPPTS, providers must follow, and contractors shall enforce, all Medicare specific coding requirements. TRICARE Management Activity (TMA) will develop specific APCs (those APCs

beginning with a “T”) for those services that are unique to the TRICARE beneficiary population (e.g., those TRICARE specific APCs for half-day partial hospitalization program (PHP) services and maternity observation stays).

V. OPPTS Reimbursement Methodology

- *General Overview.* Under the TRICARE OPPTS, hospital outpatient services are paid on a rate-per-services basis that varies according to the APC group to which the service is assigned. The APC classification system is composed of groups of services that are comparable clinically and with respect to the use of resources. Level 1 (CPT) and Level II HCPCS codes and descriptors are used to identify and group the services within each APC. Costs associated with items or services that are directly related and integral to performing a procedure or furnishing a service have been packaged into each procedure or service within an APC group with the exception of: (1) New temporary technology APCs for certain approved services that are structured based on cost rather than clinical homogeneity; and (2) separate APCs for certain medical devices, drugs, biologicals, radiopharmaceuticals and devices of brachytherapy under transitional pass-through provisions. TRICARE is adopting Medicare’s classification system, along with its nationally established APC payment amounts as prescribed in section 1833(t) of the Social Security Act and in its accompanying Medicare regulation (42 CFR part 419) for reimbursement of hospital outpatient services, to the extent practicable, in accordance with 10 U.S.C. 1079(j)(2), with the realization that there will be subtle differences occurring between the TRICARE and Medicare OPPTS methodologies based on differences in the age and general health of the populations they serve (i.e., it can be assumed that the TRICARE population is younger and healthier than the population being served by Medicare). For example, TRICARE has

already found it necessary to develop two new TRICARE specific APCs, one for maternity observation stays (T0002) and the other for a half-day partial hospitalization program (T0001) to accommodate its unique benefit structure and beneficiary population. There may also be subtle differences in the inpatient-only procedure listings being maintained by the two programs since some of the Medicare inpatient-only procedures may be determined by TRICARE, upon medical review, to be safe for administration in an outpatient setting due to its younger, healthier population. This may require the development of additional APC groups, along with nationally established payment amounts based on their median costs from the previous year’s claims history.

The payment rate for each APC is calculated by multiplying the APC’s relative weight by the conversions factor. Weights are derived based on median hospital costs for services/procedures assigned to the hospital outpatient APC groups. Billed charges for items integral to performing the major procedure or visit, which include packaged HCPCS codes (i.e., codes with SI = “N”) and revenue codes appearing on the same claim, are converted to costs by multiplying each revenue center charge by the appropriate hospital-specific CCR. Centers for Medicare and Medicaid Services (CMS) currently use a four-tiered hierarchy of cost center CCRs to match a cost center to every possible revenue code appearing in the outpatient claims, with the top tier being the most common cost center and the lowest tier being the default CCR. If a hospital’s cost center CCR was deleted by trimming, another cost center CCR in the revenue hierarchy can be applied. If no other department CCR can be applied to the revenue code on the claim, CMS uses the hospital’s overall CCR for the revenue code.

The costs of the above services/procedures are then standardized for geographic wage variations by dividing

the labor-related portion of the operating and capital costs (currently estimated at 60 percent on the average for each billed item) by the hospital inpatient prospective payment system (IPPS) wage index. The standardized labor-related cost and the nonlabor-related cost component for each billed item are summed to derive the total standardized cost for each separately payable HCPCS code. Extreme costs outside three standard deviations from the geometric mean will be eliminated prior to calculating the median cost for each separately payable HCPCS code. The median costs of these procedures will then be mapped to their assigned APCs, and the median costs of those assigned procedures will be used in establishing the overall APC median cost.

The relative payment weights are calculated for each APC by dividing the median cost of each APC by the median cost for APC 0606 (Level 3 Clinic Visit), which is \$83.88 for CY 2007, as a reconfiguration of the visit APCs. APC 0606 was chosen in order to maintain consistency in using a median for calculating unscaled weights representing the median cost of some of

the most frequently provided services. The relative payment weights were further adjusted by 1.364598352 for budget neutrality, based on a comparison of aggregate payments using CY 2006 relative weights to aggregate payments using the CY 2007 final relative weights.

The other component used in establishing national APC payment amounts is the conversion factor, updated on an annual basis in accordance with section 1833(t)(3)(C)(iv) of the Social Security Act, which provides for CY 2007 an updated amount equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. The market basket increase update factor of 3.4 percent for CY 2007, along with the required wage index budget neutrality adjustment of approximately 0.999331979, the adjustment of 0.04 percent for the difference in the pass-through set-aside, and the adjustment for the rural payment adjustment for rural SCHs (including EACHs) of 0.999975941, resulted in a standard

conversion factor for CY 2007 of \$61.468.

The national unadjusted APC payment rates that were calculated by multiplying the CY 2007 scaled weight for each APC by the final CY 2007 conversion factor apply to all the services that are classified within the APC group. These national rates (i.e., the unadjusted national rates for both APCs and the HCPCS to which OPSS payment was assigned) are listed on TMA's OPSS Web site at <http://www.tricare.mil/opss>.

o *Determination of Payment.* A payment status indicator (SI) is provided for every code in the HCPCS to identify how the service or procedure described by the code would be paid under the hospital outpatient prospective payment system (OPSS); i.e., it indicates if a service represented by a HCPCS code is payable under the OPSS or another payment system, and also which particular OPSS payment policies apply. One, and only one, SI is assigned to each APC and to each HCPCS code. Following are the CY 2007 payment status indicators, along with a description of the particular services each indicator identifies.

TABLE 8.—CY 2007 PAYMENT STATUS INDICATORS FOR HOSPITAL OPSS

Indicator	Description	OPSS payment status
A	Services paid under some payment method other than OPSS (e.g., payment for non-implantable prosthetic and orthotic devices, DME, ambulance services, and individual professional services).	Not paid under OPSS. Paid by contractors under a fee schedule or payment system other than OPSS.
B	More appropriate code required for TRICARE OPSS	Not paid under OPSS.
C	Inpatient procedures	Not paid under OPSS. Admit patient. Bill as inpatient.
E	Items or services not covered by TRICARE	Not paid under OPSS.
F	Acquisition of corneal tissue, certain CRNA services, and Hepatitis B vaccines.	Not paid under OPSS. Paid on allowable charge basis.
G	Pass-through drugs and biologicals	Paid separate APCs under OPSS.
H	(1) Pass-through device categories	(1) Separate cost-based pass-through payment; not subject to cost-share/co-payment.
	(2) Brachytherapy sources	(2) Separate cost-based non-pass-through payment.
	(3) Radiopharmaceutical agents	(3) Separate cost-based non-pass-through payment.
K	Non-pass-through drugs and biologicals and blood and blood products.	Paid separate APCs under OPSS.
N	Packaged incidental items and services	Packaged into the primary procedure APC payment amount to which the incidental item or service is normally associated.
P	Partial hospitalization	Per diem APC payments for both half-day and full-day partial hospitalization programs.
Q	Services either separately payable or packaged	Paid under OPSS; services either packaged or separately payable depending on the specific circumstances of the HCPCS billing. OCE logic will be applied in determining if the services will be packaged or separately payable.
S	Significant procedures allowed under the OPSS for which multiple procedure reduction does not apply.	Paid under OPSS; separate APC payment.
T	Surgical services allowed under OPSS with multiple procedure payment reduction.	Paid under OPSS; separate APC payment.
V	Medical visits (including clinic or emergency department visits)	Paid under OPSS; separate APC payment.
W	Invalid HCPCS or invalid revenue code with blank HCPCS	Not paid under OPSS.
X	Ancillary services	Paid under OPSS; separate APC payment.
Z	Valid revenue code with blank HCPCS and no other SI assigned	Not paid under OPSS.
TB	Reimbursement not allowed for CPT/HCPCS code submitted	Not paid under OPSS.

○ *Adjustments for Specific Hospital Payment.* The hospital DRG wage adjustment factor will be used to adjust the portion of the payment rate that is attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions, with the exception of APCs with SIs “K” and “G” because of the inseparable, subordinate status of the outpatient department within the overall hospital setting. The OPSS will also adhere to the same wage index changes as the TRICARE-DRG based payment system, except the effective date for changes will be January 1 of each year instead of October 1. This way only one wage index file will have to be maintained for both the OPSS and DRG-based payment systems. Following are the steps taken in achieving this adjustment for APCs in which multiple procedure discounting is not applied:

Step 1. Calculate 60 percent (labor-related portion) of the national unadjusted payment rate.

Step 2. Determine the wage index area in which the hospital is located and identify the wage index that applies to the specified hospital. The wage index values assigned to each hospital area reflect the new geographic statistical areas as a result of revised OMB standards (urban and rural) to which hospitals are assigned for FY 2007 under the IPSS.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined in Step 1 that represents the labor-related portion of the national unadjusted payment rate.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add the amount to the resulting product in step 4. The result is the wage index adjusted payment rate for the relevant wage index area in which the hospital is located.

Step 6. If the provider is a Sole Community Hospital (SCH), multiply the wage adjusted payment rate by 1.071 to calculate the total payment. This adjustment will apply to all services and procedures paid under the OPSS (i.e., SIs “P,” “S,” “T,” “V,” and “X”), excluding drugs, biologicals and services paid subject to pass-through payment (i.e., SIs “G,” “H,” and “K”).

Applicable deductibles and/or cost-sharing/copayment amounts will be subtracted from the wage adjusted APC

payment rate based on the eligibility status of the beneficiary at the time outpatient services were rendered (i.e., those deductibles and cost-sharing/copayment amounts applicable to Prime, Extra, and Standard beneficiary categories). TRICARE will retain its current hospital outpatient deductibles, cost-sharing/copayment amounts (refer to Tables 1 and 2 above) and catastrophic loss protection under the OPSS. The ASC cost-sharing provision (i.e., assessment of a single copayment for both the professional and facility charge for a Prime beneficiary) will be adopted as long as it is administratively feasible. This will not apply to Extra and Standard beneficiaries since their cost-sharing is based on a percentage of the total allowed amount.

○ *Additional APC Payment Adjustments.* OPSS payment amounts are discounted when more than one surgical procedure (SI= T) is performed during a single operative session. Under these circumstances, TRICARE will reimburse the full payment and the beneficiary will pay the full cost-share/copayment for the procedure having the highest payment rate, while the remaining surgical procedure payments will be reduced by 50 percent, along with the beneficiary associated cost-share/copayment to reflect the savings associated with having to prepare the patient only once and the incremental costs associated with anesthesia, operating and recovery room use, and other services required for the second and subsequent procedures. A 50 percent discount will also be applied to the OPSS payment amounts and beneficiary copayments/cost-shares for procedures terminated before anesthesia is induced, as identified by modifiers – 73 (Discounted Outpatient Procedure Prior to Anesthesia Administration) and – 52 (Reduced Services). Full payment will be received for a procedure that is started but discontinued after the induction of anesthesia as reported by modifier – 74 (Discounted Procedure). In this case, payment would recognize the costs incurred by the hospital to prepare the patient for surgery and the resources expended in the operating room and recovery room of the hospital. Discounting will also be applied to conditional, inherent, and independent bilateral procedures.

An additional payment is provided for outpatient services for which a hospital's charges, adjusted to cost, exceed the sum of the wage adjusted APC rate plus a fixed dollar threshold and a fixed multiple of the wage adjusted APC rate. Only line item services with SIs “P,” “S,” “T,” “V,” or “X” will be eligible for outlier payment

under OPSS. No outlier payments will be calculated for line item services with SIs “G,” “H,” “K,” and “N,” with the exception of blood and blood products.

For CY 2007, the outlier threshold is met when the cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus the \$1,825 fixed-dollar threshold. The fixed-dollar threshold was added to better target outliers to those high cost and complex procedures where a very costly service could present a hospital with significant financial loss. If a provider meets both of these conditions (i.e., the multiple threshold and the fixed-dollar threshold), the outlier payment is calculated at 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate. The hospital would receive the normal APC payment rate along with the additional outlier amount. For example, suppose a hospital charges \$26,000 for a procedure for which the APC adjusted amount is \$3,000 and the overall facility CCR is 0.30. The estimated cost to the hospital is \$7,800 ($0.30 \times \$26,000$). In order to determine whether the procedure is eligible for outlier payment, it first must be determined whether the cost for the service exceeds both the APC multiple outlier cost threshold of \$5,250 ($1.75 \times \$3,000$) and the fixed-dollar threshold of \$4,825 ($\$3,000 + \$1,825$). Since the estimated cost to the hospital (\$7,800) exceeds both threshold amounts, the hospital would be eligible for 50 percent of the difference, which in this case would be \$1,275 ($\$7,800 - \$5,250/2$).

○ *Payment Hierarchy for Non-OPSS Procedures.* If the outpatient procedure is not assigned an APC payment amount (i.e., is not assigned SI “G,” “H,” “K,” “P,” “S,” “T,” “V,” or “X”), but may be reimbursed under an existing TRICARE fee schedule or other prospectively determined rate (i.e., procedures assigned to SI “A”), the following hierarchy will be used in pricing the procedure. The PRICER will first look to see if there is an appropriate CMAC available for pricing. If a CMAC cannot be found, it will then look to the Durable Medical Equipment Claims: Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule for pricing. If a DMEPOS fee schedule rate is not available for pricing, it will turn to statewide prevailings. If a statewide prevailing cannot be found, the PRICER will reimburse the procedure at the billed charge.

VI. Military Readiness/Contingency Options for Payment Under OPSS

In recognition of the Department's requirement to support military readiness and contingency operations, and in response to recent congressional concerns regarding same, the agency has developed two options for implementation of OPSS. The first option involves a three-year transitional implementation of payment adjustments that may be utilized to limit the decline in payments under OPSS for TRICARE network hospitals that are in close proximity to military bases and treat a disproportionate share of military family members and/or hospitals that provide essential network specialty care. These temporary payment adjustments would target TRICARE network hospitals that are most vulnerable to OPSS revenue reductions and that are essential for continued military readiness and support of contingency operations.

This adjustment would increase payment for primary care and emergency room visits to hospital outpatient departments (HOPDs) over a 3-year transitional period. Primary care and emergency room visits to HOPDs are categorized into 10 APC categories (APC codes 604–609 and 613–616) which represent over 600,000 hospital visits annually. On average, about one quarter of the revenues from TRICARE for HOPD services are for these 10 codes, representing the biggest payment reduction under OPSS. Under this transitional payment adjustment, the APC payment levels for network hospitals for the 5 clinical visit APCs would be set at 130 percent of the Medicare APC level, while the 5 emergency room (ER) visit APCs would be increased by 150 percent in the first year of OPSS implementation. In the second year, the APC payment levels would be set at 120 percent of the Medicare APC level for clinic visits and at 130 percent for ER APCs. In the third year, the APC visit amounts would be set at 110 and 120 percent, respectively, and in the fourth year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical. Two sets of adjustment factors (i.e., one for clinic visits and the other for ER visits) are being used since revenue cuts for ER visits are generally greater than those associated with clinic visits. Transitional payment adjustments for these 10 visit codes would buffer the initial revenue reductions which will be experienced upon implementation of TRICARE's OPSS, providing hospitals with sufficient time to adjust and budget for potential revenue reductions for

hospitals most vulnerable to implementation of OPSS.

The second option involves authority for the Director, TRICARE Management Activity, or a designee, under provisions of this rule to adopt, modify, and/or extend temporary adjustments to OPSS payments for TRICARE network hospitals deemed essential for military readiness and support during contingency operations. Upon a determination by the TMA Director, or designee, at any time following implementation that it is impracticable to support military readiness or contingency operations by making OPSS payments in accordance with the same reimbursement rules implemented by Medicare, a temporary deviation may be granted. This will ensure the availability of adequate civilian healthcare resources necessary to meet all ongoing military readiness and contingencies. The criteria for adopting, modifying and/or extending temporary adjustments to OPSS payments under this authority shall be issued through TRICARE policies, instructions, procedures and guidelines as deemed appropriate by the Director, TRICARE Management Activity, or a designee, for those network hospitals essential for continued military readiness and deployment in a time of contingency operations.

VII. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review"

Section 801 of title 5, United States Code (U.S.C.), and Executive Order (E.O.) 12866 requires certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. It has been certified that this rule is not an economically significant rule, however, it is a regulatory action which has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866.

Section 202, Public Law 104-4, "Unfunded Mandates Reform Act"

It has been certified that his rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

The Regulatory Flexibility Act (RFA) requires each Federal agency prepare,

and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This is not a major rule under 5 U.S.C. 801 since the projected reduction in TRICARE payments to affected hospitals would be below the \$100 million threshold. The estimates of reduction are based on historical TRICARE costs and an assessment of potential users times average benefit costs per person for implementation of the new prospective payment system. Following is a projected government impact analysis, reflecting an overall cost savings of \$81.0 million dollars for the first 12 months of implementation based on 2006 TRICARE claims data. This rule also

IMPACT ASSESSMENT OF IMPLEMENTATION OF OPSS

[\$Millions—first 12 months]

Projected Cost Savings Based On Current Data	\$231.0
Offsets to Cost Savings:	
Application of Existing Cost-Sharing	(12.0)
Reduction/Rebalancing of Discounts	(72.0)
Transitional Adjustments	(44.0)
Military Contingency Adjustments	(8.0)
Effects of OHI	(14.0)
Net Cost Savings*	81.0

does not require a regulatory flexibility analysis, as the significant policy action was taken by Congress and the rule merely puts it into effect. The policy of the Regulatory Flexibility Act that agencies adequately evaluate all potential options for an action does not apply when Congress has already dictated the action. In addition, it has been certified that this proposed rule will not significantly affect a substantial number of small entities.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This rule will not impose significant additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511). Existing information collection requirements of the TRICARE and Medicare programs will be utilized.

Executive Order 13132, "Federalism"

This proposed rule has been examined for its impact under E.O. 13132 and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between

the national government and the States, or on the distribution of power and responsibilities among the various levels of government; therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. Chapter 55.

2. Section 199.2(b) is amended by adding definitions for Ambulatory Payment Classifications (APCs) and TRICARE Outpatient Prospective Payment System (OPPS) and placing them in alphabetical order to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Ambulatory Payment Classifications (APCs). Payment of services under the TRICARE OPSS is based on grouping outpatient procedures and services into ambulatory payment classification groups based on clinical and resource homogeneity, provider concentration, frequency of service and minimal opportunities for upcoding and code fragmentation. Nationally established rates for each APC are calculated by multiplying the APC's relative weight derived from median costs for procedures assigned to the APC group, scaled to the median cost of the APC group representing the most frequently provided services, by the conversion factor.

TRICARE Outpatient Prospective Payment System (OPPS). OPPS is a hospital outpatient prospective payment system, based on nationally established APC payment amounts and standardized for geographic wage differences that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service in a hospital outpatient department.

* * * * *

§ 199.4 [Amended]

3. Section 199.4 is proposed to be amended by removing paragraph (c)(3)(i)(C)(1) and redesignating paragraphs (c)(3)(i)(C)(2) and (c)(3)(i)(C)(3) as (c)(3)(i)(C)(1) and (c)(3)(i)(C)(2).

4. Section 199.14 is amended by revising paragraphs (a)(2)(ix)(A); redesignating paragraphs (a)(5)(i) through (a)(5)(xii) as (a)(5)(i)(A) through (a)(5)(i)(L); adding new paragraphs (a)(5)(i) introductory text and (a)(5)(ii); and revising paragraph (d)(1) to read as follows:

§ 199.14 Provider reimbursement methods.

(a) * * *
(2) * * *
(ix) * * *

(A) In general. Psychiatric and substance use disorder rehabilitation partial hospitalization services authorized by § 199.4(b)(10) and (e)(4) and provided by institutional providers authorized under § 199.6(b)(4)(xii) and (b)(4)(xiv) are reimbursed on the basis of prospectively determined, all-inclusive per diem rates pursuant to the provisions of paragraph (a)(2)(ix)(C) of this section, with the exception of hospital-based psychiatric and substance use disorder rehabilitation partial hospitalization services which are reimbursed in accordance with provisions of paragraph (a)(5)(ii) of this section. The per diem payment amount must be accepted as payment in full for all institutional services provided, including board, routine nursing service, ancillary services (includes music, dance, occupational and other such therapies), psychological testing and assessment, overhead and any other services for which the customary practice among similar providers is included as part of the institutional charges.

* * * * *

(5) * * *

(i) Outpatient Services Not Subject to Hospital Outpatient Prospective Payment System (OPPS). The following are payment methods for outpatient services that are either provided in an OPPS exempt hospital or paid outside the OPPS payment methodology under existing fee schedules or other prospectively determined rates in a hospital subject to OPPS reimbursement.

* * * * *

(ii) Outpatient Services Subject to OPPS. Outpatient services provided in hospitals subject to Medicare OPPS as specified in 42 CFR 413.65 and 42 CFR 419.20 will be paid in accordance with the provisions outlined in sections 1833(t) of the Social Security Act and its implementing Medicare regulation (42 CFR Part 419). Under the above governing provisions, CHAMPUS will recognize to the extent practicable, in accordance with 10 U.S.C. 1079(j)(2), Medicare's OPPS reimbursement

methodology to include specific coding requirements, ambulatory payment classifications (APCs), nationally established APC amounts and associated adjustments (e.g., discounting for multiple surgery procedures, wage adjustments for variations in labor-related costs across geographical regions and outlier calculations). During the transition to OPSS, temporary deviations from Medicare's statutory and/or regulatory requirements and future changes arising from its continuing experience with OPSS may be granted for any TRICARE network hospital by the Director, TRICARE Management Activity (TMA), or a designee, to accommodate CHAMPUS' unique benefit structure and beneficiary population. In addition, the Director, TMA, or a designee, may at any time after implementation adopt, modify and/or extend temporary adjustments to OPSS payments for TRICARE network hospitals deemed essential for military readiness and deployment in time of contingency operations. Any temporary adjustment to OPSS payments shall be made only on the basis of a determination that it is impracticable to support military readiness or contingency operations by making OPSS payments in accordance with the same reimbursement rules implemented by Medicare. The criteria for adopting, modifying, and/or extending deviations and/or adjustments to OPSS payments shall be issued through TRICARE policies, instructions, procedures and guidelines as deemed appropriate by the Director, TMA, or a designee.

* * * * *

(d) * * *

(1) In general. CHAMPUS pays institutional facility costs for ambulatory surgery on the basis of prospectively determined amounts, as provided in this paragraph, with the exception of ambulatory surgery procedures performed in hospital outpatient departments, which are to be reimbursed in accordance with the provisions of paragraph (a)(5)(ii) of this section. This payment method is similar to that used by the Medicare program for ambulatory surgery. This paragraph applies to payment for freestanding ambulatory surgical centers. It does not apply to professional services. A list of ambulatory surgery procedures subject to the payment method set forth in the paragraph shall be published periodically by the Director, TRICARE Management Activity (TMA). Payment to freestanding ambulatory surgery centers is limited to these procedures.

* * * * *

March 21, 2008.

L. M. Bynum,

*Alternate OSD Federal Register Liaison
Officer, Department of Defense.*

[FR Doc. E8-6514 Filed 3-31-08; 8:45 am]

BILLING CODE 5001-06-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R08-OAR-2007-0645; FRL-8549-3]

Approval and Promulgation of Air Quality Implementation Plans; Wyoming; Revisions to New Source Review Rules

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve the State Implementation Plan (SIP) revisions submitted by the State of Wyoming on December 13, 2006. The proposed revisions modify the State's Prevention of Significant Deterioration (PSD) regulations to address changes to the federal NSR regulations promulgated by EPA on December 31, 2002, and reconsidered with minor changes on November 7, 2003. The State of Wyoming has a federally-approved PSD program for new and modified sources impacting attainment areas in the State. Wyoming does not have a Nonattainment New Source Review (NNSR) program. This action is being taken under section 110 of the Clean Air Act.

DATES: Comments must be received on or before May 1, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R08-OAR-2007-0645, by one of the following methods:

- <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *E-mail:* videtich.callie@epa.gov and mastrangelo.domenico@epa.gov.

- *Fax:* (303) 312-6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).

- *Mail:* Callie Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P-AR, 1595 Wynkoop Street, Denver, Colorado 80202-1129.

- *Hand Delivery:* Callie Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P-AR, 1595 Wynkoop, Denver, Colorado 80202-1129. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:55 p.m.,

excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R08-OAR-2007-0645. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through <http://www.regulations.gov> your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly-available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Air and Radiation Program, Environmental Protection Agency

(EPA), Region 8, Mailcode 8P-AR, 1595 Wynkoop, Denver, Colorado 80202-1129.

EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Domenico Mastrangelo, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P-AR, 1595 Wynkoop, Denver, Colorado 80202-1129, (303) 312-6436, mastrangelo.domenico@epa.gov.

SUPPLEMENTARY INFORMATION:

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA*, *we*, *us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *State* or *Wyoming* mean the State of Wyoming unless the context indicates otherwise.

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What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through <http://www.regulations.gov> or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in

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