PART 1952—[AMENDED]

1. The authority citation for part 1952 continues to read:

Authority: Secs. 8, 18 Pub. L. 91-596, 84 Stat. 1608 Occupational Safety and Health Act of 1970 (29 U.S.C. 657, 667); Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736), as applicable.

2. New paragraphs (b) through (f) are added to § 1952.316 of Subpart Y to read as follows:

§ 1952.316 Changes to approved plans.

(a) Regulations.

(1) The State's regulation on the Division of Occupational Safety and Health's Access to Employee Medical Records, and amendments to State regulations covering the Labor and Industrial Relations Appeals Board; General Provisions and Definitions; Recording and Reporting Occupational Injuries and Illnesses; Inspections, Citations, and Proposed Penalties; and Variances, promulgated by the State through March 22, 1991, were approved by the Assistant Secretary on February 20, 1995.

(b) Legislation.

(1) An amendment to the Hawaii Occupational Safety and Health Law, enacted in 1987, which expands the type of information that is protected from disclosure in any discovery or civil action arising out of enforcement or administration of the law, was approved by the Assistant Secretary on February 20, 1995.

(c) Consultation Manual. The State's Consultation Policies and Procedures Manual was approved by the Assistant Secretary on February 20, 1995.

(d) Reorganized Plan. The reorganization of the Hawaii plan was approved by the Assistant Secretary on February 20, 1995.

SUMMARY: This final rule is to reform CHAMPUS quality of care standards and reimbursement methods for inpatient mental health services. The rule updates existing standards for residential treatment centers (RTC's) and establishes new standards for approval as CHAMPUS-authorized providers for substance use disorder rehabilitation facilities (SUDRFs) and partial hospitalization programs (PHPs); implements recommendations of the Comptroller General of the United States that DoD establish cost-based reimbursement methods for psychiatric hospitals and residential treatment facilities; adopts another Comptroller General recommendation that DoD remove the current incentive for the use of inpatient mental health care; and eliminates payments to residential treatment centers for days in which the patient is on a leave of absence.

DATES: This rule is effective April 6, 1995, except amendments to § 199.4 which are effective October 1, 1995.

ADDRESSES: Office of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Office of Program Development; Aurora, Colorado 80045-6900.

FOR FURTHER INFORMATION CONTACT: CAPT Deborah Kamin, NC, USN, Office of the Assistant Secretary of Defense (Health Affairs), (703) 697-8975.

Questions regarding payment of specific claims should be addressed to the appropriate CHAMPUS contractor.

SUPPLEMENTARY INFORMATION: Provisions of this rule apply to the CHAMPS program (Civilian Health and Medical Program of the Department of Veterans Affairs) in the same manner as they apply to CHAMPUS.

I. Introduction

Quality assurance and cost effectiveness of mental health care services under CHAMPUS continue to be major reform issues for the Defense Department and Congress. In recent years, a series of DoD initiatives, legislative and regulatory actions, and Congressional hearings have spotlighted both progress made and the need for more improvement.

Two recent Comptroller General Reports are indicative of the importance of these issues and the need for reform. The first of these, "Defense Health Care: Additional Improvements Needed in CHAMPUS's Mental Health Program," GAO/HRD-93-34, May 1993, stated that, although DoD has taken actions to improve the program "several problems persist." The Report (hereafter referred to as "GAO Report #1") elaborated:

For example, reviews of medical records have identified numerous instances of poor medical record documentation, potentially inappropriate admissions, excessive hospital stays, and poor-quality care. Also, inspections of RTCs (Residential Treatment Centers) continue to reveal significant health and safety problems, and corrective actions often take many months.

Moreover, DoD pays considerably higher rates for comparable services than do other public programs.

GAO Report #1, p. 2. The Report referenced the General Accounting Office's 1991 Congressional testimony regarding CHAMPUS mental health care and inspections of residential treatment facilities conducted for DoD since then:

Inspections conducted since our 1991 testimony have identified some of the same problems we described then: unlicensed and unqualified staff, inappropriate use of seclusion and medication, inadequate staff-to-patient ratios, and inadequate documentation of treatment.

The principal conclusions of this Report were: (1) "Standards, which include termination for noncompliance, should be specified and termination proceedings, time frames, and reinspection provisions * * * should be adopted;" and (2) because "DoD reimburses psychiatric hospitals and RTCs at higher rates than do other government payers, it should modify its payment system to more closely resemble other programs such as Medicare," GAO Report #1, p. 9.


Investigations to date have revealed that federal health programs have been subject to fraudulent and abusive psychiatric hospital...
practices, but apparently to a lesser extent than private insurers. Some federal control weaknesses do exist which have resulted in unnecessary hospital admissions, excessive stays, and sometimes inadequate quality of care. DOD has also identified numerous instances of quality problems and unnecessary hospital admissions. GAO Report #2, pp. 9-10.

These two recent Comptroller General Reports, as well as a substantial body of other documentation, highlight the need for a very active quality assurance program. As discussed further below, two primary issues are presented. First, there is a need for clear, specific standards for psychiatric facilities on staff qualifications, clinical practices, and all other aspects directly impacting the quality of care. These standards are needed for residential treatment facilities, substance use disorder rehabilitation facilities, and partial hospitalization programs. These standards will bring those facilities, a minority in the industry, that have been unwilling or unable to comply with necessary requirements, up to an appropriate standard of care.

The second key issue is reimbursement rates. As documented by the Comptroller General, CHAMPUS needs to discontinue payment rates based on historical billed charges and establish payment rates based on the actual costs of providing the services. This final rule puts into place as part of the CHAMPUS regulation comprehensive quality of care certification standards for residential treatment facilities, substance abuse rehabilitation facilities, and partial hospitalization programs. It also modifies current payment methodologies, which will result in rates approximating the costs of providing services in psychiatric hospitals and moving toward cost levels for residential treatment facilities. In addition, the rule addresses several other issues, addressed below.

II. Provisions of Rule to Reform Certification Standards for Mental Health Care Facilities

The Comptroller General's call for stronger management by CHAMPUS to assure quality of care in the mental health programs was based partially on a review of serious abuses on the part of some providers. The GAO presented audit findings identifying program weaknesses. Texas, which is one of four states which account for more than half of CHAMPUS mental health hospital costs, surfaced in recent audits as number one in CHAMPUS mental health expenditures. Of particular concern are practices described during 1991 hearings conducted before the Texas state senate and summarized in GAO Report #2. In over 80 hours of testimony, 175 witnesses—some beneficiaries of federal programs—brought forth allegations which included exorbitant charges for care never rendered; kickbacks for patient referrals; restraint of voluntary patients against their will; discharge of patients upon exhaustion of benefits, regardless of their condition; and isolation of family from patients, including withholding of visitation and mail/telephone privileges. While privately insured patients are the most common target of unethical practices, increasing benefit limits and payment controls by private third party payers may place federal programs at increased risk for fraudulent practices. GAO auditors point out that, because CHAMPUS reimburses mental health at rates higher than other federal programs, it may be particularly vulnerable to the minority of unethical providers seeking additional revenue sources.

In recent years, the Department has worked to strengthen oversight and monitoring of mental health programs, particularly with respect to treatment of children and adolescents. Through the contract with HMS, and other efforts, CHAMPUS has paid much more attention to care in RTCs. In [insert 30 days after date of publication] of 1992, Health Management Strategies International (HMS) expressed specific concerns about several of the CHAMPUS-authorized residential treatment centers. Numerous quality of care issues surfaced during on-site facility visits to residential treatment centers where CHAMPUS beneficiaries were receiving care.

Here are several examples:

---Staff qualifications were deficient. In some cases, patient treatment was not being directed by qualified psychiatrists. At one facility, psychiatry residents were acting as facility medical directors. In some facilities, one psychiatrist may be responsible for as many as 90 children and their families, seriously limiting professional time available for individual attention. In some RTCs, group therapy was being conducted by child care workers with high school diplomas.

---Several facilities failed to individualize treatment plans. At one facility all treatment plans were the same, regardless of history, needs or problems. Similarly, some facilities were discovered to focus on one type of treatment to the exclusion of all other approaches. This was true regardless of whether or not patients responded to this type of treatment.

---In several facilities, registered nurses were not available on a full-time basis. For example, at one facility children were ordering their own medications “as needed” and medications were dispensed—without further evaluation—by untrained child care workers. In one instance a child who developed tachy dyskinesia (a motion disorder resulting from medication) was described by a child care worker as having a “nervous tic.”

---There was evidence of excessive use of restraints and seclusion as methods of behavioral management. Examples including placing children as young as three or four in restraint and seclusion. In one facility, seclusion was used 146 times in one month. The practice of zipping children into so-called “body bags” was employed by several facilities. Use of a body bag, which leaves an opening only for the head, carries risk of overheating to the point of lethal hyperthermia. One facility policy governing this practice did not require physician evaluation of the patient for 72 to 96 hours after the event.

---Certain RTCs employed unnecessary strip searches and other intrusive acts. Searches involve adult authority figures for forcing children between the ages of four and 18 to remove all clothing and submit to cavity searches. Cavity searches involve finger probes to the mouth, vagina, and rectum. Some facilities were requiring such searches whenever the patient returned from a pass or having a visitor. In many cases, children subjected to such searches were victims of abuse and, for some, these methods of search re-enact the original trauma.

These HMS case findings pointed out shortcomings in practices in some RTCs that can be addressed through improved standards. Although standards for residential treatment centers exist, they have evolved over time from attempts to address individual issues with incremental change. Further, existing CHAMPUS standards for residential treatment centers were written as supplements to standards employed by the Joint Commission on Accreditation of Hospitl Organizations (JCAHO). In recent years, the JCAHO has moved toward a more general set of facility standards, with less specific reference to unique requirements of medical specialties. The result has been that CHAMPUS standards—which were not
intended to stand alone—do not address the full spectrum of requirements and expectations for mental health facilities and providers.

Originally drafted in the late 1970s, CHAMPUS standards for RTCs have undergone multiple revisions to ensure they reflect currently accepted clinical practice. This rule incorporates revisions necessary to update existing standards. With shorter lengths of stay in acute care facilities, mental health patients are reaching residential treatment centers at earlier—and less stable—stages of treatment. Similar to trends in other medical specialties, the growing intensity of illness among inpatients has dictated a need for higher standards of care and increasing levels of professional supervision and treatment. Current CHAMPUS standards for RTCs must be updated to reflect more clearly professional skill levels and intervention strategies employed in today’s mental health environment.

Based on a clear record of problems among some institutional mental health providers and the shortcomings of current standards, DoD has developed a comprehensive, unified set of standards for residential treatment centers, partial hospitalization programs and substance use disorder rehabilitation facilities. This rule updates existing standards to reflect current mental health practices, account for policy shifts in the JCAHO, and communicate clearly CHAMPUS policy with regard to quality and scope of care provided to its beneficiaries.

The standards will work to prevent recurrence of problems such as those discussed by defining more completely and specifically quality indicators which will be used to judge care rendered in these facilities. Among areas addressed by the standards are:

Qualifications and authority of the clinical director. Standards require the clinical director of any RTC to have completed appropriate training and have at least five years’ experience in treating children and adolescents. In addition to oversight of all clinical care provided, standards for RTCs, substance abuse rehabilitation facilities and partial hospitalization programs outline specific requirements for clinical director participation in program development, peer review, quality monitoring and improvement and coordination with the governing body.

Adequate staffing with qualified professionals. Standards require written staffing plans. Specific information is provided concerning requirements for staffing levels and professional qualifications. The rule specifies 24 hours per day, seven days per week (or, in the case of partial hospitalization programs, during all hours of operation). Standards require that all clinical care provided under clinical supervision is the responsibility of a licensed or certified mental health professional. Additionally, there must be evidence to show that ultimate authority for management of the medical aspects of care is vested in a physician.

Patient rights and limitations on use of seclusion and restraint. Standards require provisions for protection of all individual patient rights, including civil rights, provided for under federal law and the laws of the state where the residential treatment center is located. Specific requirements address privacy, personal freedoms, contact with families and environmental safety. Detailed guidelines for use, supervision and medical monitoring of behavior management—including use of seclusion and restraint—are also provided.

Implementation of individualized treatment plans addressing each patient’s needs. Responsibility of development, supervision, implementation and assessment of written, individualized and interdisciplinary treatment plans is assigned to a qualified mental health professional. Treatment goals must be communicated to the family, must undergo regular review and must include specific, measurable and observable criteria for discharge.

Comprehensive evaluation system to guide an ongoing quality improvement program. Standards provide detailed expectations with respect to evaluation systems by which quality, efficiency, appropriateness and effectiveness of care, treatments, and services are provided. The evaluation system must involve all disciplines, services, and programs of the facility, including administrative and support activities. Responsibility for development and implementation of quality assurance and quality improvement programs rests with the clinical director and must support overall facility and philosophical assumptions and values.

The standards are designed to foster interdisciplinary communication and patient protection through involvement and oversight of the Governing Body, Chief Executive Officer, Clinical Director, and Professional Staff with respect to administrative, utilization review, and clinical activities. DoD has also strengthened standards for substance abuse treatment programs in a manner similar to residential treatment centers. For partial hospitalization, these standards occur as part of implementation of this new benefit, which became effective September 29, 1993.

This rule incorporates basic requirements governing CHAMPUS approval of facilities providing mental health services as residential treatment centers, as partial hospitalization providers, and substance use disorder rehabilitation facilities. More detailed definition of these basic standards have been issued under the authority of this regulation. It should be noted that only the requirements included in this final regulation have, by themselves, the force and effect of law. Additional detail in the more lengthy standards are extensions of the regulation. They establish the agency’s interpretations of the regulation and will serve as guidelines for compliance with the regulatory requirements. The complete standards are available to the public from the Office of CHAMPUS. These more lengthy standards are finalized coincident with issuance of this final regulation.

III. Provisions of Rule to Reform Payment Methods for Mental Health Care Facilities

This rule implements payment reforms in keeping with the Comptroller General’s recommendations regarding payment reform for mental health care facilities. The Comptroller General’s findings regarding current CHAMPUS payment rates are especially noteworthy. According to the report:

“...Our work indicates that DoD pays psychiatric facilities considerably more than other government programs do for comparable services.” GAO Report #1, p.6. The Comptroller General very accurately summarized the background of the current CHAMPUS payment methods for psychiatric hospitals and RTCs:

Although the current CHAMPUS system of per diem reimbursements has helped limit program cost increases for inpatient mental health, the per diem rates were based on providers’ billed charges, not their costs. The rates were based on billing data from a period when providers’ charges were not subject to controls and had just increased significantly. Before 1989 when no upper limit on rates existed, hospitals, and RTCs essentially set their own CHAMPUS payment rates. Before the per diem calculations, hospitals and RTCs increased significantly. For example, average daily charges per CHAMPUS inpatient day rose by 17 percent from fiscal years 1987 to 1988. One RTC boosted its daily charges from an average of $331 in fiscal year 1987 to $531 in June 1988—a 60% increase.

GAO Report #1, pp 6-7.

Because CHAMPUS payments are based on historical billed charges, they substantially exceed the facilities’ actual
costs and Medicare reimbursement rates. Based on an analysis of payments to a number of high CHAMPUS volume psychiatric hospitals, the Comptroller General concluded “The hospitals made large profits, on average, on CHAMPUS patients.” GAO Report #1, p. 7.

A similar pattern emerges on payment rates for RTCs. Using fiscal year 1991 data, the Comptroller General compared CHAMPUS payments to state-authorized daily rates for a number of RTCs in Florida and Virginia, and found that the average daily CHAMPUS rate was 36 percent more than the average state rate. RTC cost data were available for three RTCs in Texas, the state with the highest total CHAMPUS RTC costs. These data showed “an average profit margin of 27 percent.” Id., p. 8. The Comptroller General also stated that the index factor used to annually update CHAMPUS RTC per diems, the consumer price index for urban medical services (CPI–U), results in excessive increases. The GAO Report says the hospital market basket index factor that CHAMPUS and Medicare use for hospital payments “would be more appropriate than the CPI–U because it reflects increases in items hospitals pay for goods and services” rather than “increases in charges by health practitioners and facilities.” Id.

The problem of excessive payments also involves substance use disorder rehabilitation facilities, which continue to be paid by CHAMPUS billed charges. According to the Comptroller General:

These facilities set their own fees and can increase them freely—without controls over their charges. Some of the facilities are paid more on a daily basis than are psychiatric hospitals. Id.

Based on these findings, the Comptroller General recommended that the Secretary of Defense:

Establish a system of reimbursing psychiatric facilities, RTCs, and specialized treatment facilities based on a cost-based system similar to Medicare, adjusted appropriately for differences in beneficiary demographics, rather than the present per diem or billed charges system.

Id., p. 10.

Under the proposed rule, CHAMPUS payments to specialty psychiatric hospitals and units and residential treatment facilities would have gradually transitioned from the present system of per diem rates based on historical billed charges to a new system of per diem rates based on detailed facility cost reports. Comments from providers and the professional community pointed out the significant administrative complexity and costs associated with payments based on cost reporting. They proposed alternatives premised on adjustments to the current system. We have been persuaded by these comments and have made adjustments to current payment structures which, although not based on detailed facility cost reports, move CHAMPUS reimbursement rates significantly closer to the costs of delivering care in mental health facilities. This rule is based on the legal authority of 10 USC 1079(j)(2) which authorizes CHAMPUS to adopt payment methods for institutional providers similar to those applicable to Medicare. Under the final rule, CHAMPUS payments to specialty psychiatric hospitals and units will remain at FY95 rates for a two-year period beginning in FY96. Additionally, effective [insert 30 days after date of publication], the cap on per diem rates for these hospitals and units will be reduced from the current 80th percentile to the 70th percentile of all CHAMPUS base year charges in high volume hospitals. In FY98, payments will again be updated using the Medicare update factor for hospitals and units exempt from the Medicare Prospective Payment System.

With respect to RTCs, the rule makes similar adjustments to current payment methodologies. Per diem rates will remain at FY95 rates during fiscal years 1996 and 1997 and will be subject to a cap set at the 70th percentile of all CHAMPUS RTC per diem rates. RTCs with FY95 payment rates below the 30th percentile of all RTC CHAMPUS per diem rates will be exempt from the two year freeze in rates, instead continuing the current methodology for annual updates, up to the 30th percentile rate. Beginning in FY 1998, payment updates for all RTCs will be based on the Medicare update factor used for hospitals and units exempt from Medicare’s Prospective Payment System.

We estimate that payment methodologies under this rule will lead to aggregate expenditures which approximate average costs in psychiatric hospitals and units. While cost data are not generally available for RTCs, we estimate that under this rule, aggregate expenditures for RTC care will move closer to the level of average facility costs. We expect that over the next two years, we will obtain more data on actual RTC costs that will facilitate an assessment of whether additional regulatory changes should be considered.

With respect to substance use disorder rehabilitation facilities, this rule includes services provided by these facilities under the CHAMPUS DRG-based payment system. Currently, most substance use disorder rehabilitation services reimbursed by CHAMPUS are provided by facilities covered by the CHAMPUS DRG system or mental health per diem system. Only a small portion are provided by facilities that continue to be paid on the basis of billed charges. Under Medicare, these facilities are covered by the Medicare Prospective Payment System. Based on these factors, we believe inclusion of services provided by substance use disorder rehabilitation facilities should be included with the similar services already covered by the CHAMPUS DRG-based payment system. Partial hospitalization for substance use disorder rehabilitation will be reimbursed in the same manner as psychiatric partial hospitalization programs and the rates will be frozen at the FY95 level for fiscal years 1996 and 1997.

The payment system changes appear at the proposed revisions to section 199.14.

IV. Other Provisions of Rule

A. Therapeutic Leave of Absence Days

Currently, DoD pays RTCs for days a patient is away from the facility on an approved therapeutic leave of absence. The payment amount is 100% of the normal per diem for the first three days and 75% for additional days. It is our view that current rates are not justified by any costs to the facility. In addition, we are aware of guidance by a public payer that pays for leave days. Therefore, for care provided on or after July 1, 1995, this rule eliminates payment for days in which patients are on leave from the residential treatment center. We received a number of comments objecting to this on the grounds that therapeutic leave of absence are an important part of therapy, and should be recognized in reimbursement for services. We agree that therapeutic leaves are an important component in the patient’s overall treatment plan. However, because payment rates to RTCs under this rule will probably remain above average costs, we believe they will be sufficient to cover facility costs associated with reserving space for the patient’s return. This change applies only to RTCs; in psychiatric hospitals, substance use disorder rehabilitation facilities and partial hospitalization programs, leave days are not reimbursed by CHAMPUS.

B. Reversing Incentive for Inpatient Care

Another of the recommendations of the Comptroller General was to “reverse the financial incentives to use inpatient care by introducing larger copayments for CHAMPUS inpatient care.” GAO
Report #1, p. 10. This recommendation was based on the Comptroller General’s conclusion that there is a “bias toward patients receiving inpatient rather than outpatient care” because inpatient care is less expensive for dependents of active duty members than outpatient care. Id., p. 8-9. These beneficiaries currently pay approximately $10.00 per day or $25 per admission, whichever is greater, for inpatient care. For outpatient care, dependents of active duty members pay a $150 deductible (subject to a $300 family limit) and 20 percent of the allowable payment for individual professional services. Consequently, as a general matter, there is a financial incentive for beneficiaries to seek services on an inpatient, rather than an outpatient basis. Under 10 U.S.C. section 1079(i)(2), DoD has authority to establish mental health copayment requirements different from those for other CHAMPUS services. This rule establishes a per day copayment of $20 for dependents of active duty beneficiaries. This is based on the fact that an outpatient mental health visit is generally approximately $100, meaning that the copayment would be $20. Thus, an inpatient day would have a roughly equal beneficiary copayment as an outpatient visit (excluding the deductible). One commenter objected to this proposal. Based on DoD experience in delivery of mental health services, information collected during utilization management reviews, and reports from the GAO, our observation is that inpatient mental health care is more vulnerable to overutilization. We believe this modest increase in inpatient cost share addresses the Comptroller General’s recommendation, without impairing access to care or imposing hardship on beneficiaries. (With respect to avoidance of hardship, we note that the catastrophic cap for active duty dependents is $1000 per family per year.) To ensure adequate notice of providers and beneficiaries we have established an effective date of October 1, 1995 for the copayment requirements as stated above.

C. Equalization of Alcoholism and Drug Abuse Benefit Provisions

The frequent coexistence of alcohol and other chemical dependency or abuse suggests existing differences in benefit structures for treatment of alcohol and drug abuse should be eliminated. Effective for admissions on or after October 1, 1995, this rule includes treatment for both alcohol and drug abuse under a broad benefit package designed to include treatment of all substance use disorders.

IV. Additional Discussion of Public Comments

The proposed rule was published in the Federal Register June 29, 1994 (59 FR Page 33465). We received 23 comment letters, all of which were from providers and provider associations. Many of the comments were quite similar in wording and content. Some were very detailed and provided helpful insight and analysis. We thank those who provided input on this important issue. Significant items raised by commenters and our analysis of the comments are summarized below.

1. GAO Recommendations are Based Upon Outdated Information. We received a significant number of comments regarding our reliance on GAO reports for developing components of the proposed rule. Findings and recommendations provided in GAO reports relied to some extent on information gathered prior to realization of impact from several DoD quality, cost, and utilization management initiatives. Although substantial progress has been made as a result of earlier DoD efforts, ongoing utilization reviews and facility inspections continue to reveal departures from minimum CHAMPUS health and safety standards. Additionally, in many areas CHAMPUS continues to reimburse mental health services at significantly higher rates than many other third party payers. While the GAO analysis does not reflect the specific impact of recent initiatives, we believe the themes which emerged from their two reports remain current.

2. Specificity of Standards. Several commenters asserted that standards in the proposed rule were stated too broadly, leaving excessive room for interpretation and significant doubt as to the exact CHAMPUS requirements. Examples included the absence of stated requirements for specific staff-to-patient ratios and specific numbers for professional staffing. A similar comment was that terms like “essentially stabilized” and “reasonable and observable” treatment goals should be better defined. Commenters pointed out that specific standards which provide explicit requirements for all aspects of facility certification should be published for public review and comment prior to their application in the certification process. Response: A more detailed set of standards which provide the agency’s interpretation of standards contained in the rule are available from CHAMPUS. These were available for public review concurrent with publication of the proposed rule. The more detailed set of standards does not include specific requirements with respect to professional staff mix and staff-to-patient ratios because these will vary depending upon the characteristics of each facility. Consistent with regulatory standards in the rule and further described in the supplemental set available from OCHAMPUS, facilities should develop staffing patterns which reflect the characteristics and special needs of the population served, the patient census, and acuity/intensity of services required. With respect to specific definitions of terms, the unique requirements brought by each patient to the treatment setting necessarily require individual assessments, and professional judgment as to required level of care for the presenting symptoms or dysfunction and progress being made in addressing the patient’s specific needs. As such, we do not think it appropriate to establish a fixed list of criteria which must be applied to all patients.

3. Requirement for Physician Medical Directors. Several professional associations agreed with a requirement for physician medical directors, but associations representing non-physician mental health professionals objected to this. Several commenters recommended that current non-physician medical directors who are serving successfully should be exempt from this requirement.

Response: We have reconsidered the provisions in the proposed rule regarding physician oversight of all clinical services and agree that some of the language may have had the effect of unduly restricting the scope of practice for some providers, particularly doctoral level psychologists. We are also aware that widely recognized accrediting bodies, as well as several states, permit independent practice and hospital admitting privileges for certain non-physician providers. We have made revisions to language contained in the proposed rule to assure our standards are consistent with those of the Joint Commission on Accreditation of Hospital Organizations (JCAHO) and in keeping with changing practice patterns in the mental health community. Because treatment of mental health patients often includes pharmacologic intervention and evaluation and treatment for related or co-existing medical problems, physician management for these components of therapy is still required. We require medical management of patients to be under the supervision of a physician medical director. However, we do agree that oversight of the spectrum of clinical services provided in a program

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may be accomplished by doctoral level psychologists. We have added language which allows clinical directors to be physicians or, where permitted by law and by the facility, doctoral level psychologists who meet CHAMPUS requirements for individual professional providers.

4. Admitting Privileges for Non-physician Providers. A number of commenters objected to proposed language which limited admitting privileges to physicians. They argued that such limitations on certain non-physician mental health professionals, for example, master’s level clinical social workers, were unnecessarily restrictive and counter to legislative and industry trends toward an expanded scope of practice for these providers.

Response. We are aware of these changes and agree that, where permitted by law and by the facility, individuals who meet the CHAMPUS definition of individual professional mental health provider should be allowed to refer patients for admission. We have included language in the final rule which reflects this position.

5. Qualifications for CEOs. We received a number of comments suggesting that upgraded CEO requirements should not apply to individuals who, although they do not meet these standards, are currently serving in that capacity successfully.

Response. We believe the proposed standards for CEOs are appropriate, given the level and scope of responsibility attached to this position. However, we have included language which makes CEO qualification standards effective October 1, 1997. This should provide sufficient time for CEOs currently serving to undertake appropriate education and/or training to meet increased requirements.

6. Upgraded Standards are Costly and May Limit Treatment Options for CHAMPUS Beneficiaries. A number of commenters suggested that standards in the proposed rule were costly to implement. They argued that the increased cost of doing business, in addition to potential reductions in reimbursement caused by the rule’s payment reforms, may cause some providers to drop participation in CHAMPUS programs. Commenters viewed this as a particular problem for providers with limited CHAMPUS volume and those in rural areas. Some commenters argued that treatment methods not relying upon a medical model should be expanded, rather than changed to conform.

Response. Standards in this final rule are based upon accepted standards of practice, requirements of the Joint Commission on Accreditation of Healthcare Organizations, and input from Department consultants and the provider community. Although we have made significant progress in addressing quality issues raised by GAO’s study and highlighted in various forms, rapidly evolving practice patterns and treatment settings require CHAMPUS standards which reflect the character and pace of these changes. We believe these updated standards are necessary minimums which ensure CHAMPUS beneficiaries receive high quality care by appropriately trained professionals and staff. We believe the cost of upgraded standards will be accommodated within projected reimbursement rates. Facilities unable or unwilling to comply with these standards are not in a position to provide a proper standard of care.

7. Inclusion of Spiritual and Skills Assessments. A number of commenters questioned inclusion of new requirements for spiritual and skills assessments in the proposed standards and requested more detailed description of this requirement.

Response. Spiritual assessments are part of a comprehensive, multidisciplinary assessment which should address the full range of a patient’s clinical needs, including the impact of religious, ethnic and cultural influences upon the patient or family. Spiritual assessments, which occur in the context of obtaining a social history, are not new to the CHAMPUS standards and are included specifically in standards of other widely recognized accrediting bodies. A skills assessment is an important component of patient evaluation and includes activities of daily living, perceptual-motor skills, sensory integration factors, cognitive skills, communication skills, social interaction skills, creative abilities, vocational skills, and the impact of physical limitations. Activity services related to this assessment should be part of the therapeutic plan and should be supervised by a qualified mental health professional.

8. Requirement for Clinical Formulation. Several commenters questioned the need for clinical formulation in addition to development of a treatment plan. Additionally, several comments pointed out the standards allowed less time for completion of a treatment plan (10 days) than for development of the clinical formulation (14 days) which forms the basis of the treatment plan.

Response. The clinical formulation summarizes significant clinical interpretations from each of the multidisciplinary assessments, forming the basis for development of a master treatment plan. Interrelating findings from all assessments, the clinical formulation should clearly describe problems to be addressed in the treatment plan and indicate appropriate focus for the treatment strategies. We view this as a necessary, and not redundant, part of the process for developing a plan of care responsive to the unique requirements of each patient. We agree the proposed time requirements were not consistent with
this logic and have modified language accordingly.

Treatment plans must be completed within 10 days; clinical formulations no longer have a specific deadline, but must be completed prior to development of the interdisciplinary treatment plan.

9. Family Therapy. A large number of commenters raised the issue of logistical problems which prevent difficulty in accomplishing family therapy for CHAMPUS beneficiaries. An example frequently used was the deployment of military members which caused geographic separations. The argument was made that CHAMPUS should be more flexible regarding this requirement.

Response. Family therapy is not a new requirement for CHAMPUS beneficiaries. Geographical distance is not considered a reason to exclude the family from a treatment plan. For patients separated from their families by deployment or for other reasons, CHAMPUS allows geographically distant family therapy. If one or both parents reside a minimum of 250 miles from the RTC, the RTC has the flexibility to arrange for therapy with parents at the distant locality. If family therapy is clinically contraindicated, rationale for this conclusion must be documented in the patient’s record.

10. Annual Facility Evaluation. We received several comments arguing that a service specific annual evaluation was overly burdensome to facilities and “unheard of” outside academic settings.

Response. The proposed rule identified this requirement in the context of facility development of a strategic plan which contains specific goals and objectives for each program component or service and patient population served. Sound business practices would suggest regular organizational assessments to identify progress toward established performance and fiscal goals and objectives. The Department, as well as other accrediting agencies, expect governing bodies, through their CEOs, to provide sufficient resources to achieve the organization’s missions, goals, philosophy and objectives. Without a clear idea of resource allocation and performance across the range of services provided, it is unclear how facilities would evaluate outcomes, or the need for change. We do not agree that this is overly burdensome and find it surprising that such reviews would be limited only to academic settings.

11. Education Hours in Partial Hospitalization Programs. The proposed rule does not count educational hours towards total hours for “full day” partial hospitalization programs. Several commenters argued that, by not including time spent in school, those hours, combined with the required six hours for a full day partial program, result in an excessively long day for patients.

Response. Patients who meet the criteria for admission to partial hospitalization programs do not require a professionally managed milieu twenty-four hours a day, as do individuals in residential treatment programs. Therefore, we find it reasonable to expect that school hours may be accommodated separately from the hours spent in therapy and other treatment activities. Determinations as to school hours vs. time spent in treatment or other activities should be considered as part of an overall assessment of the patient’s needs and addressed in an individualized treatment plan.

12. Benefit Limitations. One provider association objected to CHAMPUS limits on treatment of substance use disorders, stating that these limits do not consider the chronic nature of this problem.

Response. Compared to many third party payers, CHAMPUS provides one of the more generous benefits for treatment of substance use disorders. We do recognize the chronic as well as individual nature of these problems and, consistent with that, provide an allowance for waivers of benefit limits when continued treatment is justified.

13. Burden and Expense Associated With Cost Based Reimbursement. The overwhelming majority of comments on the proposed cost based reimbursement system argued that the cost and administrative burden associated with these changes, for both the Department and providers, far exceeded any benefit to the government. A number of commenters pointed out that the GAO reports which provided impetus for payment reform were based on outdated information which did not reflect the results of earlier initiatives. Commenters suggested that, if DoD is required to implement additional cost containment measures, these could be accomplished more efficiently through adjustments to existing payment mechanisms.

Response. After full consideration of comments from the provider community, as well as our continuing analysis of costs associated with implementation of a cost based system for mental health, we agree that implementation of the proposed system is not appropriate at this time. Although cost containment and utilization management programs have achieved program savings, we agree with GAO conclusion that additional improvements are needed. While the GAO report may not reflect the full measure of cost and quality improvements achieved by earlier efforts, continuing program reviews and findings gathered through utilization management programs suggest CHAMPUS mental health programs require additional controls.

In keeping with comments from the industry and our own analysis, additional cost containment in CHAMPUS mental health programs will be accomplished through adjustments to current reimbursement mechanisms. For specialty psychiatric hospitals and units, payment will be held at FY95 rates for two years, beginning in FY96 and extending through FY97. Additionally, April 6, 1995, payment will be capped at a rate not to exceed the 70th percentile of payment rates in all high volume CHAMPUS psychiatric hospitals. We estimate that these adjustments will result in CHAMPUS payments at the level of average aggregate costs for psychiatric hospitals and units, thereby addressing concerns expressed by the GAO.

The general lack of availability with respect to RTC cost information presented some difficulties in our attempt to analyze impact of payment reforms for this community. In measures similar to those for psychiatric hospitals, RTC payment rates for facilities at or above the 30th percentile of all CHAMPUS RTC payment rates in FY95 will be held constant, with no additional update through fiscal years FY96 and FY97. Additionally, effective April 6, 1995, payments will be capped at level not to exceed the 70th percentile of all RTC rates nationally. For those RTCs paid at level below the 30th percentile of national CHAMPUS RTC rates, payments will be updated by the lesser of the CPI–U for medical care or the amount that brings the rate up to the 30th percentile level. The update factor for payments beginning in FY98 will be the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system. In order to determine the effectiveness of RTC cost containment measures established in this final rule, the Department will continue to explore avenues for obtaining accurate cost data for RTC services.

V. Rulemaking Procedures

This rule is a significant regulatory action as determined by the Office of Management and Budget. Also, we certify that this rule will not significantly affect a large number of
small entities within the meaning of the
Regulatory Flexibility Act.
This rule does not impose new
information collection requirements.

List of Subjects in 32 CFR Part 199
Claims, handicapped, health
insurance, and military personnel.

Accordingly, 32 CFR part 199 is
amended as follows:

PART 199—[AMENDED]
1. The authority citation for part 199
is revised to read as follows:

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

2. Section 199.4 is amended by
revising the heading of paragraph (e)(4),
paragraph (e)(4) introductory text,
(e)(4)(i), (e)(4)(ii), (e)(4)(iv), and the
introductory text of paragraph (f)(2)(ii),
and by adding new paragraphs (e)(4)(v),
and (f)(2)(ii)(D), as follows:

§ 199.4 Basic program benefits.

(e) * * * * *

(4) Treatment of substance use
disorders. Emergency and inpatient
hospital care for complications of
alcohol and drug abuse or dependency
and detoxification are covered as for any
other medical condition. Specific
coverage for the treatment of substance
use disorders includes detoxification,
rehabilitation, and outpatient care
provided in authorized substance use
disorder rehabilitation facilities.

(i) Emergency and inpatient hospital
services. Emergency and inpatient
hospital services are covered when
medically necessary for the active
medical treatment of the acute phases
of substance abuse withdrawal
(detoxification), for stabilization, and for
treatment of medical complications of
substance use disorders. Emergency and
inpatient hospital services are
considered medically necessary only
when the patient's condition is such
that the personnel and facilities of a
hospital are required. Stays provided for
substance use disorder rehabilitation in
a hospital-based rehabilitation facility
are covered, subject to the provisions of
paragraph (e)(4)(ii) of this section.

Inpatient hospital services also are
subject to the provisions regarding the
limit on inpatient mental health
services.

(ii) Authorized substance use disorder
treatment. Only those services provided
by CHAMPUS-authorized institutional
providers are covered. Such a provider
must be either an authorized hospital, or
an organized substance use disorder
treatment program in an authorized free-
standing or hospital-based substance
use disorder rehabilitation facility.
Covered services consist of any or all of
the services listed below. A qualified
mental health provider (physicians,
clinical psychologists, clinical social
workers, psychiatric nurse specialists)
(see paragraph (c)(3)(ix) of this section)
shall prescribe the particular level of
treatment. Each CHAMPUS beneficiary
is entitled to three substance use
disorder treatment benefit periods in his
or her lifetime, unless this limit is
waived pursuant to paragraph (e)(4)(v)
of this section. (A benefit period begins
with the first date of covered treatment
and ends 365 days later, regardless of
the total services actually used within
the benefit period. Unused benefits
cannot be carried over to subsequent
benefit periods. Emergency and
inpatient hospital services (as described
in paragraph (e)(4)(i) of this section) do
not constitute substance abuse treatment
for purposes of establishing the
beginning of a benefit period.)

(A) Rehabilitative care. Rehabilitative
care in a authorized hospital or
substance use disorder rehabilitative
facility, whether free-standing or
hospital-based, is covered on either a
residential or partial care (day or night
program) basis. Coverage during a single
benefit period is limited to no more than
inpatient stay (exclusive of stays
classified in DRG 433) in hospitals
subject to CHAMPUS DRG-based
payment system or 21 days in a DRG-
exempt facility for rehabilitation care,
unless the limit is waived pursuant to
paragraph (e)(4)(v) of this section. If the
patient is medically in need of chemical
detoxification, but does not require the
personnel or facilities of a general
hospital setting, detoxification services
are covered in addition to the
rehabilitative care, but in a DRG-exempt
facility for detoxification services are
limited to 7 days unless the limit is
waived pursuant to paragraph (e)(4)(v)
of this section. The medical necessity
for the detoxification must be
documented. Any detoxification
services provided by the substance use
disorder rehabilitation facility must be
under general medical supervision.

(B) Outpatient care. Outpatient
treatment provided by an approved
substance use disorder rehabilitation
facility, whether free-standing or
hospital-based, is covered for up to 60
visits in a benefit period, unless the
limit is waived pursuant to paragraph
(e)(4)(v) of this section.

(C) Family therapy. Family therapy
provided by an approved substance use
disorder rehabilitation facility, whether
free-standing or hospital-based, is
covered for up to 15 visits in a benefit
period, unless the limit is waived
pursuant to paragraph (e)(4)(v) of this
section.

* * * * *

(iv) Confidentially. Release of any
patient identifying information,
including that required to adjudicate a
claim, must comply with the provisions
of section 544 of the Public Health
Service Act, as amended, (42 U.S.C.
290dd–3), which governs the release of
medical and other information from
the records of patients undergoing treatment
of substance abuse. If the patient refuses
to authorize the release of medical
records which are, in the opinion of the
Director, CHAMPUS, or a designee,
necessary to determine benefits on a
claim for treatment of substance abuse
the claim will be denied.

(v) Waiver of benefit limits. The
specific benefit limits set forth in
paragraphs (e)(4)(i) of this section may
be waived by the Director, OCHAMPUS
in special cases based on a
determination that all of the following
criteria are met:

(A) Active treatment has taken place
during the period of the benefit limit
and substantial progress has been made
according to the plan of treatment.

(B) Further progress has been delayed
due to the complexity of the illness.

(C) Specific evidence has been
presented to explain the factors that
interfered with further treatment
progress during the period of the
benefit limit.

(D) The waiver request includes
specific time frames and a specific plan
treatment which will complete the
course of treatment.

* * * * *

(ii) Inpatient cost-sharing. Except in
the case of mental health services (see
paragraph (f)(2)(ii)(D) of this section),
deponents of active duty members of
the Uniformed Services or their
sponsors are responsible for the
payment of the first $25 of the allowable
institutional costs incurred with each
covered inpatient admission to a
hospital or other authorized
institutional provider (refer to § 199.6),
or the amount the beneficiary or sponsor
would have been charged had the
inpatient care been provided in a
Uniformed Service hospital, whichever
is greater.

* * * * *

(D) Inpatient cost-sharing for mental
health services. For care provided on or
after October 1, 1995, the inpatient
cost-sharing for mental health services is $20
per day for each day of the inpatient
admission. This $20 per day cost
administrative responsibility for the operation of the facility according to governing body policies. The chief executive officer shall have five years' administrative experience in the field of mental health. On October 1, 1997, the CEO shall possess a degree in business administration, public health, hospital administration, nursing, social work, or psychology, or meeting similar educational requirements as prescribed by the Director, OCHAMPUS.

(5) Clinical Director. The clinical director, appointed by the governing body, shall be a psychiatrist or doctoral level psychologist who meets applicable CHAMPUS requirements for individual professional providers and is licensed to practice in the state where the residential treatment center is located. The clinical director shall possess requisite education and experience, credentials applicable under state practice and licensing laws appropriate to the professional discipline, and a minimum of five years' clinical experience in the treatment of children and adolescents. The clinical director shall be responsible for planning, development, implementation, and monitoring of all clinical activities.

(6) Medical director. The medical director, appointed by the governing body, shall be licensed to practice medicine in the state where the residential treatment center is located and shall possess requisite education and experience, including graduation from an accredited school of medicine or osteopathy, an approved residency in psychiatry and a minimum of five years clinical experience in the treatment of children and adolescents. The Medical Director shall be responsible for the planning, development, implementation, and monitoring of all activities relating to medical treatment of patients. If qualified, the Medical Director may also serve as Clinical Director.

(7) Medical or professional staff organization. The governing body shall establish a medical or professional staff organization to assure effective implementation of clinical privileging, professional conduct rules, and other activities directly affecting patient care.

(8) Personnel policies and records. The RTC shall maintain written personnel policies, updated job descriptions and personnel records to assure the selection of qualified personnel and successful job performance of those personnel.

(9) Staff development. The facility shall provide appropriate training and development programs for administrative, professional support, and direct care staff.
(10) Fiscal accountability. The RTC shall assure fiscal accountability to applicable government authorities and patients. 

(11) Designated teaching facilities. Students, residents, interns or fellows providing direct clinical care are under the supervision of a qualified staff member approved by an accredited university. The teaching program is approved by the Director, OCHAMPUS. 

(12) Emergency reports and records. The facility notifies OCHAMPUS of any serious occurrence involving CHAMPUS beneficiaries. 

(B) Treatment services. 

(1) Staff composition. 

(i) The RTC shall follow written plans which assure that medical and clinical patient needs will be appropriately addressed. 

(ii) The RTC shall ensure adequate coverage by fully qualified staff during all hours of operation, including physician availability, other professional staff coverage, and support staff in the respective disciplines. 

(2) Staff qualifications. The RTC will have a sufficient number of qualified mental health professionals and support staff to address patients' clinical needs and coordinate the services provided. RTCs which employ individuals with master's or doctoral level professionals in the management of medical care are vested in a physician. 

(3) Patient rights. The RTC shall provide adequate protection for all patient rights, including rights provided by law, privacy, personnel rights, safety, confidentiality, informed consent, grievances, and personal dignity. 

(i) The facility has a written policy regarding patient abuse and neglect. 

(ii) Facility marketing and advertising meets professional standards. 

(iii) All necessary preauthorization requirements, that the admission is medically and/or psychologically necessary and the program is appropriate to meet the patient's needs. 

(4) Behavioral management. The RTC shall adhere to a comprehensive, written plan of behavioral management, developed by the clinical director and the medical or professional staff and approved by the governing body. 

(a) All necessary restraint procedures in an emergency situation. 

(b) All necessary implementation for the use of restraint or seclusion are used only in extraordinary circumstances, are carefully monitored, and are fully documented. 

(c) Only trained and clinically privileged RNs or qualified mental health professionals may be responsible for the implementation of seclusion and restraint procedures in an emergency situation. 

(5) Admission process. The RTC shall maintain written policies and procedures to ensure that, prior to an admission, a determination is made, and approved pursuant to CHAMPUS preauthorization requirements, that the admission is medically and/or psychologically necessary and the program is appropriate to meet the patient's needs. Medical and/or psychological necessity determinations shall be rendered by qualified mental health professionals who meet CHAMPUS requirements for individual professional providers and who are permitted by law and by the facility to refer patients for admission. 

(6) Assessments. The professional staff of the RTC shall complete a current multidisciplinary assessment which includes, but is not limited to, physical, psychological, developmental, family, educational, social, spiritual and skills assessment of each patient admitted. 

(7) Clinical formulation. A qualified mental health professional of the RTC will complete a clinical formulation on all patients. The clinical formulation will be reviewed and approved by the responsible individual professional provider and will incorporate significant findings from each of the multidisciplinary assessments. It will provide the basis for development of an interdisciplinary treatment plan. 

(8) Treatment planning. A qualified mental health professional shall be responsible for the development, supervision, documentation, and assessment of a written, individualized, interdisciplinary plan of treatment, which shall be completed within 10 days of admission and shall include individual, measurable, and observable goals for incremental progress and discharge. A preliminary treatment plan is completed within 24 hours of admission and includes at least an admission note and orders written by the attending mental health professional. The master treatment plan is reviewed and revised at least every 30 days, or when major changes occur in treatment. 

(9) Discharge planning and transition planning. The RTC shall maintain a transition planning process to address adequately the anticipated needs of the patient prior to the time of discharge. The planning involves determining necessary modifications in the treatment plan, facilitating the termination of treatment, and identifying resources to maintain therapeutic stability following discharge. 

(10) Clinical documentation. Clinical records shall be maintained on each patient to plan care and treatment and provide ongoing evaluation of the patient's progress. All care and treatment plans are documented and each clinical record contains at least the following: demographic data, consent forms, pertinent legal documents, all treatment plans and patient assessments, consultation and laboratory reports, physician orders, progress notes, and a discharge summary. All documentation will adhere to applicable provisions of the JCAHO and requirements set forth in § 199.7(b)(3). An appropriately qualified records administrator or associate will supervise and maintain the quality of the records. These requirements are in addition to other records requirements of this Part, and documentation requirements of the Joint Commission on Accreditation of Healthcare Organizations. 

(11) Progress notes. RTC's shall document the course of treatment for patients and families using progress notes which provide information to review, analyze, and modify the treatment plans. Progress notes are legible, contemporary, signed and dated and adhere to applicable provisions of the Manual of Mental Health, Chemical Dependency, and Mental Retardation/Development Disabilities Services and requirements set forth in § 199.7(b)(3). 

(12) Therapeutic services. 

(i) Individual, group, and family psychotherapy are provided to all patients, consistent with each patient's treatment plan, by qualified mental health providers. 

(ii) A range of therapeutic activities, directed and staffed by qualified
personnel are offered to help patients meet the goals of the treatment plan. (iii) Therapeutic educational services are provided or arranged that are appropriate to the patient’s educational and therapeutic needs.

(13) Ancillary services. A full range of ancillary services is provided. Emergency services include policies and procedures for handling emergencies with qualified personnel and written agreements with each facility providing the service. Other ancillary services include physical health, pharmacy and dietary services.

(C) Standards for physical plant and environment.

(1) Physical environment. The buildings and grounds of the RTC shall be maintained so as to avoid health and safety hazards, be supportive of the services provided to patients, and promote patient comfort, dignity, privacy, personal hygiene, and personal safety.

(2) Physical plant safety. The RTC shall be of permanent construction and maintained in a manner that protects the lives and ensures the physical safety of patients, staff, and visitors, including conformity with all applicable building, fire, health, and safety codes.

(3) Disaster planning. The RTC shall maintain and reissue written plans for taking care of casualties and handling other consequences arising from internal and external disasters.

(D) Standards for evaluation system.

(1) Quality assessment and improvement. The RTC shall develop and implement a comprehensive quality assurance and quality improvement program that monitors the quality, efficiency, appropriateness, and effectiveness of the care, treatments, and services it provides for patients and their families, primarily utilizing explicit clinical indicators to evaluate all functions of the RTC and contribute to an ongoing process of program improvement. The Clinical Director is responsible for developing and implementing quality assessment and improvement activities throughout the facility.

(2) Utilization review. The RTC shall implement a utilization review process, pursuant to a written plan approved by the professional staff, the administration, and the governing body, that assesses the appropriateness of admission, continued stay, and timeliness of discharge as part of an effort to provide quality patient care in a cost-effective manner. Findings of the utilization review process are used as a basis for revising a plan of operation, including a review of staff qualifications and staff composition.

(3) Patient records review. The RTC shall implement a process, including monthly reviews of a representative sample of patient records, to determine the completeness and accuracy of the patient records and the timeliness and pertinence of record entries, particularly with regard to regular recording of progress/non-progress in treatment.

(4) Drug utilization review. The RTC shall implement a comprehensive process for the monitoring and evaluating of the prophylactic, therapeutic, and empiric use of drugs to assure that medications are provided appropriately, safely, and effectively.

(5) Risk management. The RTC shall implement a comprehensive risk management program, fully coordinated with other aspects of the quality assurance and quality improvement program, to prevent and control risks to patients and staff and costs associated with clinical aspects of patient care and safety.

(6) Infection control. The RTC shall implement a comprehensive system for the surveillance, prevention, control, and reporting of infections acquired or brought into the facility.

(7) Safety. The RTC shall implement an effective program to assure a safe environment for patients, staff, and visitors, including an incident report system, a continuous safety surveillance system, and an active multidisciplinary safety committee.

(8) Facility evaluation. The RTC annually evaluates accomplishment of the goals and objectives of each clinical program and service of the RTC and reports findings and recommendations to the governing body.

(E) Participation agreement requirements. In addition to other requirements set forth in paragraph (b)(4)(vii), of this section in order for the services of an RTC to be authorized, the RTC shall have entered into a Participation Agreement with OCHAMPUS. The period of a participation agreement shall be specified in the agreement, and will generally be for not more than five years. Participation agreements entered into prior April 6, 1995 must be renewed not later than October 1, 1995. In addition to review of a facility’s application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a Participation Agreement. Retroactive approval is not given. In addition, the Participation Agreement shall include provisions that the RTC shall, at a minimum:

(1) Render residential treatment center inpatient services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation;

(2) Accept payment for its services based upon the methodology provided in §199.14(f) or such other method as determined by the Director, OCHAMPUS;

(3) Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary’s liability, as defined in section 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director, OCHAMPUS, to collect those amounts, which represents the beneficiary’s liability, as defined in §199.4;

(5) Comply with the provisions of §199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(6) Submit claims for services provided to CHAMPUS beneficiaries at least 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the RTC agrees not to bill the beneficiary or the beneficiary’s family for any amounts disallowed by CHAMPUS;

(7) Certify that:

(i) it is and will remain in compliance with the provisions of paragraph (b)(4)(vii) of this section establishing standards for Residential Treatment Centers;

(ii) it has conducted a self assessment of the facility’s compliance with the CHAMPUS Standards for Residential Treatment Centers Serving Children and Adolescents with Mental Disorders, as issued by the Director, OCHAMPUS and notified the Director, OCHAMPUS of any matter regarding which the facility is not in compliance with such standards; and

(iii) it will maintain compliance with the CHAMPUS Standards for Residential Treatment Centers Serving Children and Adolescents with Mental Disorders, as issued by the Director, OCHAMPUS, except for any such standards regarding which the facility notifies the Director, OCHAMPUS that it is not in compliance.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The RTC shall inform OCHAMPUS in writing of the designated individual;

(9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified...
by an independent accounting firm or other agency as authorized by the Director, OCHAMPUS;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning preauthorization, concurrent care review, claims processing, beneficiary liability, and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(i) Examination of fiscal and all other records of the RTC which would confirm compliance with the participation agreement and designation as an authorized CHAMPUS RTC provider;

(ii) Conducting such audits of RTC records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the RTC and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required;

(v) Audits conducted by the United States General Accounting Office.

(F) Other requirements applicable to RTCs.

(1) Even though an RTC may qualify as a CHAMPUS-authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the RTC also meeting all conditions set forth in section 491.4 especially all requirements of paragraph (b)(4) of that section.

(2) The RTC shall provide inpatient services to CHAMPUS beneficiaries in the same manner it provides inpatient services to all other patients. The RTC may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The RTC shall assure that all certifications and information provided to the Director, OCHAMPUS incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized status will be denied or terminated, and the RTC will be ineligible for consideration for approved provider status for a two year period.

(xii) Psychiatric partial hospitalization programs. Paragraph (b)(4)(xii) of this section establishes standards and requirements for psychiatric partial hospitalization programs.

(A) Organization and administration. (1) Definition. Partial hospitalization is defined as a time-limited, ambulatory, active treatment program that offers therapeutically intensive, coordinated, and structured clinical services within a stable therapeutic milieu. Partial hospitalization programs serve patients who exhibit psychiatric symptoms, disturbances of conduct, and decompensating conditions affecting mental health.

(2) Eligibility.

(i) Every psychiatric partial hospitalization program must be certified pursuant to CHAMPUS certification standards. Such standards shall incorporate the basic standards set forth in paragraphs (b)(4)(xii)(A) through (D) of this section, and shall include such additional elaborate criteria and standards as the Director, OCHAMPUS determines are necessary to implement the basic standards. Each psychiatric partial hospitalization program must be either a distinct part of an otherwise authorized institutional provider or a freestanding program.

(ii) To be eligible for CHAMPUS certification, the facility is required to be licensed and fully operational for a period of at least six months (with a minimum patient census of at least 30 percent of bed capacity) and operate in substantial compliance with state and federal regulations.

(iii) The facility is currently accredited by the joint commission on accreditation of healthcare organizations under the current edition of the Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disability.

(iv) The facility has a written participation agreement with OCHAMPUS. On October 1, 1995, the PHP is not a CHAMPUS-authorized provider and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director, OCHAMPUS. Partial hospitalization is capable of providing an interdisciplinary program of medical and therapeutic services a minimum of three hours per day, five days per week, and may include full- or half-day, evening, and weekend treatment programs.

(3) Governing body.

(i) The PHP shall have a governing body which is responsible for the policies, bylaws, and activities of the facilities. If the PHP is owned by a partnership or single owner, the partners or single owner are regarded as the governing body. The facility will provide an up-to-date list of names, addresses, telephone numbers, and titles of the members of the governing body.

(ii) The governing body ensures appropriate and adequate services for all patients and oversees continuing development and improvement of care. Where business relationships exist between the governing body and facility, appropriate conflict-of-interest policies are in place.

(iii) Board members are fully informed about facility services and the governing body conducts annual review of its performance in meeting purposes, responsibilities, goals and objectives.

(4) Chief executive officer. The chief executive officer, appointed by and subject to the direction of the governing body, shall assume overall administrative responsibility for the operation of the facility according to governing body policies. The chief executive officer shall have five years' administrative experience in the field of mental health. On October 1, 1997, the CEO shall possess a degree in business administration, public health, hospital administration, nursing, social work, or psychology, or meet similar educational requirements as prescribed by the Director, OCHAMPUS.

(5) Clinical Director. The clinical director, appointed by the governing body, shall be a psychiatrist or doctoral level psychologist who meets applicable CHAMPUS requirements for individual professional providers and is licensed to practice in the state where the PHP is located. The clinical director shall possess requisite education and experience, credentials applicable under state practice and licensing laws appropriate to the professional discipline, and a minimum of five years' clinical experience in the treatment of mental disorders specific to the ages and
disabilities of the patients served. The medical director shall be responsible for planning, development, implementation, and monitoring of all clinical activities.

(6) Medical director. The medical director, appointed by the governing body, shall be licensed to practice medicine in the state where the residential treatment center is located and shall possess requisite education and experience, including graduation from an accredited school of medicine or osteopathy, an approved residency in psychiatry and a minimum of five years clinical experience in the treatment of mental disorders specific to the ages and disabilities of the patients served. The Medical Director shall be responsible for the planning, development, implementation, and monitoring of all activities relating to medical treatment of patients. If qualified, the Medical Director may also serve as Clinical Director.

(7) Medical or professional staff organization. The governing body shall establish a medical or professional staff organization to assure effective implementation of clinical privileging, professional conduct rules, and other activities directly affecting patient care.

(8) Personnel policies and records.

The PHP shall maintain written personnel policies, updated job descriptions, personnel records to assure the selection of qualified personnel and successful job performance of those personnel.

(9) Staff development. The facility shall provide appropriate training and development programs for administrative, professional support, and direct care staff.

(10) Fiscal accountability. The PHP shall assure fiscal accountability to applicable government authorities and patients.

(11) Designated teaching facilities. Students, residents, interns, or fellows providing direct clinical care are under the supervision of a qualified staff member approved by an accredited university. The teaching program is approved by the Director, OCHAMPUS.

(12) Emergency reports and records. The facility notifies OCHAMPUS of any serious occurrence involving CHAMPUS beneficiaries.

(B) Treatment services.

(1) Staff composition.

(i) The PHP shall ensure that patient care needs will be appropriately addressed during all hours of operation by a sufficient number of fully qualified (including license, registration or certification requirements, educational attainment, and professional experience) health care professionals. Clinicians providing individual, group, and family therapy meet CHAMPUS requirements as qualified mental health providers, and operate within the scope of their licenses. The ultimate authority for managing care is vested in a psychiatrist or licensed doctor level psychologist. The management of medical care is vested in a physician.

(ii) The PHP shall establish and follow written plans to assure adequate staff coverage during all hours of operation, including physician availability, other professional staff coverage, and support staff in the respective disciplines.

(2) Staff qualifications. The PHP will have a sufficient number of qualified mental health providers, administrative, and support staff to address patients' clinical needs and to coordinate the services provided. PHPs which employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the all-inclusive per diem rate, provided the individual works under the clinical supervision of a fully qualified mental health provider employed by the PHP. All other program services shall be provided by trained, licensed staff.

(3) Patient rights.

(i) The PHP shall provide adequate protection for all patient rights, including rights provided by law, privacy, personal rights, safety, confidentiality, informed consent, grievances, and personal dignity.

(ii) The facility has a written policy regarding patient abuse and neglect.

(iii) Facility marketing and advertising meets professional standards.

(4) Behavioral management. The PHP shall adhere to a comprehensive, written plan of behavior management, developed by the clinical director and the medical or professional staff and approved by the governing body, including strictly limited procedures to assure that restraint or seclusion are used only in extraordinary circumstances, are carefully monitored, and are fully documented. Only trained and clinically privileged RNs or qualified mental health professionals may be responsible for implementation of seclusion and restraint procedures in an emergency situation.

(5) Admission process. The PHP shall maintain written policies and procedures to ensure that prior to an admission, a determination is made, and approval is granted by OCHAMPUS preauthorization requirements, that the admission is medically and/or psychologically necessary and the program is appropriate to meet the patient's needs. Medical and/or psychological necessity determinations shall be rendered by qualified mental health professionals who meet CHAMPUS requirements for individual professional providers and who are permitted by law and by the facility to refer patients for admission.

(6) Assessments. The professional staff of the PHP shall complete a multidisciplinary assessment which includes, but is not limited to physical health, psychological health, physiological, developmental, family, educational, spiritual, and skills assessment of each patient admitted. Unless otherwise specified, all required clinical assessments are completed prior to development of the interdisciplinary treatment plan.

(7) Clinical formulation. A qualified mental health provider of the PHP will complete a clinical formulation on all patients. The clinical formulation will be reviewed and approved by the responsible individual professional provider and will incorporate significant findings from each of the multidisciplinary assessments. It will provide the basis for development of an interdisciplinary treatment plan.

(8) Treatment planning. A qualified mental health professional with admitting privileges shall be responsible for the development, supervision, implementation, and assessment of a written, individualized, interdisciplinary plan of treatment, which shall be completed by the fifth day following admission to a full-day PHP, or by the seventh day following admission to a half-day PHP, and shall include measurable and observable goals for incremental progress and discharge. The treatment plan shall undergo review at least every two weeks, or when major changes occur in treatment.

(9) Discharge and transition planning. The PHP shall develop an individualized transition plan which addresses anticipated needs of the patient at discharge. The transition plan involves determining necessary modifications in the treatment plan, facilitating the termination of treatment, and identifying resources for maintaining therapeutic stability following discharge.

(10) Clinical documentation. Clinical records shall be maintained on each patient to plan care and treatment and provide ongoing evaluation of the patient's progress. All care is documented and each clinical record contains at least the following demographic data, consent forms,
pertinent legal documents, all treatment plans and patient assessments, consultation and laboratory reports, physician orders, progress notes, and a discharge summary. All documentation will adhere to applicable provisions of the JCAH0 and requirements set forth in § 199.7(b)(3). An appropriately qualified records administrator or technician will supervise and maintain the quality of the records. These requirements are in addition to other records requirements of this Part, and documentation requirements of the Joint Commission on Accreditation of Health Care Organizations.

11 Progress notes. PHSs shall document the course of treatment for patients and families using progress notes which provide information to review, analyze, and modify the treatment plans. Progress notes are legible, contemporaneous, sequential, signed and dated and adhere to applicable provisions of the Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities, and requirements set forth in section 199.7(b)(3).

12 Therapeutic services.

(i) Individual, group, and family therapy are provided to all patients, consistent with each patient’s treatment plan by qualified mental health providers.

(ii) A range of therapeutic activities, directed and staffed by qualified personnel, are offered to help patients meet the goals of the treatment plan.

(iii) Educational services are provided or arranged that are appropriate to the patient’s needs.

13 Ancillary services. A full range of ancillary services are provided. Emergency services include policies and procedures for handling emergencies with qualified personnel and written agreements with each facility providing these services. Other ancillary services include physical health, pharmacy and dietary services.

14 Standards for physical plant and environment.

(i) Physical environment. The buildings and grounds of the PHP shall be maintained so as to avoid health and safety hazards, be supportive of the services provided to patients, and promote patient comfort, dignity, privacy, personal hygiene, and personal safety.

(ii) Physical plant safety. The PHP shall be of permanent construction and maintained in a manner that protects the lives and ensures the physical safety of patients, staff, and visitors, including conformity with all applicable building, fire, health, and safety codes.

15 Disaster planning. The PHP shall maintain and rehearse written plans for taking care of casualties and handling other consequences arising from internal and external disasters.

16 Standards for evaluation system.

(i) Quality assessment and improvement. The PHP shall develop and implement a comprehensive quality assurance and quality improvement program that monitors the quality, efficiency, appropriateness, and effectiveness of care, treatments, and services the PHP provides for patients and their families. Explicit clinical indicators shall be used to evaluate all functions of the PHP and contribute to an ongoing process of program improvement. The clinical director is responsible for developing and implementing quality assessment and improvement activities throughout the facility.

(ii) Utilization review. The PHP shall implement a utilization review process, pursuant to a methodology approved by the professional staff, the administration, and the governing body, that assesses distribution of services, clinical necessity of treatment, appropriateness of admission, continued stay, and timeliness of discharge, as part of an overall effort to provide quality patient care in a cost-effective manner. Findings of the utilization review process are used as a basis for revising the plan of operation, including a review of staff qualifications and staff composition.

(iii) Patient records. The PHP shall implement a process, including regular monthly reviews of a representative sample of patient records, to determine completeness, accuracy, timeliness of entries, appropriate signatures, and pertinence of clinical entries. Conclusions, recommendations, actions taken, and the results of actions are monitored and reported.

(iv) Drug utilization review. The PHP shall implement a comprehensive process for the monitoring and evaluating of the prophylactic, therapeutic, and empiric use of drugs to assure that drugs are provided appropriately, safely, and effectively.

(v) Risk management. The PHP shall implement a comprehensive risk management program, fully coordinated with other aspects of the quality assurance and quality improvement program, to prevent and control risks to patients and staff, and to minimize costs associated with clinical aspects of patient care and safety.

(vi) Infection control. The PHP shall implement a comprehensive system for the surveillance, control, and reporting of infections acquired or brought into the facility.

17 Safety. The PHP shall implement an effective program to assure a safe environment for patients, staff, and visitors, including an incident reporting system, disaster training and safety education, a continuous safety surveillance system, and an active multidisciplinary safety committee.

18 Facility evaluation. The PHP annually evaluates accomplishment of the goals and objectives of each clinical program component or facility service of the PHP and reports findings and recommendations to the governing body.

19 Participation agreement requirements. In addition to other requirements set forth in paragraph (b)(4)(iii) of this section, in order for the services of a PHP to be authorized, the PHP shall have entered into a Participation Agreement with OCHAMPUS. The period of a participation agreement shall be specified in the agreement, and will generally be for not more than five years. On October 1, 1995, the PHP shall not be considered to be a CHAMPUS authorized provider and CHAMPUS payments shall not be made for services provided by the PHP until the date the participation agreement is signed by the Director, OCHAMPUS. In addition to review of a facility’s application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

1. Render partial or hospitalization program services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation.

2. Accept payment for its services based upon the methodology provided in section 199.14, or such other method as determined by the Director, OCHAMPUS;

3. Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the facility of the CHAMPUS beneficiary only those amounts that represent the beneficiary’s liability, as defined in § 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

4. Make all reasonable efforts acceptable to the Director, OCHAMPUS, to collect those amounts, which represent the beneficiary’s liability, as defined in § 199.4;

5. Comply with the provisions of § 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;
(6) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the PHP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS;

(7) Certify that:

(i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric partial hospitalization programs;

(ii) It has conducted a self assessment of the facility’s compliance with the CHAMPUS Standards for Psychiatric Partial Hospitalization Programs, as issued by the Director, OCHAMPUS, and notified the Director, OCHAMPUS of any matter regarding which the facility is not in compliance with such standards; and

(iii) It will maintain compliance with the CHAMPUS Standards for Psychiatric Partial Hospitalization Programs, as issued by the Director, OCHAMPUS, except for any such standards regarding which the facility notifies the Director, OCHAMPUS that it is not in compliance with.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The PHP shall inform OCHAMPUS in writing of the designated individual;

(9) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified by an independent accounting firm or other agency as authorized by the Director, OCHAMPUS;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review and other matters;

(11) Grant the Director, OCHAMPUS, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(i) Examination of fiscal and all other records of the PHP which would confirm compliance with the participation agreement and designation as an authorized CHAMPUS PHP provider;

(ii) Conducting such audits of PHP records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting onsite inspections of the facilities of the PHP and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required;

(v) Audits conducted by the United States General Account Office.

(12) Other requirements applicable to PHPs.

(1) Even though a PHP may qualify as a CHAMPUS-authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the PHP also meeting all conditions set forth in section 199.4 of this part.

(2) The PHP shall provide patient services to CHAMPUS beneficiaries in the same manner it provides inpatient services to all other patients. The PHP may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The PHP shall assure that all certifications and information provided to the Director, OCHAMPUS incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the PHP will be ineligible for consideration for authorized provider status for a two year period.

* * * * *

(xiv) Substance use disorder rehabilitation facilities. Paragraph (b)(4)(xvii) of this section establishes standards and requirements for substance use order rehabilitation facilities (SUDRF). This includes both inpatient rehabilitation centers for the treatment of substance use disorders and partial hospitalization centers for the treatment of substance use disorders:

(A) Organization and administration.

(1) Definition of inpatient rehabilitation center. An inpatient rehabilitation center is a facility, or distinct part of a facility, that provides medically monitored, interdisciplinary addiction-focused treatment to beneficiaries who have psychoactive substance use disorders. Qualified health care professionals provide 24-hour, seven-day-per-week, medically monitored assessment, treatment, and evaluation. An inpatient rehabilitation center is appropriate for patients whose addiction-related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas. Inpatient rehabilitation is differentiated from:

(i) A acute psychoactive substance use treatment and from treatment of acute biomedical/emotional/behavioral problems; which problems are either life-threatening and/or severely incapacitating and often occur within the context of a discrete episode of addiction-related biomedical or psychiatric dysfunction;

(ii) A partial hospitalization center, which serves patients who exhibit emotional/behavioral dysfunction but who can function in the community for defined periods of time with support in one or more of the major life areas;

(iii) A group home, sober-living environment, halfway house, or three-quarter way house;

(iv) Therapeutic schools, which are educational programs supplemented by addiction-focused services;

(v) Facilities that treat patients with primary psychiatric programs other than psychoactive substance use or dependence; and

(vi) Facilities that care for patients with the primary diagnosis of mental retardation or developmental disability.

(2) Definition of partial hospitalization center for the treatment of substance use disorders. A partial hospitalization center for the treatment of substance use disorders is an addiction-focused service that provides active treatment to adolescents between the ages of 13 and 18 or adults aged 18 and over. Partial hospitalization is a generic term for day, evening, or weekend programs that treat patients with psychoactive substance use disorders according to a comprehensive, individualized, integrated schedule of care. A partial hospitalization center is organized, interdisciplinary, and medically monitored. Partial hospitalization is appropriate for those whose addiction-related symptoms or concomitant physical and emotional/behavioral problems can be managed outside the hospital environment for defined periods of time with support in one or more of the major life areas.
(3) Eligibility.
   (i) Every inpatient rehabilitation center and partial hospitalization center for the treatment of substance use disorders must be certified pursuant to CHAMPUS certification standards. Such standards shall incorporate the basic standards set forth in paragraphs (b)(4)(xv) (A) through (D) of this section, and shall include such additional elaborative criteria and standards as the Director, OCHAMPUS determines are necessary to implement the basic standards.
   (ii) To be eligible for CHAMPUS certification, the SUDRF is required to be licensed and fully operational (with a minimum patient census of the lesser of: six patients or 30 percent of bed capacity) for a period of at least six months and operate in substantial compliance with state and federal regulations.
   (iii) The SUDRF is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations under the Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services, or by the Commission on Accreditation of Rehabilitation Facilities as an alcoholism and other drug dependency rehabilitation program under the Standards Manual for Organizations Serving People with Disabilities, or other designated standards approved by the Director, OCHAMPUS.
   (iv) The SUDRF has a written participation agreement with OCHAMPUS. On October 1, 1995, the SUDRF is not considered a CHAMPUS-authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director, OCHAMPUS.

(4) Governing body.
   (i) The SUDRF shall have a governing body which is responsible for the policies, bylaws, and activities of the facility. If the SUDRF is owned by a partnership or single owner, the partners or single owner are regarded as the governing body. The facility will provide an up-to-date list of names, addresses, telephone numbers and titles of the members of the governing body.
   (ii) The governing body ensures appropriate and adequate services for all patients and oversees continuing development and improvement of care. Where business relationships exist between the governing body and facility, appropriate conflict-of-interest policies are in place.
   (iii) Board members are fully informed about facility services and the governing body conducts annual reviews of its performance in meeting purposes, responsibilities, goals and objectives.
   (iv) Staff development.

(5) Chief executive officer. The chief executive officer, appointed by and subject to the direction of the governing body, shall assume overall administrative responsibility for the operation of the facility according to governing body policies. The chief executive officer shall have five years' administrative experience in the field of mental health or addictions. On October 1, 1997 the CEO shall possess a degree in business administration, public health, hospital administration, nursing, social work, or psychology, or meet similar educational requirements as prescribed by the Director, OCHAMPUS.

(6) Clinical Director. The clinical director, appointed by the governing body, shall be a qualified psychiatrist or doctoral level psychologist who meets applicable CHAMPUS requirements for individual professional providers and is licensed to practice in the state where the SUDRF is located. The clinical director shall possess requisite education and experience, including credentials applicable under state practice and licensing laws appropriate to the professional discipline. The clinical director shall satisfy at least one of the following requirements: certification by the American Society of Addiction Medicine; one year or 1,000 hours of experience in the treatment of psychoactive substance use disorders; or is a psychiatrist or doctoral level psychologist with experience in the treatment of substance use disorders. The clinical director shall be responsible for planning, development, implementation, and monitoring of all clinical activities.

(7) Medical director. The medical director, appointed by the governing body, shall be licensed to practice medicine in the state where the center is located and shall possess requisite education including graduation from an accredited school of medicine or osteopathy. The medical director shall satisfy at least one of the following requirements: certification by the American Society of Addiction Medicine; one year or 1,000 hours of experience in the treatment of psychoactive substance use disorders; or is a psychiatrist with experience in the treatment of substance use disorders. The medical director shall be responsible for the planning, development, implementation, and monitoring of all activities relating to medical treatment of patients. If qualified, the Medical Director may also serve as Clinical Director.

(8) Medical or professional staff organization. The governing body shall establish a medical or professional staff organization to assure effective implementation of clinical privileging, professional conduct rules, and other activities directly affecting patient care.

(9) Personnel policies and records. The SUDRF shall maintain written personnel policies, updated job descriptions, personnel records to assure the selection of qualified personnel and successful job performance of those personnel.

(10) Staff development. The SUDRF shall provide appropriate training and development programs for administrative, support, and direct care staff.

(11) Fiscal accountability. The SUDRF shall assure fiscal accountability to applicable government authorities and patients.

(12) Designated teaching facilities. Students, residents, interns, or fellows providing direct clinical care are under the supervision of a faculty member approved by an accredited university or approved training program. The teaching program is approved by the Director, OCHAMPUS.

(13) Emergency reports and records. The facility notifies OCHAMPUS of any serious occurrence involving CHAMPUS beneficiaries.

(8) Treatment services.

(1) Staff composition.
   (i) The SUDRF shall follow written plans which assure that medical and clinical patient needs will be appropriately addressed during all hours of operation by a sufficient number of fully qualified (including license, registration or certification requirements, educational attainment, and professional experience) health care professionals and support staff in the respective disciplines. Clinicians providing individual, group and family therapy meet CHAMPUS requirements as qualified mental health providers and operate within the scope of their licenses. The ultimate authority for planning, development, implementation, and monitoring of all clinical activities is vested in a psychiatrist or doctoral level clinical psychologist. The management of medical care is vested in a physician.
   (ii) The SUDRF shall establish and follow written plans to assure adequate staff coverage during all hours of operation of the center, including physician availability and other professional staff coverage 24 hours per day, seven days per week for an inpatient rehabilitation center and during all hours of operation for a partial hospitalization center.
(2) Staff qualifications. Within the scope of its programs and services, the SUDRF has a sufficient number of professional, administrative, and support staff to address the medical and clinical needs of patients and to coordinate the services provided. SUDRFs that employ individuals with master’s or doctoral level degrees in a mental health discipline who do not meet the licensure, certification and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the DRG, provided the individual works under the clinical supervision of a fully qualified mental health provider employed by the SUDRF.

(3) Patient rights.

(i) The SUDRF shall provide adequate protection for all patient rights, safety, confidentiality, informed consent, grievances, and personal dignity.

(ii) The SUDRF has a written policy regarding patient abuse and neglect.

(iii) SUDRF marketing and advertising meets professional standards.

(4) Behavioral management. When a SUDRF uses a behavioral management program, the center shall adhere to a comprehensive, written plan of behavioral management, developed by the clinical director and the medical or professional staff and approved by the governing body. It shall be based on positive reinforcement methods and, except for infrequent use of temporary physical holds or time outs, does not include the use of restraint or seclusion. Only trained and clinically privileged RNs or qualified mental health professionals may be responsible for the implementation of seclusion and restraint in an emergency situation.

(5) Admission process. The SUDRF shall maintain written policies and procedures to ensure that, prior to an admission, a determination is made, and approved pursuant to CHAMPUS preauthorization requirements, that the admission is medically and/or psychologically necessary and the program is appropriate to meet the patient’s needs. Medical and/or psychological necessity determinations shall be rendered by qualified mental health professionals who meet CHAMPUS requirements for individual professional providers and who are permitted by law and by the facility to refer patients for admission.

(6) Assessment. The professional staff of the SUDRF shall provide a complete, multidisciplinary assessment of each patient within 24 hours, but is not limited to, medical history, physical health, nursing needs, alcohol and drug history, emotional and behavioral factors, age-appropriate social circumstances, psychological condition, education status, and skills. Unless otherwise specified, all required clinical assessments are completed prior to development of the multidisciplinary treatment plan.

(7) Clinical formulation. A qualified mental health care professional of the SUDRF will complete a clinical formulation on all patients. The clinical formulation will be reviewed and approved by the responsible individual professional provider and will incorporate significant findings from each of the multidisciplinary assessments. It will provide the basis for development of an interdisciplinary treatment plan.

(8) Treatment planning. A qualified health care professional with admitting privileges shall be responsible for the development, supervision, implementation, and assessment of a written, individualized, and measurable treatment plan of treatment, which shall be completed within 10 days of admission to an inpatient rehabilitation center or by the fifth day following admission to full day partial hospitalization center, and by the seventh day of treatment for half day partial hospitalization. The treatment plan shall include individual, measurable, and observable goals for incremental progress towards the treatment plan objectives and goals and discharge. A preliminary treatment plan is completed within 24 hours of admission and includes at least a physician’s admission note and orders. The master treatment plan is regularly reviewed for effectiveness and revised when major changes occur in treatment.

(9) Discharge and transition planning. The SUDRF shall maintain a transition planning process to address adequately the anticipated needs of the patient prior to the time of discharge.

(10) Clinical documentation. Clinical records shall be maintained on each patient to plan care and treatment and provide ongoing evaluation of the patient’s progress. All care is documented and each clinical record contains at least the following: demographic data, consent forms, pertinent legal documents, all treatment plans and patient assessments, consultation and laboratory reports, physician orders, progress notes, and a discharge summary. All documentation will adhere to applicable provisions of the JCAHO and requirements set forth in §199.7(b)(3). An appropriately qualified recovery technician or supervisor of a recovery technician will supervise and maintain the quality of the records. These requirements are in addition to other records requirements of this Part, and provisions of the JCAHO Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services.

(11) Progress notes. Timely and complete progress notes shall be maintained to document the course of treatment for the patient and family.

(12) Therapeutic services.

(i) Individual, group, and family psychotherapy and addiction counseling services are provided to all patients, consistent with each patient’s treatment plan by qualified mental health providers.

(ii) A range of therapeutic activities, directed and staffed by qualified personnel, are offered to help patients meet the goals of the treatment plan.

(iii) Therapeutic educational services are provided or arranged that are appropriate to the patient’s educational and therapeutic needs.

(13) Ancillary services. A full range of ancillary services is provided. Emergency services include policies and procedures for handling emergencies with qualified personnel and written agreements with each facility providing the service. Other ancillary services include physical health, pharmacy and dietary services.

(C) Standards for physical plant and environment.

(1) Physical environment. The buildings and grounds of the SUDRF shall be maintained so as to avoid health and safety hazards, be supportive of the services provided to patients, and promote patient comfort, dignity, privacy, personal hygiene, and personal safety.

(2) Physical plant safety. The SUDRF shall be maintained in a manner that protects the lives and ensures the physical safety of patients, staff, and visitors, including conformity with all applicable building, fire, health, and safety codes.

(3) Disaster planning. The SUDRF shall maintain and rehearse written plans for taking care of casualties and handling other consequences arising from internal or external disasters.

(D) Standards for evaluation system.

(1) Quality assessment and improvement. The SUDRF develop and implement a comprehensive quality assurance and quality improvement program that monitors the quality, efficiency, appropriateness, and effectiveness of the care, treatments, and services it provides for patients and their families, utilizing clinical data to determine whether these services contribute to an ongoing process of program improvement. The clinical director is
responsible for developing and implementing quality assessment and improvement activities throughout the facility.

(2) Utilization review. The SUDRF shall implement a utilization review process, pursuant to a written plan approved by the professional staff, the administration, and the governing body, that assesses the appropriateness of admissions, continued stay, and timeliness of discharge as part of an admissions, continued stay, and discharge process, pursuant to a written plan, including a review of staff qualifications and staff composition.

(3) Patient records review. The center shall implement a process, including monthly reviews of a representative sample of patient records, to determine the completeness and accuracy of the patient records and the timeliness and pertinence of record entries, particularly with regard to regular recording of progress/non-progress in treatment plan.

(4) Drug review. For an inpatient rehabilitation center and, when applicable, a partial hospitalization center, shall implement a comprehensive process for the monitoring and evaluating of the prophylactic, therapeutic, and empiric use of drugs to assure that medications are provided appropriately, safely, and effectively.

(5) Risk management. The SUDRF shall implement a comprehensive risk management program, fully coordinated with other aspects of the quality assurance and quality improvement program, to prevent and control risks to patients and staff and costs associated with clinical aspects of patient care and safety.

(6) Infection control. The SUDRF shall implement a comprehensive system for the surveillance, prevention, control, and reporting of infections acquired or brought into the facility.

(7) Safety. The SUDRF shall implement an effective program to assure a safe environment for patients, staff, and visitors.

(8) Facility evaluation. The SUDRF annually evaluates accomplishment of the goals and objectives of each clinical program and service of the SUDRF and reports findings and recommendations to the governing body.

(E) Participation agreement requirements. In addition to other requirements set forth in paragraph (b)(4)(xiv) of this section, in order for the services of an inpatient rehabilitation center or partial hospitalization center for the treatment of substance abuse disorders to be authorized, the center shall have entered into a Participation Agreement with OCHAMPUS. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. On October 1, 1995, the SUDRF shall not be considered to be a CHAMPUS authorized provider and CHAMPUS payments shall not be made for services provided by the SUDRF until the date the participation agreement is signed by the Director, OCHAMPUS. In addition to review of the SUDRF's application and supporting documentation, an on-site visit by OCHAMPUS representatives may be part of the authorization process. In addition, such a Participation Agreement may not be signed until an SUDRF has been licensed and operational for at least six months. The Participation Agreement shall include at least the following requirements:

(1) Render applicable services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation;

(2) Accept payment for its services based upon the methodology provided in § 199.14, or such other method as determined by the Director, OCHAMPUS;

(3) Conduct on-site inspections of CHAMPUS facilities.

(4) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified to by an independent accounting firm or other agency as approved by the Director, OCHAMPUS, to collect those amounts which represent the beneficiary's liability, as defined in § 199.4.

(5) Examine and inspect all records of the center which would be required of a CHAMPUS provider and, in addition, such a Participation Agreement is signed by the Director, OCHAMPUS, that it is not in compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director, OCHAMPUS, of any matter regarding which the facility is not in compliance with such standards; and

(iii) It will maintain compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director, OCHAMPUS, except for any such standards regarding which the facility notifies the Director, OCHAMPUS that it is not in compliance.

(6) Grant the Director, OCHAMPUS, or designee, the right to conduct a comprehensive system for the surveillance, prevention, control, and inspection conducted by federal, state, and local government, and private agencies and organizations; and the facilities of the SUDRF and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.

(7) Audits conducted by the United States General Accounting Office, as required.

(8) Other requirements applicable to substance use disorder rehabilitation facilities.

(iii) Examining reports of evaluations and inspection conducted by federal, state, and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the SUDRF, and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.

(v) Audits conducted by the United States General Accounting Office, as required.

(9) Other requirements applicable to substance use disorder rehabilitation facilities.

(1) Even though a SUDRF may qualify as a CHAMPUS-authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the SUDRF meeting all conditions set forth in § 199.4.

(2) The center shall provide inpatient services to CHAMPUS beneficiaries in the same manner it provides services to all other patients. The center may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or
provisions of special or limited treatment.

(3) The substance use disorder facility shall assure that all certifications and information provided to the Director, OCHAMPUS, incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the facility will be ineligible for consideration for authorized provider status for a two-year period.

4. Section 199.14 is amended by designating the current text of paragraph (a)(2)(ii)(A) as paragraph (a)(2)(ii)(A)(1), revising paragraphs (a)(2)(ii)(B) and (a)(2)(iv)(C), the heading of paragraph (a)(2)(ix), paragraphs (a)(2)(ix)(C), (f)(3), and (f)(5), and by adding new paragraphs (a)(1)(ii)(F), (a)(2)(ii)(A)(2), and (f)(6) as follows:

§ 199.14 Provider reimbursement methods.

(a) Hospitals. * * * * *

(1) CHAMPUS Diagnosis Related Group (DRG)-based payment system. * * * *

(ii) Applicability of the DRG system. * * * *

(F) Substance Use Disorder Rehabilitation facilities. * * * *

With admissions on or after July 1, 1995, substance use disorder rehabilitation facilities, authorized under § 199.6(b)(4)(xiv), are subject to the DRG-based payment system. * * * * *

(2) CHAMPUS mental health per diem payment system.

* * * * *

(ii) Hospital-specific per diems for higher volume hospitals and units.

* * * *

(A) Per diem amount. * * * *

(2) In states that have implemented a payment system in connection with which hospitals in that state have been exempted from the CHAMPUS DRG-based payment system pursuant to paragraph (a)(1)(ii)(A) of this section, psychiatric hospitals and units may have per diem amounts established based on the payment system applicable to such hospitals and units in the state. The per diem amount, however, may not exceed the cap amount applicable to other higher volume hospitals.

(B) Cap.

(1) As it affects payment for care provided to patients prior to April 6, 1995, the base period per diem amount may not exceed the 80th percentile of the average daily charge weighted for all discharges throughout the United States from all higher volume hospitals.

(2) Applicable to payments for care provided to patients on or after April 6, 1996, the base period per diem amount may not exceed the 70th percentile of the average daily charge weighted for all discharges throughout the United States from all higher volume hospitals. For this purpose, base year charges shall be deemed to be charges during the period of July 1, 1991 to June 30, 1992, adjusted to correspond to base year (FY 1988) charges by the percentage change in average daily charges for all higher volume hospitals and units between the period of July 1, 1991 to June 30, 1992 and the base year.

* * * * *

(iv) Base period and update factors. * * * * *

(C) Update factors.

(1) The hospital-specific per diems and the regional per diems calculated for the base period pursuant to paragraphs (a)(2)(ii)(A) of this section shall remain in effect for federal fiscal year 1989; there will be no additional update for fiscal year 1989.

(2) Except as provided in paragraph (a)(2)(iv)(C)(3) of this section, for subsequent federal fiscal years, each per diem shall be updated by the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system.

(3) As an exception to the update required by paragraph (a)(2)(iv)(C)(2) of this section, all per diems in effect at the end of fiscal year 1995 shall remain in effect, with no additional update, throughout fiscal years 1996 and 1997. For fiscal year 1998 and thereafter, the per diems in effect at the end of fiscal year 1997 will be updated in accordance with paragraph (a)(2)(iv)(C)(2).

(4) Hospitals and units with hospital-specific rates will be notified of their respective rates prior to the beginning of each Federal fiscal year. New hospitals shall be notified at such time as the hospital rate is determined. The actual amounts of each regional per diem that will apply in any Federal fiscal year shall be published in the Federal Register at approximately the start of that fiscal year.

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(ix) Per diem payment for psychiatric and substance use disorder rehabilitation partial hospitalization services. * * * *

(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)(xi) and (b)(4)(xiv), are reimbursed on the basis of prospectively determined, all-inclusive per diem rates. The per diem payment amount must be accepted as payment in full for all institutional services provided, including board, routine nursing services, ancillary services (includes art, music, dance, occupational and other such therapies), psychological testing and assessments, over-the-counter and any other services for which the customary practice among similar providers is included as part of the institutional charges.

* (C) Per diem rate. For any full day partial hospitalization program (minimum of six hours), the maximum per diem payment amount is 40 percent of the average inpatient per diem amount per case established under the CHAMPUS mental health per diem reimbursement system for both high and low volume psychiatric hospitals and units (as defined in § 199.14(a)(2)) for the fiscal year. A partial hospitalization program of less than six hours (with a minimum of three hours) will be paid a per diem rate of 75 percent of the rate for a full-day program.

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(f) Reimbursement of Residential Treatment Centers. * * * * *

(3) For care on or after April 6, 1995, the per diem amount may not exceed a cap of the 70th percentile of all established Federal fiscal year 1994 RTC rates nationally, weighted by total CHAMPUS days provided at each rate during the first half of Federal fiscal year 1994, and updated to FY95. For Federal fiscal years 1996 and 1997, the cap shall remain unchanged. For Federal fiscal years after fiscal year 1997, the cap shall be adjusted by the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system.

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(5) Subject to the applicable RTC cap, adjustments to the RTC rates may be made annually.

(i) For Federal fiscal years through 1995, the adjustment shall be based on the Consumer Price Index-Urban (CPI-U) for medical care as determined applicable by the Director, OCHAMPUS.

(ii) For purposes of rates for Federal fiscal years 1996 and 1997:

(A) For any RTC whose 1995 rate was at or above the thirtieth percentile of all established Federal fiscal year 1995 RTC rates nationally, weighted by total CHAMPUS days provided at each rate during the first half of Federal fiscal
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

Approval and Promulgation of Implementation Plans; Texas State Implementation Plan Revision; Corrections for Reasonably Available Control Technology (RACT) Rules; Volatile Organic Compounds (VOC) RACT Catch-Ups

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving revisions to the Texas State Implementation Plan (SIP) submitted by the State of Texas on June 8, 1992, and additional revisions which were submitted on November 13, 1992. These SIP revisions contain regulations which require the implementation of RACT for various types of VOC sources. These revisions respond to the requirements of section 182(b)(2) of the Federal Clean Air Act, as amended in 1990 (CAA), for States to adopt RACT rules by November 15, 1992, for major VOC sources which are not covered by an existing EPA Control Techniques Guideline (CTG) and for all sources covered by an existing CTG. These revisions also include corrections to the monitoring, recordkeeping, and reporting requirements for Victoria County, in order to make the VOC rules more enforceable in that County.

DATES: This final rule is effective on May 8, 1995, unless critical or adverse comments are received by April 6, 1995. If the effective date is delayed, timely notice will be published in the Federal Register (FR).

ADDRESS: Comments should be mailed to Guy R. Donaldson, Acting Chief, Air Planning Section (6T–AP), U.S. EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733. Copies of the State's submittals and other information relevant to this action are available for inspection during normal business hours at the following locations:

U.S. Environmental Protection Agency, Region 6, Air Programs Branch (6T–A), 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street S.W., Washington, DC 20460.

Texas Natural Resource Conservation Commission, Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753.

Anyone wishing to review these documents at the U.S. EPA office is asked to contact the person below to schedule an appointment 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Mr. Mick Cote, Planning Section (6T–AP), Air Programs Branch, U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 655–7219.

SUPPLEMENTARY INFORMATION:

Background

Section 182(b)(2) of the CAAA of 1990, requires States to adopt RACT rules for all areas designated nonattainment for ozone and classified as moderate or above. There are three parts to the section 182(b)(2) RACT requirement: (1) RACT for sources covered by an existing CTG—i.e., a CTG issued prior to the enactment of the CAAA of 1990; (2) RACT for sources covered by a post-enactment CTG; and (3) all major sources not covered by a CTG. This action does not address requirements to implement RACT at sources covered by post-enactment CTG’s. Texas has identified sources in these post-enactment CTG source categories. RACT requirements will be addressed for these sources in future actions.

Section 182(b)(2) calls for nonattainment areas that previously were exempt from certain VOC RACT requirements to “catch up” to those nonattainment areas that became subject to those requirements under the preamended Act. In addition, it requires newly designated ozone nonattainment areas to adopt RACT rules consistent with those for previously designated nonattainment areas. In addition, the major source threshold is lowered for certain nonattainment areas (50 tons/yr for serious areas and 25 tons/yr in severe areas). States are required to ensure that RACT is implemented based on these new major source definitions.

In Texas, there are four ozone nonattainment areas: Dallas/Fort Worth (moderate), Beaumont/Port Arthur (serious), El Paso (serious) and Houston (severe). These VOC RACT revisions pending before EPA expand the applicability of control requirements to include the newly-designated perimeter counties (Chambers, Collin, Denton, Fort Bend, Hardin, Liberty, Montgomery, and Waller). In addition, the applicability of control requirements has been expanded to include all previously DESIGNATED ozone nonattainment counties (Brazoria, Dallas, El Paso, Galveston, Harris, Jefferson, Orange, and Tarrant). The existing requirements for Gregg, Nueces, and Victoria Counties have been relocated to a separate (new) subsection in each applicable section. Non-CTG RACT rules for mirror backing coating facilities have been added. Finally, monitoring/recordkeeping requirements for VOC sources in Victoria County were revised to be made more enforceable.

Procedural Background

The Clean Air Act (the Act) requires states to observe certain procedural requirements in developing implementation plans for submission to the EPA. Section 110(a)(2) of the Act provides that each implementation plan submitted by a state must be adopted after reasonable notice and public hearing. Section 110(l) of the Act similarly provides that each revision to an implementation plan submitted by a state under the Act must be adopted by such state after reasonable notice and public hearing. The EPA also must determine whether a submittal is complete and therefore warrants further EPA review and action (see section 110(k)(1) and 57 FR 13565). The EPA’s completeness criteria for SIP submittals are set out at 40 Code of Federal Regulations (CFR) part 51, appendix V. The EPA attempts to make completeness determinations within 60 days of