

ADDRESSES: The public hearing is being held in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW., Washington, DC 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building.

Send Submissions to CC:PA:LPD:PR (REG-139483-13), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday to CC:PA:LPD:PR (REG-139483-13), Couriers Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 or sent electronically via the Federal eRulemaking Portal at www.regulations.gov (IRS-2015-0047).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Ryan A. Bowen at (202) 317-6937; concerning submissions of comments, the hearing and/or to be placed on the building access list to attend the hearing Regina Johnson at (202) 317-6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The notice of public hearing on a proposed rulemaking that is the subject of this document is under sections 367 and 482 of the Internal Revenue Code.

Need for Correction

As published, the notice of public hearing on proposed rulemaking contains an omission in its summary that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the notice of public hearing on proposed rulemaking (REG-139483-13), that are subject to FR Doc. 2016-00961, is corrected as follows:

On page 3069, in the preamble, second column, under the caption **SUMMARY**, the last line of the paragraph is corrected to read "Code. This document also provides notice of public hearing on the proposed regulations under section 482 clarifying the coordination of the transfer pricing rules under section 482 with other Internal Revenue Code provisions."

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2015-HA-0109]

RIN 0720-AB65

TRICARE; Mental Health and Substance Use Disorder Treatment

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: This rulemaking proposes comprehensive revisions to the TRICARE regulation to reduce administrative barriers to access to mental health benefit coverage and to improve access to substance use disorder (SUD) treatment for TRICARE beneficiaries, consistent with earlier Department of Defense and Institute of Medicine recommendations, current standards of practice in mental health and addiction medicine, and governing laws. This proposed rule has four main objectives: (1) To eliminate quantitative and qualitative treatment limitations on SUD and mental health benefit coverage and align beneficiary cost-sharing for mental health and SUD benefits with those applicable to medical/surgical benefits; (2) to expand covered mental health and SUD treatment under TRICARE, to include coverage of intensive outpatient programs and treatment of opioid use disorder; (3) to streamline the requirements for mental health and SUD institutional providers to become TRICARE authorized providers; and (4) to develop TRICARE reimbursement methodologies for newly recognized mental health and SUD intensive outpatient programs and opioid treatment programs.

DATES: Written comments received at the addresses indicated below will be considered for possible revisions to this rule in development of the final rule. Comments must be received on or before April 1, 2016.

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

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting documents.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301-9010.

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

FOR FURTHER INFORMATION CONTACT: Dr. Patricia Moseley, Defense Health Agency, Clinical Support Division, Condition-Based Specialty Care Section, 703-681-0064.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

1. The Need for the Regulatory Action

This proposed rule seeks to comprehensively update TRICARE mental health and substance use disorder benefits, consistent with earlier Department of Defense and Institute of Medicine recommendations, current standards of practice in mental health and addiction medicine, and our governing laws. The Department of Defense remains intently focused on ensuring the mental health of our service members and their families, as this continues to be a top priority. The Department is also working to further de-stigmatize mental health treatment and expand the ways by which our beneficiaries can access authorized mental health services. This proposed regulatory action is in furtherance of these goals and imperative in order to eliminate requirements that may be viewed as barriers to medically necessary and appropriate mental health services.

(a) Eliminating Quantitative and Qualitative Treatment Limitations on SUD and Mental Health Benefit Coverage and Aligning Beneficiary Cost-Sharing for Mental Health and SUD Benefits With Those Applicable to Medical/Surgical Benefits

The requirements of the Mental Health Parity Act (MHPA) of 1996 and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008, as well as the plan benefit provisions contained in the Patient Protection and Affordable Care Act (PPACA) do not apply to the TRICARE program. The provisions of MHPAEA and PPACA serve as models for TRICARE in proposing changes to existing benefit coverage. These changes intend to reduce administrative barriers

to treatment and increase access to medically or psychologically necessary mental health care consistent with TRICARE statutory authority.

Section 703 of the National Defense Authorization Act (NDAA) National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2015, signed into law December 19, 2014, amends section 1079 of title 10 of the U.S.C. to remove prior existing statutory limits and requirements on TRICARE coverage of inpatient mental health services. This proposed rule is necessary to conform the regulation to provisions in the recently enacted law. Specifically, TRICARE coverage is no longer subject to an annual limit on stays in inpatient mental health facilities of 30 days for adults and 45 days for children. In addition, TRICARE coverage is no longer subject to a 150-day annual limit for stays at Residential Treatment Centers (RTCs) for eligible beneficiaries.

In addition to the elimination of these statutory inpatient day limits, and corresponding waiver provisions, the proposed rule also seeks to eliminate other regulatory quantitative and qualitative treatment limitations, consistent with principles of mental health parity and our governing laws. These include the 60-day partial hospitalization program limitation; annual and lifetime limitations on SUD treatment; presumptive limitations on outpatient services including the number of psychotherapy sessions per week and family therapy sessions for the treatment of SUD per benefit period; and limitations on the smoking cessation program. While there are clear waiver provisions in place for all of the existing quantitative treatment benefit limitations in order to ensure that beneficiaries have access to medically or psychologically necessary and appropriate care, these presumptive limitations may serve as an administrative barrier and thus disincentive to continued care regardless of the continued medical necessity of such care.

Additionally, this rulemaking proposes to remove the categorical exclusion on treatment of gender dysphoria. This proposed change will permit coverage of all non-surgical medically necessary and appropriate care in the treatment of gender dysphoria, consistent with the program requirements applicable for treatment of all mental or physical illnesses. Surgical care remains prohibited by statute at 10 U.S.C. 1079(a)(11), as discussed further below.

Finally, following the recent repeal (section 703 of the NDAA for FY 15) of the statutory authority (previously

codified at 10 U.S.C. 1079(i)(2)) for separate beneficiary financial liability for mental health benefits, the proposed rule revises the cost-sharing requirements for mental health and SUD benefits to be consistent with those that are applicable to TRICARE medical and surgical benefits.

(b) Expanding Coverage To Include Mental Health and SUD Intensive Outpatient Programs and Treatment of Opioid Use Disorder

Currently, TRICARE benefits do not fully reflect the full range of contemporary SUD treatment approaches (*i.e.*, outpatient counseling and intensive outpatient program (IOP)) that are now endorsed by the American Society of Addiction Medicine (ASAM), the Department of Health and Human Services (DHHS) Substance Abuse and Mental Health Services Administration (SAMHSA), and the VA/DoD Clinical Practice Guidelines (CPGs) for SUDs. Some existing benefit coverage restrictions inhibit access to community based outpatient services; may cause beneficiaries to be separated from their families while they are receiving treatment in geographically distant facilities; and may result in beneficiaries electing to forgo treatment. Further, restrictions may lead to difficulty receiving appropriate step-down care following acute inpatient and residential treatment services. TRICARE currently limits SUD treatment to TRICARE-authorized SUD Rehabilitation Facilities (SUDRFs) and hospitals.

An amendment to the regulation is necessary to authorize TRICARE benefit coverage of medically and psychologically necessary services and supplies which represent appropriate medical care and that are generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of mental disorders. Office-based individual outpatient treatment is an effective, empirically-validated level of treatment for substance use disorder endorsed by The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, Third Edition, 2013. Furthermore, TRICARE coverage of medication assisted treatment (MAT) for opioid use disorder, extended through regulatory revisions, as published in the **Federal Register** on October 22, 2013 (78 FR 62427), is currently limited to MAT provided by a TRICARE authorized SUDRF. This proposed revision of the TRICARE SUD treatment benefit will allow office-based opioid treatment (OBOT) by individual TRICARE-authorized physicians and

will also add coverage of qualified opioid treatment programs (OTPs) as TRICARE authorized institutional providers of SUD treatment for opioid use disorder, which will expand access to this type of care.

(c) Streamlining Requirements for Institutional Mental Health and SUD Providers To Become TRICARE Authorized Providers

The current TRICARE certification requirements for institutional mental health and SUD providers were implemented over 20 years ago and designed to create comprehensive, stand-alone standards to address the full spectrum of requirements and expectations for mental health facilities and providers, rather than as mere supplements to the standards employed by the Joint Commission, which at the time had moved toward a more general set of facility standards. Over the last several decades, the accreditation process for institutional providers has evolved, and these standards are now monitored through a number of industry-accepted accrediting bodies. While TRICARE's comprehensive certification standards were once considered necessary to ensure quality and safety, these comprehensive certification requirements are now proving to be overly restrictive and at times inconsistent with current industry-based institutional provider standards and organization. There are currently several geographic areas that are inadequately served because providers in those regions do not meet TRICARE certification requirements, even though they may meet the industry standard. The proposed rule seeks to streamline TRICARE regulations to be consistent with industry standards for authorization of qualified institutional providers of mental health and SUD treatment. It is anticipated that these revisions will result in an increase in the number and geographic coverage areas of participating institutional providers of mental health and SUD treatment for TRICARE beneficiaries.

(d) TRICARE Reimbursement Methodologies for Newly Recognized Mental Health and SUD Intensive Outpatient Programs and Opioid Treatment Programs

Along with recognition of several new categories of TRICARE authorized providers, the proposed rule establishes reimbursement methodologies for these providers. Specifically, new reimbursement methodologies have been proposed for IOPs for mental health and SUD treatment as well as OTPs, as these providers have not

previously been recognized by TRICARE and thus appropriate reimbursement methodologies must be established. Existing reimbursement methodologies for SUDRFs, RTCs, and PHPs will continue to apply.

2. Legal Authority for the Regulatory Action

This regulation is proposed under the authorities of 10 U.S.C., section 1073, which authorizes the Secretary of Defense to make decisions concerning TRICARE and to administer the medical and dental benefits provided in title 10 U.S.C., chapter 55. The Department is authorized to provide medically necessary and appropriate medical care for mental and physical illnesses, injuries and bodily malfunctions, including hospitalization, outpatient care, drugs, and treatment of mental conditions under 10 U.S.C. 1077(a)(1) through (3) and (5). Although section 1077 identifies the types of health care to be provided in military treatment facilities (MTFs) to those authorized such care under section 1076, these same types of health care (with certain specified exceptions) are authorized for coverage within the civilian health care sector for ADFMs under section 1079 and for retirees and their dependents under section 1086. In general, the scope of TRICARE benefits covered within the civilian health care sector and the TRICARE authorized providers of those benefits are found at 32 CFR 199.4 and 199.6, respectively.

TRICARE beneficiary cost-sharing is governed by statute and regulation based upon both the beneficiary category and TRICARE option being utilized. Pursuant to 10 U.S.C. 1079(b)(1), dependents of members of the uniformed services utilizing TRICARE Standard are responsible for a \$25 beneficiary cost-share for each covered inpatient admission to a hospital, 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. Section 1079(i)(2) permits the Secretary to prescribe separate payment requirements for the provision of mental health services and, under this authority, the Secretary did prescribe different copays for mental health versus medical/surgical benefits for active duty family members under the TRICARE Standard option as well as for retirees, their family members, and survivors under the TRICARE Prime option.

Under TRICARE Standard, an inpatient cost-sharing amount for mental health services of \$20 per day for each day of inpatient admission was

established by regulation (32 CFR 199.4(f)(2)(ii)(D)) and applies to admissions to any hospital for mental health services, any residential treatment facility, any substance use rehabilitation facility, and any partial hospitalization program (PHP) providing mental health services.

Section 731 of the NDAA for FY 1994 (Pub. L. 103–160) directed the Secretary of Defense to implement a health benefit option modelled on health maintenance organization plans offered in the private sector. This uniform health maintenance organization (HMO) benefit is known as TRICARE Prime and was implemented through regulation (32 CFR 199.17 and 199.18). Pursuant to 10 U.S.C. 1097(e), the Secretary of Defense is authorized to prescribe by regulation a premium, deductible, copayment, or other charge for health care for Prime beneficiaries. The specific cost-sharing requirements for Prime are found at 32 CFR 199.18. Under TRICARE Prime, the regulation (32 CFR 199.18(f)(3)(ii) and (e)(3)) established an outpatient copay of \$25 per mental health visit and \$17 per group outpatient mental health visit and \$40 per diem charge for inpatient mental health for retirees, their family members, and survivors. In establishing TRICARE Prime, these separate and higher copayments for mental health services were determined to be necessary to preserve the distinct treatment of mental health services as authorized by law in effect at the time.

Section 703 of the NDAA for FY 2015 enacted a statutory amendment to 10 U.S.C. 1079, effective December 19, 2014. This action removed the authority for separate patient cost-sharing of mental health services and necessitates regulatory changes to re-classify partial hospitalization services as outpatient services for purposes of cost-sharing and to bring the active duty family member Standard inpatient cost-sharing regulations into alignment with the statute. The proposed regulatory changes further equalize the retiree and dependent mental health copay amounts to the medical/surgical copay amounts under TRICARE Prime.

With respect to institutional provider reimbursement, pursuant to 10 U.S.C. 1079(i)(2), the Secretary is required to publish regulations establishing the amount to be paid to any provider of services, including hospitals, comprehensive outpatient rehabilitation facilities, and any other institutional facility providing services for which payment may be made. The amount of such payments shall be determined, to the extent practicable, in accordance with the same reimbursement rules as apply to payments to providers of

services of the same type under Medicare. TRICARE provider reimbursement methods are found at 32 CFR 199.14. When it is not practicable to adopt Medicare's methods or Medicare has no established reimbursement methodology (e.g. Medicare does not reimburse freestanding SUDRFs or PHPs that are not hospital-based or part of a Community Mental Health Clinic, while TRICARE does), TRICARE establishes its own rates through proposed and final rulemaking. This rule invites comments on the approach proposed to be adopted by TRICARE.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule makes a number of comprehensive revisions to the TRICARE mental health and SUD treatment coverage. In an effort to further de-stigmatize SUD care, treatment of SUDs is no longer separately identified as a limited special benefit under 32 CFR 199.4(e) but rather has now been incorporated into the general mental health provisions in § 199.4(b) governing institutional benefits and § 199.4(c) governing professional service benefits. Further, this proposed rule seeks to eliminate a number of mental health and SUD quantitative and qualitative treatment limitations, and corresponding waiver provisions, instead relying on determinations of medical necessity and appropriate utilization management tools, as are used for all other medical and surgical benefits. Proposed revisions include eliminating:

- All inpatient mental health day limits, following the statutory revisions to 10 U.S.C. 1079;
- The 60-day partial hospitalization and SUDRF residential treatment limitations;
- Annual and lifetime limitations on SUD treatment;
- Presumptive limitations on outpatient services including the six-hours per year limit on psychological testing; the limit of two sessions per week for outpatient therapy; and limits for family therapy (15 visits) and outpatient therapy (60 visits) provided in free-standing or hospital based SUDRFs;
- The limit of two smoking cessation quit attempts in a consecutive 12 month period and 18 face-to-face counseling sessions per attempt; and
- The regulatory prohibition that categorically excludes all treatment of gender dysphoria.

The rule also proposes changes to cost-sharing for mental health treatment for TRICARE Prime and Standard/Extra

beneficiaries to align with the applicable cost-sharing provisions for other non-mental health inpatient and outpatient benefits. Additionally, revisions have been proposed to clearly identify services that will be cost-shared on an inpatient (*e.g.*, inpatient admissions to a hospital, residential treatment center, SUDRF residential treatment program, or skilled nursing facility) versus outpatient (including partial hospitalization programs, intensive outpatient treatment services, and opioid treatment program services) cost-sharing basis to ensure consistency with the statutory requirements in 10 U.S.C. 1079 and 1086. In many cases, these proposed modifications to cost-sharing would enhance TRICARE beneficiary access to care through lower out-of-pocket costs.

The proposed regulatory language defines and authorizes new services by TRICARE authorized institutional and individual providers of SUD care outside of SUDRF settings at §§ 199.2 and 199.6. Revisions to treatment benefits at § 199.4 and § 199.6 would allow intensive outpatient programs (IOPs) for mental health and SUD treatment; care in opioid treatment programs (OTPs); and outpatient SUD treatment (*i.e.*, office-based opioid treatment, psychosocial treatment and family therapy) by individual TRICARE authorized providers.

Significant revisions to 32 CFR 199.6 are proposed in order to eliminate the administratively burdensome provider certification process and streamline approval for institutional mental health and SUD providers to become TRICARE authorized providers. In multiple regions providers may meet industry standards but do not meet TRICARE certification requirements. Consequently providers in these regions are unable to serve TRICARE beneficiaries. The applicable provisions for residential treatment centers, psychiatric and SUD partial hospitalization programs, and SUDRFs, have been rewritten in their entirety to address institutional provider eligibility, organization and administration, participation agreement requirements and any other requirements for approval as a TRICARE authorized provider. The requirement and formal process of certification is proposed for elimination. Similarly, new regulatory provisions have been proposed for the newly recognized categories of institutional providers, namely IOPs and OTPs.

Finally, amendments to 32 CFR 199.14, which specifies provider reimbursement methods, are proposed to establish allowable all-inclusive per

diem payment rates for psychiatric and SUD PHP, IOP and OTP services.

C. Costs and Benefits

The proposed amendment is not anticipated to have an annual effect on the economy of \$100 million or more. An independent government cost estimate found that this proposed rule is estimated to have a net increase in costs of approximately \$55 million. The government's regulatory impact analysis based on this cost estimate can be found in the docket folder associated with this proposed rule at <http://www.regulations.gov/#/docketDetail;D=DOD-2015-HA-0109>. To summarize, provisions to implement mental health parity account for approximately \$34 million (62%) of the \$55 net cost increase. While modifying mental health cost-sharing will increase costs, these revisions are required as the former statutory authority for mental health-specific cost sharing has been deleted from the statute (section 703 of the NDAA for FY15). As a result, the existing statutory cost-shares are utilized and this aligns mental health cost-shares with the current medical-surgical cost-shares. The largest cost increase (\$21.6 million) is attributable to lowering outpatient mental health cost-sharing for Non-Active Duty Dependent (NADD) TRICARE beneficiaries (from \$25 per visit to the medical/surgical outpatient cost-sharing of \$12 per visit).

Elimination of the statutory day limits for inpatient psychiatric and Residential Treatment Center (RTC) care for children (to comply with section 703 of the NDAA for FY15) will only minimally increase costs. This is because these previously published presumptive day limits were also subject to waivers and TRICARE had been reimbursing for medically necessary inpatient stays with waivers when continued medical necessity was supported. Eliminating the limit of two sessions per week for outpatient therapy is estimated to incur an increased cost (\$7.5 million), but this is based on the conservative assumption that the proportion of NADD beneficiaries who will pursue three psychotherapy sessions per week is comparable to the proportion of Active Duty Service Members (ADSMs) who do so (17%), even though ADSMs incur no cost-sharing and most receive psychotherapy within MTFs instead of civilian providers. Eliminating other limits (*e.g.*, annual and lifetime limits on SUD treatment, smoking cessation program limits, and others as outlined above) will have a relatively minimal increase in costs. Overall, the benefit of removing these quantitative limits to mental

health treatment will ensure that all beneficiaries receive the appropriate amount of care based on medical and psychological necessity.

Creating additional levels, providers, and types of mental health care (*e.g.*, intensive outpatient programs, opioid treatment programs, non-surgical coverage for gender dysphoria, and also allowing outpatient substance use treatment) will increase costs to the program by approximately \$16.8 million. Some of the cost increases will be offset through utilization of lower and less expensive levels of care (*e.g.*, IOP versus residential or full day PHP) and prevention of relapse requiring more costly, intensive inpatient intervention. Currently, PHPs are the only step-down care from inpatient substance use disorder treatment currently covered by TRICARE. In many rural and sparsely-populated states, such as Utah, Arizona, New Mexico, South Dakota, Wyoming, Idaho, and Montana, there are relatively few PHPs (on average 20 or fewer, with 4 states having fewer than 10 PHPs). IOPs in these rural states, on the other hand, are four times more plentiful than PHPs, and TRICARE coverage of IOP substance use disorder treatment will greatly increase beneficiary access to SUD treatment, particularly in these remote geographic areas. Similarly, in FY14, 15,000 services of psychotherapy by individual professional providers were denied for beneficiaries with an SUD. Coverage of outpatient SUD treatment by TRICARE authorized individual providers will facilitate early intervention for SUDs and help reduce relapse following more intensive treatment though the availability of outpatient aftercare from these professionals. Additionally, TRICARE currently has an estimated 15,000 to 20,000 beneficiaries with opioid use disorder who, under the current benefit, cannot access medication-assisted treatment (MAT; *e.g.*, buprenorphine or methadone). According to SAMHSA, there are approximately 1155 OTPs in the United States and 31,363 physicians with a DEA waiver to provide MAT for opioid use disorder, but none of these facilities or providers is TRICARE-authorized or eligible to be reimbursed by TRICARE under current regulation. Once the changes proposed in this rule are implemented, TRICARE beneficiaries will have ready access to MAT on an outpatient basis as recommended by ASAM and clinical practice guidelines developed jointly by the Department of Veterans Affairs (VA) and DoD.

Streamlining requirements for institutional providers to become TRICARE authorized providers of

mental health and SUD care will incur an estimated increased cost of \$3.2 million due to an anticipated increase in the number of institutional providers joining the TRICARE network. To focus on RTC care as an example, TRICARE strives to provide a robust mental health treatment benefit to our child beneficiaries, but access to RTC care for children is significantly limited in many geographic areas by TRICARE's existing certification requirements. Less than one sixth of RTCs certified by the Joint Commission are currently TRICARE certified, and only about one half of individual states have at least one TRICARE-certified RTC. California, Oklahoma, Alabama, and Louisiana all have no TRICARE-certified RTCs but do have sizeable TRICARE populations. Revising TRICARE institutional provider authorization requirements for RTCs will make it much more likely that parents will seek RTC care for their children whose behavioral health condition is so severe as to require RTC services, and this change to the TRICARE behavioral health benefit is projected to increase utilization of RTC services by 20 percent. Ultimately, the net increase in costs associated with this proposed rule will greatly be outweighed by the enhanced mental health benefits, options and access available to beneficiaries.

II. Discussion of the Proposed Rule

A. Background

TRICARE implemented both financial and treatment controls to manage care, ensure quality, and control costs for medically or psychologically necessary and appropriate mental health and substance use care. In part, these controls have been implemented in response to Congressional concerns. In the National Defense Authorization Act for Fiscal Year 1991 and the Defense Appropriations Act for Fiscal Year 1991, Congress addressed the problem of spiraling costs for mental health services under the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). As stated by the House Armed Services Committee:

The cost of mental health and substance abuse is of particular concern to the committee. While CHAMPUS expenditures have generally increased by 50 percent between 1986 and 1989, CHAMPUS mental health expenditures have more than doubled. Last year mental health costs accounted for about one-quarter of CHAMPUS's total spending far above the typical proportion in private employers' health care plans. These statutes established: (1) The new day limits for inpatient mental health services: 30 days for acute care for patients 19 years of age and older, 45 days for acute care for patients

under 19 years of age, and 150 days of residential treatment—each of these limits subject to waiver that takes into account the level, intensity and availability of the care needs of the patient; and (2) mandated prior authorization for all nonemergency inpatient mental health admissions.

Additionally, in the early 1990s, two Comptroller General Reports highlighted the need for mental health program reform within the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). At the time, there were widespread concerns with the quality of mental health care within CHAMPUS as well as fraud and abuse. The Reports highlighted weaknesses within the benefit that resulted in unnecessary hospital admissions, excessive inpatient stays and sometimes, inadequate quality of care. The first of these two reports, "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." A second Comptroller General Report, "Psychiatric Fraud and Abuse: Increased Scrutiny of Hospital Stays is Needed to Lessen Federal Health Program Vulnerability," (GAO/HRD-93-92, September 1993) called for improvements in the CHAMPUS mental health program to include reversing the financial incentives to use inpatient care by introducing larger copayments for CHAMPUS inpatient care.

In response to these concerns, the certification standards for mental health facilities as well as treatment limits and cost-sharing requirements applicable to mental health and SUD services under the TRICARE program were implemented in a 1995 Final Rule, "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS): Mental Health Services." These standards, limits, and requirements have remained in place over the last 20 years.

In 1996, Congress enacted the Mental Health Parity Act of 1996 (MHPA 1996) which required employment-related group health plans and health insurance coverage offered in connection with group health plans to provide parity in aggregate lifetime and annual dollar limits for mental health benefits and medical and surgical benefits. In October 2008, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) was signed into law as part of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008. The changes made by MHPAEA consist of new requirements, including parity for

substance use disorder benefits, as well as amendments to the existing mental health parity provisions enacted in MHPA. This law requires group health insurance plans that provide both medical/surgical and mental health or substance use disorder benefits to meet parity standards. Specifically, financial requirements (*e.g.*, deductibles, copayments, or coinsurance) and treatment limitations (*e.g.*, days of coverage and number of visits) that apply to mental health or substance use disorder benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits. The MHPAEA was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, to also apply to individual health insurance coverage. TRICARE is not a group health plan subject to the MHPA 1996, the MHPAEA of 2008, or the Health Care and Education Reconciliation Act of 2010. However, the provisions of these acts serve as a model for TRICARE in proposing changes to existing benefit coverage so as to reduce administrative barriers to treatment and increase access to medically or psychologically necessary mental health care consistent with TRICARE statutory authority.

In July 2011, DoD issued a Report to Congress entitled, "Comprehensive Plan on Prevention, Diagnosis, and Treatment of Substance Use Disorders and Disposition of Substance Use Offenders in the Armed Forces," in which the Department identified to Congress the need to revise certain aspects of TRICARE regulatory language governing SUD treatment services to provide a benefit that takes into account generally accepted standards of practice. The report is available for download at <http://health.mil/About-MHS/Defense-Health-Agency/Special-Staff/Congressional-Relations/Reports-to-Congress>. DoD's findings were affirmed in 2012 by an independent study conducted by the Institute of Medicine (IOM) entitled, "Substance Use Disorders in the U.S. Armed Forces," (available at www.iom.edu/reports/2012/Substance-Use-Disorders-in-the-Armed-Forces.aspx).

The Department seeks to revise and streamline TRICARE regulations to be consistent with industry standards, as well as to incorporate applicable recommendations from the July 2011 Congressional report, the IOM 2012 study, and evidence-based practices delineated by the U.S. Department of Veterans Affairs (VA) and DoD clinical

practice guidelines (VA/DoD CPGs) for SUD to improve access to medically or psychologically necessary SUD treatment for TRICARE beneficiaries in accordance with generally accepted standards of practice.

B. Expanded TRICARE Coverage of Mental Health and SUD Treatment

1. Eliminating Quantitative and Qualitative Treatment Limitations on SUD and Mental Health Benefit Coverage

There are existing waiver provisions for all of the quantitative treatment benefit limitations to ensure beneficiaries have access to medically or psychologically necessary and appropriate treatment. However, these limitations, which were designed to contain costs and address abuses decades ago, along with differential financial cost-sharing requirements relative to medical/surgical care are currently viewed as barriers to coverage of mental health services.

This proposed rule seeks to remove a number of quantitative and qualitative limits for coverage of mental health and SUD care under the TRICARE Program, including:

- All inpatient mental health day (30 days maximum for adults and 45 days maximum for children at 32 CFR 199.4(b)(9)) and annual day limits (150 days at 32 CFR 199.4(b)(8)) for RTC care for beneficiaries 21 years and younger, following the statutory revisions to 10 U.S.C. 1079;
- The 60-day limitation on partial hospitalization (32 CFR 199.4(b)(10)(iv)) and SUDRF residential treatment (32 CFR 199.4(e)(4)(ii)(A));
- Annual (60 days in a benefit period) and lifetime (three treatment episodes—32 CFR 199.4(e)(4)(ii)) limitations on SUD treatment;
- Presumptive limitations on outpatient services including the six-hour per year limit on psychological testing (32 CFR 199.4(c)(3)(ix)(A)(5)) and the limit of two sessions per week for outpatient therapy (32 CFR 199.4(c)(3)(ix)(B));
- Limits on family therapy (15 visits (32 CFR 199.4(e)(4)(ii)(C)) and outpatient therapy (60 visits—(32 CFR 199.4(e)(4)(ii)(B)) provided in free-standing or hospital based SUDRFs; and
- The limit of two smoking cessation quit attempts in a consecutive 12 month period and 18 face-to-face counseling sessions per attempt (32 CFR 199.4(e)(30)).

This proposed rule will allow coverage of outpatient treatment that is medically or psychologically necessary, including family therapy and other

covered diagnostic and therapeutic services, by a TRICARE authorized institutional provider or by authorized individual mental health providers without limits on the number of treatment sessions. The removal of these limitations also recognizes that SUDs are chronic conditions with periodic phases of relapse and readmission, often requiring multiple interventions over several years to achieve full remission. All claims submitted for services under TRICARE remain subject to review for quality and appropriate utilization in accordance with the Quality and Utilization Review Peer Review Organization Program, under 10 U.S.C. 1079(n) and 32 CFR 199.15.

The proposed rule also removes certain regulatory exclusions for the treatment of gender dysphoria for TRICARE beneficiaries who are diagnosed by a TRICARE authorized, qualified mental health professional, practicing within the scope of his or her license, to be suffering from a mental disorder, as defined in 32 CFR. 199.2. It is no longer justifiable to categorically exclude and not cover currently accepted medically and psychologically necessary treatments for gender dysphoria (such as psychotherapy, pharmacotherapy, and hormone replacement therapy) that are not otherwise excluded by statute. (Section 1079(a)(11) of title 10, U.S.C., excludes from CHAMPUS coverage surgery which improves physical appearance but is not expected to significantly restore functions, including mammary augmentation, face lifts, and sex gender changes.)

2. Aligning Beneficiary Cost-Sharing for Mental Health and SUD Benefits With Those Applicable to Medical/Surgical Benefits

Following the recent repeal of statutory authority for separate beneficiary financial liability for mental health benefits, the proposed rule eliminates any differential in cost-sharing between mental health and SUD benefits and medical/surgical benefits. The following regulatory changes to 32 CFR 199.4(f) and 32 CFR 199.18 will reduce financial barriers to both outpatient and inpatient mental health and SUD benefits while, consistent with statutory requirements, minimizing out-of-pocket risk for those beneficiaries.

TRICARE Prime Co-Pays

Active duty family members enrolled in TRICARE Prime pay no copayment for inpatient or outpatient services. Currently, retirees and their dependents enrolled in Prime pay higher copays for inpatient and outpatient mental health

services than for other similar non-mental health services. Retirees and all other non-active duty dependents enrolled in Prime would see the following changes:

- The co-pay for individual outpatient mental health visits would be reduced from \$25 to \$12.
- The co-pay for group outpatient mental health visits would be reduced from \$17 to \$12.

The per diem charge of \$40 for mental health and SUD inpatient admissions would be reduced to the non-mental health per diem rate of \$11, with a minimum charge of \$25 per admission.

TRICARE Standard Cost-Sharing

Currently, active duty family members (ADFM) utilizing TRICARE Standard/Extra pay a higher per diem for mental health inpatient care than for other inpatient stays. ADFMs would see the following change:

- The per diem cost-share for inpatient mental health services would be reduced from \$20/day to the daily charge (\$18/day for FY16) that would have been charged had the inpatient care been provided in a Uniformed Services hospital.

Retirees and their dependents who are not enrolled in Prime but use non-network providers (Standard) for mental health care are generally required to pay 25% of the allowable charges for inpatient care (for inpatient services subject to the DRG-based payment system or mental health per diem payment system, beneficiaries pay the lesser of the per diem amount (which is equivalent to 25% of the CHAMPUS-determined allowable costs) or 25% of the hospital's billed charges). This would not change. Retirees and their dependents using Standard and Extra are currently responsible for their outpatient deductible and outpatient cost-sharing of 25% (Standard)/20% (Extra) of the CHAMPUS-determined allowable costs. This also would not change.

It is also being proposed that cost-sharing for partial hospitalization programs (PHPs) be changed from inpatient to outpatient to more accurately reflect the services being rendered, ensure consistency with the applicable statutes governing cost-sharing, and to further ensure parity between the surgical/medical and mental health benefit. The definition of partial hospitalization, by its very nature, is inconsistent with the definition of inpatient care. Notwithstanding, in a final rule (58 FR 35403) published on July 1, 1993, and pursuant to the authority granted to the Secretary to establish different cost-

shares for mental health care [10 U.S.C. 1079(j)(2)], partial hospitalization is currently classified as an inpatient level of care for the purposes of cost-sharing by beneficiaries. This classification was originally adopted out of concern that the cost-sharing associated with outpatient care would result in substantially higher out-of-pocket expenses for TRICARE beneficiaries which, in turn, would provide a financial incentive for beneficiaries to seek a higher level of care (*i.e.*, acute or residential) than may be necessary. As a result, authority was employed to cost-share partial hospitalization services on an inpatient basis. It is important to note, however, beneficiaries now have the ability to minimize cost-sharing through enrollment options available under the TRICARE managed care program. As noted above, ADFMs enrolled in TRICARE Prime/Prime Remote, do not pay co-pays for inpatient or outpatient services. For retirees and their dependents enrolled in Prime, the current inpatient per diem charge of \$40 for partial hospitalization program services would be reduced to an outpatient co-pay of \$12 per day of services.

Realigning cost-sharing of partial hospitalization program services from inpatient to outpatient will impact ADFMs utilizing TRICARE Standard/Extra. Specifically, for ADFMs, the current inpatient per diem charge of \$20/day (with a minimum \$25 charge per admission) for partial hospitalization program services would instead be subject to the applicable outpatient deductible and cost-sharing of 20% (Standard)/15% (Extra) of the PHP per diem rate. For example, if the full-day PHP per diem rate is \$382, the cost-sharing for ADFMs would be \$57.30 under Extra and \$76.40 under Standard. However, these ADFMs would still retain the option of enrolling in TRICARE Prime/Prime Remote, where the cost-sharing is \$0 (*i.e.*, no cost-sharing is applied). The financial liability of ADFMs under Extra and Standard would be further limited by the annual \$1,000 catastrophic cap.

In an analysis to evaluate the potential financial impact on non-Prime ADFMs (*i.e.*, ADFMs utilizing TRICARE Extra and Standard options) of converting to PHP outpatient cost-sharing, it was found that in FY 2014 there were only 143 non-Prime ADFMs that had full-day or half-day PHP care. On average, they received 17 PHP services during the year with an average allowed amount per service of \$343. Based on these figures, non-Prime ADFMs' out-of-pocket liability (accumulated cost-sharing) would be

approximately \$875 under Extra, or \$1,166 under Standard. (However, Standard ADFM liability in this example would be limited by the \$1,000 catastrophic cap.) This analysis indicates that a very small number of non-Prime ADFMs have historically used PHP care and that those who have would, on average, either already hit or would be likely to hit the catastrophic cap. It is estimated that shifting to outpatient cost-sharing for PHP might cause about 50 to 80 additional non-Prime ADFMs to hit the catastrophic cap due to the higher PHP cost-sharing.

Conversion of PHP cost-sharing from inpatient to outpatient would more accurately reflect the services being provided. Further, Congress revoked the statutory authority granted to the Secretary to establish different cost-shares for mental health care. These factors provide the impetus for adoption of outpatient cost-sharing for PHPs.

3. Intensive Outpatient Program (IOP) Care for Psychiatric and Substance Use Disorders

Substance Use Disorder IOP services are currently not identified as separate levels of care from partial hospitalization in TRICARE regulations. Although hospital-based and free-standing facilities that are TRICARE authorized to offer partial hospitalization services can provide less intensive IOP, covered at the half-day partial hospitalization rate, the existing TRICARE certification requirements for these programs restrict the typical SUD IOP from being recognized as a separate program and provider type in its own right. SUD IOPs offer a validated level of care endorsed by ASAM, and the provision of IOP services through institutional providers also would have the potential benefit of expanding the volume of TRICARE participating providers and improving access to care.

While TRICARE beneficiaries may currently receive treatment for SUD or psychiatric disorders at a TRICARE authorized PHP, the proposed rule clearly authorizes IOP care as a covered benefit for treatment of SUD and psychiatric disorders. This proposed rule would authorize IOP care by a new class of institutional provider, which will provide a less restrictive setting than an inpatient or partial hospital setting. IOP care institutional providers will be required to be accredited by an accrediting body approved by the Director, Defense Health Agency, and meet the proposed requirements outlined in 32 CFR 199.6(b)(4)(xviii) in order to become TRICARE authorized.

Similar to IOPs for SUD treatment, psychiatric IOPs are not currently

explicitly reimbursed by TRICARE. This lack of authorization for IOP psychiatric care has restricted coverage options for TRICARE beneficiaries who may require step-down services from an inpatient stay or a PHP. As described regarding SUD IOP, psychiatric IOP services are considered separate levels of care from psychiatric partial hospitalization. Although current regulatory language defines partial hospitalization broad enough to permit coverage of IOP treatment conducted under the auspices of partial hospitalization, the absence of explicit IOP treatment coverage, along with the requirement that all IOP level of care be rendered by a TRICARE certified PHP, has limited access to this level of care and has led to confusion regarding TRICARE coverage of these services. The proposed regulatory language explicitly authorizing IOP treatment and establishing an authorized provider category will resolve these issues.

4. Treatment of Opioid Use Disorder

This rule proposes expanded treatment of opioid use disorder, with the provision of medication assisted treatment (MAT), through both TRICARE authorized institutional and individual providers. In addition to SUD IOPs, this rule proposes TRICARE coverage of opioid treatment programs (OTPs), with the inclusion of a definition of OTPs in 32 CFR 199.2 and the requirements for OTPs to become TRICARE authorized institutional providers outlined in 32 CFR 199.6(b)(4)(xix). Additionally, this rule proposes coverage of OBOT, as defined in 32 CFR 199.2, and coverage of MAT on an outpatient basis as extended in 32 CFR 199.4(c)(3)(ix)(A)(9).

5. Outpatient Substance Use Disorder Treatment by Individual Professional Providers

By current regulation, reimbursement for office-based SUD outpatient treatment provided by TRICARE authorized individual mental health providers, as specified in 32 CFR 199.6, is not permitted. Such outpatient SUD treatment services currently must be provided by a TRICARE approved institutional provider (*i.e.*, a hospital-based or free-standing SUDRF). However, although some accredited TRICARE authorized SUDRFs provide office-based SUD outpatient treatment, institutional providers of SUD care primarily provide services to patients requiring a higher level of SUD care. This creates a counter-therapeutic restriction on access to office-based outpatient treatment. To address this limitation in access, the proposed

regulation would revise the current reimbursement regime to provide coverage for individual outpatient SUD care, such as office-based outpatient treatment, outside of a SUDRF.

The 2007 report of the DoD Task Force on Mental Health (recommendation 5.3.4.8) stated, "TRICARE should allow outpatient substance abuse care to be provided by qualified professionals, regardless of whether they are affiliated with a day hospital or residential treatment program, including standard individual or group outpatient care." The DoD Task Force recommendation is consistent with the American Psychiatric Association, ASAM, and SAMHSA endorsement of individual therapies as an accepted and recommended clinical practice, also endorsed by National Institute on Drug Abuse, National Quality Forum, and VA/DoD CPG for Management of Substance Use Disorders. These proposed changes to the regulation would remove barriers to coverage of care for beneficiaries who are appropriate for treatment in an outpatient office setting, but who would otherwise only be able to access care at a SUDRF as required by current regulations.

This proposed rule also covers services of TRICARE authorized individual mental health providers, within the scope of their licensure or certification, offering medically or psychologically necessary SUD treatment services (including outpatient and family therapy) outside of a SUDRF, to include MAT and treatment of opioid use disorder by a TRICARE authorized physician delivering OBOT on an outpatient basis.

C. Streamlined Requirements for Institutional Providers To Become TRICARE Authorized Institutional Providers of Mental Health and Substance Use Disorder Care

Nearly two decades ago, the Final Rule: "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS): Mental Health Services," as published in 60 FR 12419, March 7, 1995, reformed quality of care standards and reimbursement methods for inpatient mental health services. In the 1995 Final Rule, standards were developed to address identified problems of quality of care, fraud, and abuse in RTCs, SUDRFs, and PHPs. They were developed to provide "clear [and] specific standards for psychiatric facilities on staff qualifications, clinical practices, and all other aspects directly impacting the quality of care."

Since publication of the 1995 Final Rule, several organizations that accredit

various forms of healthcare delivery have developed strong standards to protect patient care in mental health facilities. There are now a number of industry-accepted accrediting bodies with standards that meet or exceed the current TRICARE-established standards (e.g., TJC, Commission on Accreditation of Rehabilitation Facilities). Also in the interim, scientific knowledge, standards of care and patient safety, technology, and psychotropic pharmaceuticals have improved. Alongside with updating the current benefits, we believe streamlining procedures to qualify as a TRICARE authorized institutional provider will not only increase access to approved care, but also decrease the overall cost of certifying duplicative and now unnecessary quality standards first implemented by the 1995 Final Rule.

This proposed rule simplifies the regulation to account for existing industry-wide accepted accreditation standards for TRICARE institutional providers of mental health care, including RTCs, freestanding PHPs, and freestanding SUDRFs. Requirements for TRICARE certification beyond industry-accepted accreditation, while once considered necessary to ensure quality and safety, are now proving to be unnecessarily restrictive and inconsistent with current institutional provider standards and organization. Specifically, the proposed rule streamlines procedures and requirements for SUDRFs, RTCs, PHPs, IOPs and OTPs to qualify as TRICARE authorized providers, relying primarily on accreditation by a national body approved by the Director, as opposed to detailed, lengthy, stand-alone TRICARE requirements (e.g., regarding such things as the qualifications and authority of the clinical director, staff composition and qualifications, and standards for physical plant and environment, amongst others). In general, mental health and SUD institutional providers may become TRICARE authorized institutional providers if the facility is accredited by an accrediting organization approved by the Director and agrees to execute a participation agreement with TRICARE, as outlined in the proposed regulations. This streamlined approval process is a greatly simplified process from the current, detailed certification process for current institutional providers.

Furthermore, given that there are now a growing number of accrediting bodies established for institutional providers of mental health care and industry standards that are widely accepted, the proposed rule eliminates by name references to specific accrediting bodies (e.g., The Joint Commission (TJC)),

where appropriate. Instead, the specific mention of accrediting bodies is replaced with the term, "an accrediting organization, approved by Director." This will allow the Defense Health Agency (DHA) flexibility in selecting and recognizing the authority of various accrediting bodies to assist in authorization of institutional providers of mental health care and SUD care. Rather than name all the approved accrediting bodies in regulation, DHA will identify specific accrediting bodies for various types of mental health care in TRICARE sub-regulatory policy found at manuals.tricare.osd.mil.

D. TRICARE Reimbursement Methodologies for Newly Recognized Mental Health and SUD Intensive Outpatient Programs and Opioid Treatment Programs and Cost-Sharing Methodology

The newly recognized IOPs and methadone OTPs established in this rule will be reimbursed using bundled per diem amounts based on the intensity, frequency and duration of services and/or drugs provided in these well-established treatment programs. Since IOPs provide a step-down in services from an inpatient stay or full-day PHP (i.e., the intensity, frequency and duration of the services provided in IOPs are considered to be less than those provided in an inpatient or PHP setting), the per diems will be proportionally reduced from currently established full-day PHP per diems. This proportional reduction in per diems is consistent with past methodologies used in establishing full-day and half-day PHP payments. Since IOPs are also provided in PHPs as a step-down in intensity of care, the IOP designation will be used in lieu of half-day PHP for beneficiaries typically receiving treatment two to five hours per day, two to five times a week, as directed by their individualized treatment plan, in a PHP authorized setting. The IOP services, whether provided in a PHP or newly recognized IOP setting, will be paid a regionally adjusted per diem rate of 75 percent of the rate for a full-day PHP. In other words, PHP treatments of less than six hours—with a minimum of two hours—will be recognized as IOPs for coverage and reimbursement under the program.

OTPs that administer methadone as a treatment for SUD will be reimbursed a bundled weekly per diem payment to include the cost of the medication, along with integrated psychosocial and medical treatment support services. When buprenorphine or naltrexone is administered, OTPs will, on the other hand, be reimbursed on a fee-for-service

basis (*i.e.*, separate payments will be allowed for both the medication and accompanying support services) due to the variability in the recommended dosage and frequency of the administered drugs based on conditions requiring medical oversight. The individual fee-for-service payments for buprenorphine and naltrexone will be subject to outpatient cost-sharing on a per-visit basis, while the cost-sharing for methadone OTP services will be applied on a weekly basis. Established per diem rates for OTPs administering methadone will be updated annually by the Medicare update factor used for that program's Inpatient Prospective Payment System. 32 CFR 199.14(a)(4)(ix) is amended in its entirety to reflect payment for psychiatric and SUD PHP, IOP and OTP services as discussed above.

1. Intensive Outpatient Program Reimbursement

Under current regulatory provisions [32 CFR 199.14(a)(2)(ix)(C)], the maximum per diem payment amount for a full-day partial hospitalization program (minimum of six hours) is 40 percent of the average per diem amount per case established under the TRICARE mental health per diem reimbursement system for both high and low volume psychiatric hospitals and units. Likewise, PHPs less than six hours (with a minimum of three hours) are paid a per diem rate at 75 percent of the rate for a full-day program. In analysis of the reimbursement methodology to be used for reimbursement of IOPs, it became apparent that the step-down in intensity, frequency and duration of treatment designated as half-day PHPs, were in fact, intensive outpatient services provided within a PHP authorized setting. While there is some variability in the intensity, frequency and duration of treatment under both programs (that is, less than six hours per day with a minimum of three hours for half-day PHPs; and two to five times per week, two to five hours per day for IOPs), it appears that both the services rendered and the professional provider categories responsible for providing the services are quite similar. As a result of this observation/analysis, a decision has been made to use the IOP designation in lieu of half-day PHP for treatment of less than six hours per day—with a minimum of two hours per day—rendered in a PHP authorized setting. While the minimum hours have been reduced from three to two hours per day for coverage/reimbursement, they are still within the acceptable range for IOP services typically provided in a PHP. Since intensive outpatient services can

be provided in either a PHP or newly authorized IOP setting, and IOP services are essentially the same as half-day PHP services, it is only logical that IOP per diems be set at 75 percent of the full-day PHP per diem. This would be the case regardless of whether the IOP services were provided in a PHP or IOP.

2. Opioid Treatment Program Reimbursement and Cost-Sharing

As defined in this proposed rule, OTPs are outpatient settings for opioid treatment that use a therapeutic maintenance drug for a drug addiction when medically or psychologically necessary and appropriate for the medical care of a beneficiary undergoing supervised treatment for a SUD. The program includes an initial assessment, along with integrated psychosocial and medical treatment and support services. Since OTPs are individually tailored programs of medication therapy, separate reimbursement methodologies are being established based on the particular medication being administered for treatment of the SUD. By far the most common medication used in OTPs is methadone. Methadone OTP care includes initial medical intake/assessment, urinalysis and drug dispensing and screening as part of the bundled rate, as well as ongoing counseling services. Based on a preliminary review of industry billing practices, the proposed weekly bundled per diem for administration of methadone will include a daily drug cost of \$3, along with a \$15 per day cost for integrated psychosocial and medical support services. The daily projected per diem costs (\$18/day) will be converted to a weekly per diem rate of \$126 (\$18/day × 7 days) and billed once a week to TRICARE using the Healthcare Common Procedure Coding System (HCPCS) code H0020, "Alcohol and/or drug services; methadone administration and/or service." The bundled per diem rate is how Medicaid and other third-party payers typically reimburse for methadone treatment in OTPs. The methadone OTP rate will be updated annually by the Medicare update factor used for other mental health care services rendered (*i.e.* the Inpatient Prospective Payment System update factor) under TRICARE. The updated rates will be effective October 1 of each year, and will be published annually on the TRICARE Web site. Outpatient cost-sharing will be applied to a weekly per diem, since the copayment amounts for Prime NADDs and ADFMs under Extra and Standard would be near, or in some cases, above the daily charge for OTPs, essentially resulting in a non-benefit.

While the other two medications (buprenorphine and naltrexone) are more likely to be prescribed and administered in an OBOT setting, OTP reimbursement methodologies are being established for both medications to allow OTPs the full range of medications currently available for treatment of SUDs. Since the reimbursement of buprenorphine and naltrexone administered in OTPs are not conducive to the bundled per diem methodology due to variations in dosage and frequency of the drug and the non-drug services (*e.g.*, administration fees and counseling services) will be reimbursed separately on a fee-for-service basis. We recognize that Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes are updated on a regular basis. The following referenced codes are current as of the writing of this proposed rule. If necessary, updated codes will be included in the TRICARE Policy Manual or TRICARE Reimbursement Manual found at manuals.tricare.osd.mil. In the case of Buprenorphine, the OTP will bill TRICARE using the HCPCS code H0047, "Alcohol and/or other drug use services, not otherwise specified," for the medical intake/assessment, drug dispensing and monitoring and counseling, along with HCPCS code J8499, "Prescription drug, oral, non-chemotherapeutic, nos," for the prescribed medication. The OTP will include the National Drug Code for the Buprenorphine, along with the dosage and acquisition cost on its claim. Prevailing rates will be established for drug related services (*e.g.*, drug monitoring and counseling services) billed under HCPCS code H0047, while the drug itself will be reimbursed at 95 percent of the average wholesale price. Outpatient cost-sharing will be applied on a per-visit basis. The preliminary weekly cost estimate for Buprenorphine OTPs is \$115 per week, assuming that the patient is stabilized and visiting the OTP twice a week. This is based on an estimated drug cost of \$10 per day and an estimated non-drug cost of \$22.50 per visit [(7 × \$10) + (2 × \$22.50) = \$115/week]. These amounts mentioned above are preliminary and estimates and not intended to reflect final reimbursement rates.

Naltrexone, unlike methadone and buprenorphine, is not an agonist or partial agonist, but an inhibitor designed to block the brain's opiate receptors, diminishing the urges and cravings for alcohol, heroin, and prescription painkillers such as oxycodone. Due to the extreme cost of

injectable naltrexone and the fact that it is only administered once a month, the drug, its administration fee and ongoing counseling will be paid separately on a fee-for-service basis. The OTP will bill TRICARE using HCPCS code H0047 for the counseling services and other OTP services. Prevailing rates will be established for drug related services (e.g., drug monitoring and counseling services) billed under HCPCS code H0047. The naltrexone injection will be billed using the HCPCS code J2315 with the number of milligrams used, while its administration fee will be billed using CPT code 96372. OTP outpatient cost-sharing will be applied on a per-visit basis, which in this case would be once a month. The projected monthly amount for naltrexone is \$1,177 (\$1,129 for the injectable drug (J2315) + \$25 for the drug's administration fee (CPT 96372) + \$22.50 for other related services (H0047) = \$1,176.50). These amounts may be subject to change based on health care market forces, but are not expected to change significantly.

The Director will have discretionary authority in establishing the reimbursement methodologies for new drugs and biologicals that may become available for the treatment of SUDs in OTPs. The type of reimbursement (e.g., fee-for-service versus bundled per diem payments) will be dependent in large part on the variability of the dosage and frequency of the medication being administered.

While TRICARE provider reimbursement methods are normally tied to Medicare reimbursement, there were no Medicare reimbursement rules applicable to the above providers of services. As a result, DoD particularly invites public comment on these proposed reimbursement methodologies in an effort to ensure they bear a reasonable relationship to the cost of providing such services.

3. Removal of **Federal Register** Publication of TRICARE Hospital-Specific Rates and Fixed Daily Copayment Amounts

Under current regulatory provisions [32 CFR 199.4(f)(3)(ii)(B) and 32 CFR 199.14(a)(2)(iv)(C)(4)], annually updated psychiatric hospital regional per diems and fixed daily copayment amounts are to be published in the **Federal Register** at approximately the start of each fiscal year. While the initial intent of this regulatory requirement was to provide widespread notice of changes to regional psychiatric hospital per diems and fixed copayment amounts, its relevancy has been subsequently overshadowed by the public's online accessibility to the TRICARE manuals

and reimbursement rates on the official Web site of the Military Health System and the DHA (www.health.mil). As a result, the public has ready online access to psychiatric hospital regional per diems and fixed daily copayment amounts, as well as maximum rates for mental health rates, to include freestanding psychiatric PHPs in the TRICARE Reimbursement Manual or on the official Web site of the Military Health System and the DHA (www.health.mil). Because of the readily available online access to updated mental health rates and the ongoing administrative burden of publishing annual notices to the **Federal Register**, it is being proposed that the regulatory requirements be removed and that updates to psychiatric hospital regional per diems and fixed copayment amounts be maintained on the Agency's official Web site. However, psychiatric hospitals and units with hospital-specific rates will continue to be notified individually of their rates due to confidentiality restrictions. The new proposed per diem rates for IOPs and methadone OTPs will also be maintained and available to the public on the official Web site of the Military Health System and the DHA (www.health.mil).

E. Additional Proposed Regulatory Revisions

There are a number of additional proposed revisions that are more technical and administrative in nature that we would like to highlight here to ensure the public is made aware of these changes and the purpose for the proposed changes. Within 32 CFR 199.2, the definition of "adequate medical documentation, mental health records" is revised to eliminate specific reference to Joint Commission standards and instead reference "standards of an accrediting organization approved by the Director" consistent with the changes in accreditation requirements as part of the proposed streamlining of TRICARE approval of institutional providers. The definition of "mental disorder" has been revised to include SUD. The definition of "Director" has been revised to incorporate the Director of the Defense Health Agency, consistent with DoD's current organizational structure. Additionally, throughout the proposed revisions, the term "Director" has been substituted for all other terms such as "Director, CHAMPUS" and "Director, TRICARE Management Activity." A definition of "qualified mental health provider" has been added for easy reference (as it was previously discussed in 32 CFR 199.4 but not specifically defined), and the

definitions of "Case managers" and "Consultants" have been amended to include qualified mental health providers. Additionally, the elimination of quantitative limitations has also necessitated a number of revisions to other sections of the regulation that referenced these limits, including 32 CFR 199.4(e)(2), 32 CFR 199.7(e)(2) and 32 CFR 199.15(a)(6). Also, 32 CFR 199.14(a)(2)(iv)(C)(2) clarifies that the Medicare's Inpatient Prospective Payment System update factor is used for TRICARE's mental health rates.

Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Subsequently, the Department completed an Independent Government Cost Estimate and the results are referenced in C. Cost and Benefits. This proposed rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the proposed rule has been reviewed by the Office of Management and Budget (OMB).

Congressional Review Act, 5 U.S.C. 804(2)

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of \$100 million or more or have certain other impacts. This proposed rule is not a major rule under the Congressional Review Act.

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

The Regulatory Flexibility Act requires that each Federal agency analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small

businesses, nonprofit organizations, and small governmental jurisdictions. This proposed rule is not an economically significant regulatory action, and it will not have a significant impact on a substantial number of small entities. Therefore, this proposed rule is not subject to the requirements of the RFA.

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

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$140 million. This proposed rule will not mandate any requirements for state, local, or tribal governments or the private sector.

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

This rulemaking does not contain a "collection of information" requirement, and will not impose additional information collection requirements on the public under Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. chapter 35).

Executive Order 13132, "Federalism"

This proposed rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national Government and the States, or on the distribution of powers and responsibilities among the various levels of Government. Therefore, consultation with State and local officials is not required.

Public Comments Invited

This rulemaking is being issued as a proposed rule. DoD invites public comments on all provisions of the proposed rule. All submissions will be considered for possible revision to be included in the final rule.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Mental health, Mental health parity, Military personnel, Substance use disorder treatment.

For the reasons stated in the preamble, the Department of Defense proposes to amend 32 CFR part 199 as set forth below:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

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

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

■ 2. Section 199.2(b) is amended by:

- a. Revising the definitions of "Adequate medical documentation, mental health records", "Case management", "Case managers", "Consultation", and "Director";
- b. Adding definitions for "Intensive outpatient program (IOP)" and "Medication assisted treatment (MAT)" in alphabetical order;
- c. Removing the definition of "Mental disorder";
- d. Adding definitions for "Mental disorder, to include substance use disorder", "Office-based opioid treatment" and "Opioid treatment program" in alphabetical order;
- e. Revising the definitions of "Other special institutional providers" and "Partial hospitalization";
- f. Adding a definition for "Qualified mental health provider" in alphabetical order;
- g. Revising the definition of "Residential treatment center (RTC)";
- h. Adding a definition for "Substance use disorder rehabilitation facility (SUDRF)" in alphabetical order; and
- i. Revising the definition of "Treatment plan".

The revisions and additions read as follows:

§ 199.2 Definitions

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(b) * * *

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Adequate medical documentation, mental health records. Adequate medical documentation provides the means for measuring the type, frequency, and duration of active treatment mechanisms employed and progress under the treatment plan. Under CHAMPUS, it is required that adequate and sufficient clinical records be kept by the provider to substantiate that specific care was actually and appropriately furnished, was medically or psychologically necessary (as defined by this part), and to identify the individual(s) who provided the care. Each service provided or billed must be documented in the records. In determining whether medical records are adequate, the records will be reviewed under the generally acceptable standards (e.g., the standards of an accrediting organization approved by the Director, and the provider's state or

local licensing requirements) and other requirements specified by this part. The psychiatric and psychological evaluations, physician orders, the treatment plan, integrated progress notes (and physician progress notes if separate from the integrated progress notes), and the discharge summary are the more critical elements of the mental health record. However, nursing and staff notes, no matter how complete, are not a substitute for the documentation of services by the individual professional provider who furnished treatment to the beneficiary. In general, the documentation requirements of a professional provider are not less in the outpatient setting than the inpatient setting. Furthermore, even though a hospital that provides psychiatric care may be accredited under The Joint Commission (TJC) manual for hospitals rather than the behavioral health standards manual, the critical elements of the mental health record listed above are required for CHAMPUS claims.

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Case management. Case management is a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual's health needs, including mental health needs, using communication and available resources to promote quality, cost effective outcomes.

Case managers. A licensed registered nurse, licensed clinical social worker, licensed psychologist, licensed physician, or qualified mental health provider who has a minimum of two (2) years case management experience.

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Consultation. A deliberation with a specialist physician, dentist, or qualified mental health provider requested by the attending physician primarily responsible for the medical care of the patient, with respect to the diagnosis or treatment in any particular case. A consulting physician or dentist or qualified mental health provider may perform a limited examination of a given system or one requiring a complete diagnostic history and examination. To qualify as a consultation, a written report to the attending physician of the findings of the consultant is required.

Note: Staff consultations required by rules and regulations of the medical staff of a hospital or other institutional provider do not qualify as consultation.

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Director. The Director of the Defense Health Agency, Director, TRICARE Management Activity, or Director,

Office of CHAMPUS. Any references to the Director, Office of CHAMPUS, or OCHAMPUS, or TRICARE Management Activity, shall mean the Director, Defense Health Agency (DHA). Any reference to Director shall also include any person designated by the Director to carry out a particular authority. In addition, any authority of the Director may be exercised by the Assistant Secretary of Defense (Health Affairs).

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Intensive outpatient program (IOP). A treatment setting capable of providing an organized day or evening program that includes assessment, treatment, case management and rehabilitation for individuals not requiring 24-hour care for mental health disorders, to include substance use disorders, as appropriate for the individual patient. The program structure is regularly scheduled, individualized and shares monitoring and support with the patient's family and support system.

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Medication assisted treatment (MAT). MAT for diagnosed opioid use disorder is a holistic modality for recovery and treatment that employs evidence-based therapy, including psychosocial treatments and psychopharmacology, and FDA-approved medications as indicated for the management of withdrawal symptoms and maintenance.

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Mental disorder, to include substance use disorder. For purposes of the payment of CHAMPUS benefits, a mental disorder is a nervous or mental condition that involves a clinically significant behavioral or psychological syndrome or pattern that is associated with a painful symptom, such as distress, and that impairs a patient's ability to function in one or more major life activities. A substance use disorder is a mental condition that involves a maladaptive pattern of substance use leading to clinically significant impairment or distress; impaired control over substance use; social impairment; and risky use of a substance(s). Additionally, the mental disorder must be one of those conditions listed in the current edition of the Diagnostic and Statistical Manual of Mental Disorders. "Conditions Not Attributable to a Mental Disorder," or V codes, are not considered diagnosable mental disorders. Co-occurring mental and substance use disorders are common and assessment should proceed as soon as it is possible to distinguish the substance related symptoms from other independent conditions.

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Office-based opioid treatment. TRICARE authorized providers acting within the scope of their licensure or certification to prescribe outpatient supplies of the medication to assist in withdrawal management (detoxification) and/or maintenance of opioid use disorder, as regulated by 42 CFR part 8, addressing office-based opioid treatment (OBOT).

* * * * *

Opioid Treatment Program. Opioid Treatment Programs (OTPs) are service settings for opioid treatment, either free standing or hospital based, that adhere to the Department of Health and Human Services' regulations at 42 CFR part 8 and use medications indicated and approved by the Food and Drug Administration. Treatment in OTPs provides a comprehensive, individually tailored program of medication therapy integrated with psychosocial and medical treatment and support services that address factors affecting each patient, as certified by the Center for Substance Abuse Treatment (CSAT) of the Department of Health and Human Services's Substance Abuse and Mental Health Services Administration. Treatment in OTPs can include management of withdrawal symptoms (detoxification) from opioids and medically supervised withdrawal from maintenance medications. Patients receiving care for substance use and co-occurring disorders care can be referred to, or otherwise concurrently enrolled in, OTP services.

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Other special institutional providers. Certain specialized medical treatment facilities, either inpatient or outpatient, other than those specifically defined, that provide courses of treatment prescribed by a doctor of medicine or osteopathy; when the patient is under the supervision of a doctor of medicine or osteopathy during the entire course of the inpatient admission or the outpatient treatment; when the type and level of care and services rendered by the institution are otherwise authorized in this part; when the facility meets all licensing or other certification requirements that are extant in the jurisdiction in which the facility is located geographically; which is accredited by the Joint Commission or other accrediting organization approved by the Director if an appropriate accreditation program for the given type of facility is available; and which is not a nursing home, intermediate facility, halfway house, home for the aged, or other institution of similar purpose.

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Partial hospitalization. A treatment setting capable of providing an interdisciplinary program of medically monitored therapeutic services, to include management of withdrawal symptoms, as medically indicated. Services may include day, evening, night and weekend treatment programs which employ an integrated, comprehensive and complementary schedule of recognized treatment approaches. Partial hospitalization is a time-limited, ambulatory, active treatment program that offers therapeutically intensive, coordinated, and structured clinical services within a stable therapeutic environment. Partial hospitalization is an appropriate setting for crisis stabilization, treatment of partially stabilized mental disorders, to include substance disorders, and a transition from an inpatient program when medically necessary.

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Qualified mental health provider. Psychiatrists or other physicians; clinical psychologists, certified psychiatric nurse specialists, certified clinical social workers, certified marriage and family therapists, TRICARE certified mental health counselors, pastoral counselors under a physician's supervision, and supervised mental health counselors under a physician's supervision.

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Residential treatment center (RTC). A facility (or distinct part of a facility) which meets the criteria in § 199.6(b)(4)(vii).

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Substance use disorder rehabilitation facility (SUDRF). A facility or a distinct part of a facility that meets the criteria in § 199.6(b)(4)(xiv).

* * * * *

Treatment plan. A detailed description of the medical care being rendered or expected to be rendered a CHAMPUS beneficiary seeking approval for inpatient and other benefits for which preauthorization is required as set forth in § 199.4(b). Medical care described in the plan must meet the requirements of medical and psychological necessity. A treatment plan must include, at a minimum, a diagnosis (either International Statistical Classification of Diseases and Related Health Problems (ICD) or Diagnostic and Statistical Manual or Mental Disorders (DSM)); detailed reports of prior treatment, medical history, family history, social history, and physical examination; diagnostic test results; consultant's reports (if any); proposed treatment by type (such as surgical, medical, and psychiatric); a description

of who is or will be providing treatment (by discipline or specialty); anticipated frequency, medications, and specific goals of treatment; type of inpatient facility required and why (including length of time the related inpatient stay will be required); and prognosis. If the treatment plan involves the transfer of a CHAMPUS patient from a hospital or another inpatient facility, medical records related to that inpatient stay also are required as a part of the treatment plan documentation.

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- 3. Section 199.4 is amended by:
- a. Revising paragraphs (a)(1)(i) and the paragraph heading of (a)(12);
- b. Adding paragraphs (a)(14), (b)(1)(vi), (b)(2)(xix) and (xx), and (b)(3)(xvi) and (xvii);
- c. Removing paragraphs (b)(4)(viii) and (ix);
- d. Removing and reserving paragraphs (b)(6)(iii) and (iv);
- e. Revising paragraph (b)(7) introductory text;
- f. Revising paragraphs (b)(8), (9), and (10);
- g. Adding paragraph (b)(11);
- h. Revising paragraph (c)(3)(ix);
- i. Removing and reserving paragraphs (e)(4) and (e)(7);
- j. Revising paragraph (e)(8)(ii)(A);
- k. Adding paragraph (e)(8)(ii)(D);
- l. Removing and reserving paragraph (e)(8)(iv)(P);
- m. Revising paragraphs (e)(8)(iv)(Q) and (R);
- n. Revising paragraph (e)(11) introductory text
- o. Revising paragraph (e)(13)(i)(B);
- p. Removing paragraph (e)(30)(iii);
- q. Revising paragraph (f)(2)(ii) introductory text;
- r. Removing paragraph (f)(2)(ii)(D);
- s. Removing and reserving paragraph (f)(2)(v);
- t. Revising paragraph (f)(3)(ii);
- u. Removing paragraph (f)(3)(iv);
- v. Revising paragraphs (g)(1) and (g)(29);
- w. Removing and reserving paragraph (g)(72); and
- x. Revising paragraph (g)(73).

The revisions and additions read as follows:

§ 199.4 Basic program benefits.

(a) * * *

(1)(i) *Scope of benefits.* Subject to all applicable definitions, conditions, limitations, or exclusions specified in this part, the CHAMPUS Basic Program will pay for medically or psychologically necessary services and supplies required in the diagnosis and treatment of illness or injury, including maternity care and well-baby care. Benefits include specified medical

services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals, other authorized institutional providers, physicians, other authorized individual professional providers, and professional ambulance service, prescription drugs, authorized medical supplies, and rental or purchase of durable medical equipment.

* * * * *

(12) *Utilization review, quality assurance, and reauthorization for all mental health services provided by institutional providers.* * * *

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(14) Confidentiality of substance use disorder treatment. Release of any patient identifying information, including that required to adjudicate a claim, must comply with the provisions of section 543 of the Public Health Service Act, as amended, (42 U.S.C. 290dd-2), and implementing regulations at 42 CFR part 2, which governs the release of medical and other information from the records of patients undergoing treatment of substance use disorder. If the patient refuses to authorize the release of medical records which are, in the opinion of the Director, Defense Health Agency, or a designee, necessary to determine benefits on a claim for treatment of substance use disorder, the claim will be denied.

(b) * * *

(1) * * *

(vi) *Substance use disorder treatment exclusions.* (A) The programmed use of physical measures, such as electric shock, alcohol, or other drugs as negative reinforcement (aversion therapy) is not covered, even if recommended by a physician.

(B) *Domiciliary settings.* Domiciliary facilities generally referred to as halfway or quarterway houses are not authorized providers and charges for services provided by these facilities are not covered.

(2) * * *

(xix) *Medication assisted treatment.* Covered drugs and medicines for the treatment of substance use disorder include the substitution of a therapeutic drug, with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing supervised treatment for a substance use disorder.

(xx) *Withdrawal management (detoxification).* For a beneficiary undergoing treatment for a substance use disorder, this includes management of a patient's withdrawal symptoms (detoxification).

(3) * * *

(xvi) *Medication assisted treatment.* Covered drugs and medicines for the treatment of substance use disorder include the substitution of a therapeutic drug, with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing supervised treatment for a substance use disorder.

(xvii) *Withdrawal management (detoxification).* For a beneficiary undergoing treatment for a substance use disorder, this includes management of a patient's withdrawal symptoms (detoxification).

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(7) *Emergency inpatient hospital services.* In the case of a medical emergency, benefits can be extended for medically necessary inpatient services and supplies provided to a beneficiary by a hospital, including hospitals that do not meet CHAMPUS standards or comply with the nondiscrimination requirements under title VI of the Civil Rights Act and other nondiscrimination laws applicable to recipients of federal financial assistance, or satisfy other conditions herein set forth. In a medical emergency, medically necessary inpatient services and supplies are those that are necessary to prevent the death or serious impairment of the health of the patient, and that, because of the threat to the life or health of the patient, necessitate, the use of the most accessible hospital available and equipped to furnish such services. Emergency services are covered when medically necessary for the active medical treatment of the acute phases of substance withdrawal (detoxification), for stabilization and for treatment of medical complications for substance use disorder. The availability of benefits depends upon the following three separate findings and continues only as long as the emergency exists, as determined by medical review. If the case qualified as an emergency at the time of admission to an unauthorized institutional provider and the emergency subsequently is determined no longer to exist, benefits will be extended up through the date of notice to the beneficiary and provider that CHAMPUS benefits no longer are payable in that hospital.

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(8) *Residential treatment for substance use disorder—(i) In general.* Rehabilitative care, to include withdrawal management (detoxification), in an inpatient residential setting of an authorized hospital or substance use disorder

rehabilitative facility, whether free-standing or hospital-based, is covered on a residential basis. The medical necessity for the management of withdrawal symptoms must be documented. Any withdrawal management (detoxification) services provided by the substance use disorder rehabilitation facility must be under general medical supervision.

(ii) *Criteria for determining medical or psychological necessity of residential treatment for substance use disorder.* Residential treatment for substance use disorder will be considered necessary only if all of the following conditions are present:

(A) The patient has been diagnosed with a substance use disorder.

(B) The patient is experiencing withdrawal symptoms or potential symptoms severe enough to require inpatient care and physician management, or who have less severe symptoms that require 24-hour inpatient monitoring or the patient's addiction-related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas.

(iii) *Services and supplies.* The following services and supplies are included in the per diem rate approved for an authorized residential treatment for substance use disorder.

(A) *Room and board.* Includes use of the residential treatment program facilities such as food service (including special diets), laundry services, supervised therapeutically constructed recreational and social activities, and other general services as considered appropriate by the Director, or a designee.

(B) *Patient assessment.* Includes the assessment of each individual accepted by the facility, and must, at a minimum, consist of a physical examination; psychiatric examination; psychological assessment; assessment of physiological, biological and cognitive processes; case management assessment; developmental assessment; family history and assessment; social history and assessment; educational or vocational history and assessment; environmental assessment; and recreational/activities assessment. Assessments conducted within 30 days prior to admission to a residential treatment program for substance use disorder (SUD) may be used if approved and deemed adequate to permit treatment planning by the residential treatment program for SUD.

(C) *Psychological testing.* Psychological testing is provided based on medical and psychological necessity.

(D) *Treatment services.* All services, supplies, equipment and space

necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: Residential treatment programs 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 all-inclusive per diem rate, but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) *Case management required.* The facility must provide case management that helps to assure arrangement of community based support services, referral of suspected child or elder abuse or domestic violence to the appropriate state agencies, and effective after care arrangements, at a minimum.

(v) *Professional mental health benefits.* Professional mental health benefits are billed separately from the residential treatment program per diem rate only when rendered by an attending, TRICARE authorized mental health professional who is not an employee of, or under contract with, the program for purposes of providing clinical patient care.

(vi) *Non-mental health related medical services.* Separate billing will be allowed for otherwise covered non-mental health related services.

(9) *Psychiatric and substance use disorder partial hospitalization services—(i) In general.* Partial hospitalization services are those services furnished by a TRICARE authorized partial hospitalization program and authorized mental health providers for the active treatment of a mental disorder. All services must follow a medical model and vest patient care under the general direction of a licensed TRICARE authorized physician employed by the partial hospitalization program to ensure medication and physical needs of all the patients are considered. The primary or attending provider must be a TRICARE authorized mental health provider (see paragraph (c)(3)(ix) of this section), operating within the scope of his/her license. These categories include physicians, clinical psychologists, certified psychiatric nurse specialists, clinical social workers, marriage and family counselors, TRICARE certified mental health counselors, pastoral counselors,

and supervised mental health counselors. All categories practice independently except pastoral counselors and supervised mental health counselors who must practice under the supervision of TRICARE authorized physicians. Partial hospitalization services and interventions are provided at a high degree of intensity and restrictiveness of care, with medical supervision and medication management. Partial hospitalization services are covered as a basic program benefit only if they are provided in accordance with paragraph (b)(9) of this section. Such programs must enter into a participation agreement with TRICARE; and be accredited and in substantial compliance with the specified standards of an accreditation organization approved by the Director.

(ii) *Criteria for determining medical or psychological necessity of psychiatric and SUD partial hospitalization services.* Partial hospitalization services will be considered necessary only if all of the following conditions are present:

(A) The patient is suffering significant impairment from a mental disorder (as defined in § 199.2) which interferes with age appropriate functioning or the patient is in need of rehabilitative services for the management of withdrawal symptoms from alcohol, sedative-hypnotics, opioids, or stimulants that require medically-monitored ambulatory detoxification, with direct access to medical services and clinically intensive programming of rehabilitative care based on individual treatment plans.

(B) The patient is unable to maintain himself or herself in the community, with appropriate support, at a sufficient level of functioning to permit an adequate course of therapy exclusively on an outpatient basis, to include outpatient treatment program, outpatient office visits, or intensive outpatient services (but is able, with appropriate support, to maintain a basic level of functioning to permit partial hospitalization services and presents no substantial imminent risk of harm to self or others). These patients require medical support; however, they do not require a 24-hour medical environment.

(C) The patient is in need of crisis stabilization, acute symptom reduction, treatment of partially stabilized mental health disorders, or services as a transition from an inpatient program.

(D) The admission into the partial hospitalization program is based on the development of an individualized diagnosis and treatment plan expected to be effective for that patient and

permit treatment at a less intensive level.

(iii) *Services and supplies.* The following services and supplies are included in the per diem rate approved for an authorized partial hospitalization program:

(A) *Board.* Includes use of the partial hospital facilities such as food service, supervised therapeutically constructed recreational and social activities, and other general services as considered appropriate by the Director, or a designee.

(B) *Patient assessment.* Includes the assessment of each individual accepted by the facility, and must, at a minimum, consist of a physical examination; psychiatric examination; psychological assessment; assessment of physiological, biological and cognitive processes; case management assessment; developmental assessment; family history and assessment; social history and assessment; educational or vocational history and assessment; environmental assessment; and recreational/activities assessment. Assessments conducted within 30 days prior to admission to a partial program may be used if approved and deemed adequate to permit treatment planning by the partial hospital program.

(C) *Psychological testing.*

(D) *Treatment services.* All services, supplies, equipment and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: Partial hospitalization programs 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 all-inclusive per diem rate, but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the partial hospitalization program.]

(iv) *Case management required.* The facility must provide case management that helps to assure the patient appropriate living arrangements after treatment hours, transportation to and from the facility, arrangement of community based support services, referral of suspected child or elder abuse or domestic violence to the appropriate state agencies, and effective after care arrangements, at a minimum.

(v) *Educational services required.* Programs treating children and adolescents must ensure the provision of a state certified educational component which assures that patients do not fall behind in educational placement while receiving partial hospital treatment. CHAMPUS will not fund the cost of educational services separately from the per diem rate. The hours devoted to education do not count toward the therapeutic intensive outpatient program or full day program.

(vi) *Family therapy required.* The facility must ensure the provision of an active family therapy treatment component, which assures that each patient and family participate at least weekly in family therapy provided by the institution and rendered by a TRICARE authorized individual professional provider of mental health services. There is no acceptable substitute for family therapy. An exception to this requirement may be granted on a case-by-case basis by the Director, or designee, only if family therapy is clinically contraindicated.

(vii) *Professional mental health benefits.* Professional mental health benefits are billed separately from the partial hospitalization per diem rate only when rendered by an attending, TRICARE authorized mental health professional who is not an employee of, or under contract with, the partial hospitalization program for purposes of providing clinical patient care.

(viii) *Non-mental health related medical services.* Separate billing will be allowed for otherwise covered, non-mental health related medical services.

(10) *Intensive psychiatric and substance use disorder outpatient services—(i) In general.* Intensive outpatient services are those services furnished by a TRICARE authorized intensive outpatient program and qualified mental health provider(s) for the active treatment of a mental disorder, to include substance use disorder.

(ii) *Criteria for determining medical or psychological necessity of intensive outpatient services.* In determining the medical or psychological necessity of intensive outpatient services, the evaluation conducted by the Director, or designee, shall consider the appropriate level of care, based on the patient's clinical needs and characteristics matched to a service's structure and intensity. In addition to the criteria set for this paragraph (b)(10) of this section, additional evaluation standards, consistent with such criteria, may be adopted by the Director, or designee. Treatment in an intensive outpatient setting shall not be considered

necessary unless the patient requires care that is more intensive than an outpatient treatment program or outpatient office visits and less intensive than inpatient psychiatric care or a partial hospital program. Intensive outpatient services will be considered necessary only if the following conditions are present:

(A) The patient is suffering significant impairment from a mental disorder, to include a substance use disorder (as defined in § 199.2), which interferes with age appropriate functioning. Patients receiving a higher intensity of treatment may be experiencing moderate to severe instability, exacerbation of severe/persistent disorder, or dangerousness with some risk of confinement. Patients receiving a lower intensity of treatment may be experiencing mild instability with limited dangerousness and low risk for confinement.

(B) The patient is unable to maintain himself or herself in the community, with appropriate support, at a sufficient level of functioning to permit an adequate course of therapy exclusively in an outpatient treatment program or an outpatient office basis (but is able, with appropriate support, to maintain a basic level of functioning to permit a level of intensive outpatient treatment and presents no substantial imminent risk of harm to self or others).

(C) The patient is in need of stabilization, symptom reduction, and prevention of relapse for chronic mental illness. The goal of maintenance of his or her functioning within the community cannot be met by outpatient office visits, but requires active treatment in a stable, staff-supported environment;

(D) The admission into the intensive outpatient program is based on the development of an individualized diagnosis and treatment plan expected to be effective for that patient and permit treatment at a less intensive level.

(iii) *Services and supplies.* The following services and supplies are included in the per diem rate approved for an authorized intensive outpatient program.

(A) *Patient assessment.* Includes the assessment of each individual accepted by the facility.

(B) *Treatment services.* All services, supplies, equipment, and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual qualified mental health provider. [Exception: Intensive outpatient

programs 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 all-inclusive per diem rate but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) *Case management.* When appropriate, and with the consent of the person served, the facility should coordinate the care, treatment, or services, including providing coordinated treatment with other services.

(v) *Professional mental health benefits.* Professional mental health benefits are billed separately from the intensive outpatient per diem rate only when rendered by an attending, TRICARE authorized qualified mental health provider who is not an employee of, or under contract with, the program for purposes of providing clinical patient care.

(vi) *Non-mental health related medical services.* Separate billing will be allowed for otherwise covered, non-mental health related medical services.

(11) *Opioid treatment programs—(i) In general.* Outpatient treatment and management of withdrawal symptoms for substance use disorder provided at a TRICARE authorized opioid treatment program are covered. If the patient is medically in need of management of withdrawal symptoms, but does not require the personnel or facilities of a general hospital setting, services for management of withdrawal symptoms are covered. The medical necessity for the management of withdrawal symptoms must be documented. Any services to manage withdrawal symptoms provided by the opioid treatment program must be under general medical supervision.

(ii) Criteria for determining medical or psychological necessity of an opioid treatment program are set forth in 42 CFR part 8.

(iii) *Services and supplies.* The following services and supplies are included in the reimbursement approved for an authorized opioid treatment program.

(A) *Patient assessment.* Includes the assessment of each individual accepted by the facility.

(B) *Treatment services.* All services, supplies, equipment, and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health

services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: opioid treatment programs that employ individuals with degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) *Case management.* Care, treatment, or services should be coordinated among providers and between settings, independent of whether they are provided directly by the organization or by an organization or by an outside source, so that the individual's needs are addressed in a seamless, synchronized, and timely manner.

(c) * * *

(3) * * *

(ix) *Treatment of mental disorders, to include substance use disorder.* In order to qualify for CHAMPUS mental health benefits, the patient must be diagnosed by a TRICARE authorized qualified mental health professional practicing within the scope of his or her license to be suffering from a mental disorder, as defined in § 199.2

(A) *Covered diagnostic and therapeutic services.* CHAMPUS benefits are payable for the following services when rendered in the diagnosis or treatment of a covered mental disorder by a TRICARE authorized qualified mental health provider practicing within the scope of his or her license. Qualified mental health providers are: Psychiatrists or other physicians; clinical psychologists, certified psychiatric nurse specialists, certified clinical social workers, certified marriage and family therapists, TRICARE certified mental health counselors, pastoral counselors under a physician's supervision, and supervised mental health counselors under a physician's supervision.

(1) *Individual psychotherapy, adult or child.* A covered individual psychotherapy session is no more than 60 minutes in length. An individual psychotherapy session of up to 120 minutes in length is payable for crisis intervention.

(2) *Group psychotherapy.* A covered group psychotherapy session is no more than 90 minutes in length.

(3) *Family or conjoint psychotherapy.* A covered family or conjoint psychotherapy session is no more than 90 minutes in length. A family or conjoint psychotherapy session of up to

180 minutes in length is payable for crisis intervention.

(4) *Psychoanalysis.* Psychoanalysis is covered when provided by a graduate or candidate of a psychoanalytic training institution recognized by the American Psychoanalytic Association and when preauthorized by the Director, or a designee.

(5) *Psychological testing and assessment.* Psychological testing and assessment is covered when medically or psychologically necessary.

Psychological testing and assessment performed as part of an assessment for academic placement are not covered.

(6) *Administration of psychotropic drugs.* When prescribed by an authorized provider qualified by licensure to prescribe drugs.

(7) *Electroconvulsive treatment.* When provided in accordance with guidelines issued by the Director.

(8) *Collateral visits.* Covered collateral visits are those that are medically or psychologically necessary for the treatment of the patient.

(9) *Medication assisted treatment.* Medication assisted treatment, combining pharmacotherapy and holistic care, to include provision in office-based opioid treatment by an authorized TRICARE provider, is covered. The practice of an individual physician in office-based treatment is, as regulated by the Department of Health and Human Services' 42 CFR 8.12, the Center for Substance Abuse Treatment (CSAT), and the Drug Enforcement Administration (DEA), along with individual state and local regulations.

(B) *Therapeutic settings—(1) Outpatient psychotherapy.* Outpatient psychotherapy generally is covered for individual, family, conjoint, collateral, and/or group sessions.

(2) *Inpatient psychotherapy.* Coverage of inpatient psychotherapy is based on medical or psychological necessity for the services identified in the patient's treatment plan.

(C) *Covered ancillary therapies.* Includes art, music, dance, occupational, and other ancillary therapies, when included by the attending provider in an approved inpatient, SUDRF, residential treatment, partial hospital, or intensive outpatient program treatment plan and under the clinical supervision of a qualified mental health professional. These ancillary therapies are not separately reimbursed professional services but are included within the institutional reimbursement.

(D) *Review of claims for treatment of mental disorder.* The Director shall establish and maintain procedures for

review, including professional review, of the services provided for the treatment of mental disorders.

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(e) * * *

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(8) * * *

(ii) * * *

(A) For purposes of CHAMPUS, dental congenital anomalies such as absent tooth buds or malocclusion specifically are excluded.

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(D) Any procedures related to sex gender changes, except as provided in paragraph (g)(29) of this section, are excluded.

* * * * *

(iv) * * *

(Q) Penile implant procedure for psychological impotency or as related to sex gender changes, as prohibited by section 1079 of title 10, United States Code.

(R) Insertion of prosthetic testicles as related to sex gender changes, as prohibited by section 1079 of title 10, United States Code.

* * * * *

(11) *Drug abuse.* Under the Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to paragraph (d) of this section). However, TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means. Drugs, including the substitution of a therapeutic drug with addictive potential for a drug of addiction, prescribed to beneficiaries undergoing medically supervised treatment for a substance use disorder as authorized under paragraphs (b) and (c) of this section are not considered to be in support of, or to maintain, an existing or potential drug abuse situation and are allowed. The Director may prescribe appropriate policies to implement this prescription drug benefit for those undergoing medically supervised treatment for a substance use disorder.

* * * * *

(13) * * *

(i) * * *

(B) *Home care is not suitable.* Institutionalization of a child because a parent (or parents) is unable to provide a safe and nurturing environment due to a mental or substance use disorder, or because someone in the home has a contagious disease, are examples of why

domiciliary care is being provided because the home setting is unsuitable.

* * * * *

(f) * * *

(2) * * *

(ii) *Inpatient cost-sharing.* Dependents of members of the Uniformed Services 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, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility), 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.

Note: The Secretary of Defense (after consulting with the Secretary of Health and Human Services and the Secretary of Transportation) prescribes the fair charges for inpatient hospital care provided through Uniformed Services medical facilities. This determination is made each fiscal year.

* * * * *

(3) * * *

(ii) *Inpatient cost-sharing.* Inpatient admissions to a hospital or other authorized institutional provider (refer to § 199.6, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility) shall be cost-shared on an inpatient basis. The cost-sharing for inpatient services subject to the TRICARE DRG-based payment system and the TRICARE per diem system shall be the lesser of the respective per diem copayment amount multiplied by the total number of days in the hospital (except for the day of discharge under the DRG payment system), or 25 percent of the hospital's billed charges. For other inpatient services, the cost-share shall be 25% of the CHAMPUS-determined allowable charges.

* * * * *

(g) * * *

(1) *Not medically or psychologically necessary.* Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness (including mental disorder, to include substance use disorder) or injury, for the diagnosis and treatment of pregnancy or well-baby care except as provided in the following paragraph.

* * * * *

(29) *Intersex surgery and sex gender changes.* Services and supplies related to intersex surgery and sex gender change, also referred to as sex reassignment surgery, as prohibited by section 1079 of title 10, United States Code. This exclusion does not apply to surgery and related medically necessary services performed to correct sex gender confusion (that is, ambiguous genitalia) which has been documented to be present at birth.

* * * * *

(73) *Economic interest in connection with mental health admissions.* Inpatient mental health services (including both acute care and RTC services) are excluded for care received when a patient is referred to a provider of such services by a physician (or other health care professional with authority to admit) who has an economic interest in the facility to which the patient is referred, unless a waiver is granted. Requests for waiver shall be considered under the same procedure and based on the same criteria as used for obtaining preadmission authorization (or continued stay authorization for emergency admissions), with the only additional requirement being that the economic interest be disclosed as part of the request. This exclusion does not apply to services under the Extended Care Health Option (ECHO) in § 199.5 or provided as partial hospital care. If a situation arises where a decision is made to exclude CHAMPUS payment solely on the basis of the provider's economic interest, the normal CHAMPUS appeals process will be available.

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■ 4. Section 199.6 is amended by revising paragraphs (b)(4)(iv)(B) and (D), (b)(4)(vii), (b)(4)(xii), (b)(4)(xiv), (b)(4)(xviii), and (b)(4)(xix) to read as follows:

§ 199.6 TRICARE-authorized providers.

(b) * * *

(4) * * *

(iv) * * *

(B) In order for the services of a psychiatric hospital to be covered, the hospital shall comply with the provisions outlined in paragraph (b)(4)(i) of this section. All psychiatric hospitals shall be accredited under an accrediting organization approved by the Director, in order for their services to be cost-shared under CHAMPUS. In the case of those psychiatric hospitals that are not accredited because they have not been in operation a sufficient period of time to be eligible to request an accreditation survey, the Director, or a designee, may grant temporary

approval if the hospital is certified and participating under Title XVIII of the Social Security Act (Medicare, Part A). This temporary approval expires 12 months from the date on which the psychiatric hospital first becomes eligible to request an accreditation survey by an accrediting organization approved by the Director.

* * * * *

(D) Although psychiatric hospitals are accredited under an accrediting organization approved by Director, their medical records must be maintained in accordance with accrediting organization's current standards manual, along with the requirements set forth in § 199.7(b)(3). The hospital is responsible for assuring that patient services and all treatment are accurately documented and completed in a timely manner.

* * * * *

(vii) *Residential treatment centers.* This paragraph (b)(4)(vii) establishes the definition of and eligibility standards and requirements for residential treatment centers (RTCs).

(A) *Organization and administration—(1) Definition.* A Residential Treatment Center (RTC) is a facility or a distinct part of a facility that provides to beneficiaries under 21 years of age a medically supervised, interdisciplinary program of mental health treatment. An RTC is appropriate for patients whose predominant symptom presentation is essentially stabilized, although not resolved, and who have persistent dysfunction in major life areas. Residential treatment may be complemented by family therapy and case management for community based resources. Discharge planning should support transitional care for the patient and family, to include resources available in the geographic area where the patient will be residing. The extent and pervasiveness of the patient's problems require a protected and highly structured therapeutic environment. Residential treatment is differentiated from:

(i) Acute psychiatric care, which requires medical treatment and 24-hour availability of a full range of diagnostic and therapeutic services to establish and implement an effective plan of care which will reverse life-threatening and/or severely incapacitating symptoms;

(ii) Partial hospitalization, which provides a less than 24-hour-per-day, seven-day-per-week treatment program for patients who continue to exhibit psychiatric problems but can function with support in some of the major life areas;

(iii) A group home, which is a professionally directed living arrangement with the availability of psychiatric consultation and treatment for patients with significant family dysfunction and/or chronic but stable psychiatric disturbances;

(iv) Therapeutic school, which is an educational program supplemented by psychological and psychiatric services;

(v) Facilities that treat patients with a primary diagnosis of substance use disorder; and

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

(2) *Eligibility.* (i) In order to qualify as a TRICARE authorized provider, every RTC must meet the minimum basic standards set forth in paragraphs (b)(4)(vii)(A) through (C) of this section, and as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards.

(ii) To qualify as a TRICARE authorized provider, the facility is required to be licensed and fully operational for six months (with a minimum average daily census of 30 percent of total bed capacity) and operate in substantial compliance with state and federal regulations.

(iii) The facility is currently accredited by an accrediting organization approved by the Director.

(iv) The facility has a written participation agreement with OCHAMPUS. The RTC 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.

(B) 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. 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;

(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 § 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director, 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 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 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 TRICARE standards and provisions of paragraph (b)(4)(vii) of this section establishing standards for Residential Treatment Centers; and

(ii) It will maintain compliance with the CHAMPUS Standards for Residential Treatment Centers Serving Children and Adolescents with Mental Disorders, as issued by the Director, except for any such standards regarding which the facility notifies the Director 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 accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(11) Grant the Director, 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 RTC which would confirm compliance with the participation agreement and designation as a TRICARE authorized RTC;

(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 Government Accountability Office.

(C) *Other requirements applicable to RTCs.* (1) Even though an RTC may qualify as a TRICARE 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 § 199.4 especially all requirements of § 199.4(b)(4).

(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, 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

authorized provider status for a two year period.

* * * * *

(xii) *Psychiatric and substance use disorder partial hospitalization programs.* This paragraph (b)(4)(xii) establishes the definition of and eligibility standards and requirements for psychiatric and substance use disorder 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. Partial hospitalization is appropriate for those whose psychiatric and addiction-related symptoms or concomitant physical and emotional/behavioral problems can be managed outside the hospital for defined periods of time with support in one or more of the major life areas. A partial hospitalization program 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.

(2) *Eligibility.* (i) To qualify as a TRICARE authorized provider, every partial hospitalization program must meet minimum basic standards set forth in paragraphs (b)(4)(xii)(A) through (D) of this section, as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each partial hospitalization program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing program. Approval of a hospital by TRICARE is sufficient for its partial hospitalization program to be an authorized TRICARE provider. Such hospital-based partial hospitalization programs are not required to be separately authorized by TRICARE.

(ii) To be approved as a TRICARE authorized provider, 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 required to be currently accredited by an accrediting organization approved by the Director.

Each PHP authorized to treat substance use disorder must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The facility is required to have a written participation agreement with OCHAMPUS. 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.

(B) Participation agreement requirements. In addition to other requirements set forth in paragraph (b)(4)(xii) 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. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility granted that all programs meet the requirements of this part. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. 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. 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 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 § 199.14, or such other method as determined by the Director;

(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 § 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director 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 TRICARE standards and provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and substance use disorder partial hospitalization programs; and

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

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The PHP shall inform the Director, or designee, 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;

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

(11) Grant the Director, 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 a TRICARE authorized 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 on-site 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.

(C) *Other requirements applicable to PHPs.* (1) Even though a PHP may qualify as a TRICARE 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 § 199.4.

(2) 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 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.* This paragraph (b)(4)(xiv) establishes the definition of eligibility standards and requirements for residential substance use disorder rehabilitation facilities (SUDRF).

(A) *Organization and administration—(1) Definition.* A SUDRF is a residential or rehabilitation 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, assessment, treatment, and evaluation. A SUDRF is appropriate for patients whose addiction-related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas. Residential or inpatient rehabilitation is differentiated from:

(i) 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 diagnoses 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) Eligibility. (i) In order to become a TRICARE authorized provider, every SUDRF must meet minimum basic standards set forth in paragraphs (b)(4)(xiv)(A) through (C) of this section, as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards.

(ii) To be approved as a TRICARE authorized provider, 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 an accrediting organization approved by the Director. Each SUDRF must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The SUDRF has a written participation agreement with OCHAMPUS. The SUDRF is not considered a TRICARE authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) 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 for the treatment of substance use disorders to be authorized, the center shall have entered into a Participation Agreement with OCHAMPUS. A single

consolidated participation agreement is acceptable for all units of the TRICARE authorized facility. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. 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. 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;

(3) Accept the CHAMPUS-determined 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 § 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director 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) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified to by an independent accounting firm or other agency as authorized by the Director;

(7) Certify that:

(i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xiv) of the section establishing standards for substance use disorder rehabilitation facilities; and

(ii) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director and notified the Director 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, except for any such standards regarding which the facility notifies the Director that it is not in compliance.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The SUDRF 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;

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

(11) Grant the Director, 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 included, but is not limited to:

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

(ii) Conducting such audits of center 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 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 Government Accountability Office.

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

(1) Even though a SUDRF may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by

CHAMPUS for particular services provided is contingent upon the SUDRF also 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, 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.

* * * * *

(xviii) *Intensive outpatient programs.* This paragraph (b)(4)(xviii) establishes standards and requirements for intensive outpatient treatment programs for psychiatric and substance use disorder.

(A) *Organization and administration—(1) Definition.*

Intensive outpatient treatment (IOP) programs are defined in § 199.2. IOP services consist of a comprehensive and complimentary schedule of recognized treatment approaches that may include day, evening, night, and weekend services consisting of individual and group counseling or therapy, and family counseling or therapy as clinically indicated for adolescents between the ages of 13 and 18 or adults aged 18 and may include case management to link patients and their families with community based support systems.

(2) *Eligibility.* (i) In order to qualify as a TRICARE authorized provider, every intensive outpatient program must meet the minimum basic standards set forth in paragraphs (b)(4)(xviii)(A) through (C) of this section, as well as additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each intensive outpatient program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing psychiatric or substance use disorder intensive outpatient program. Approval of a hospital by TRICARE is sufficient for its IOP to be

an authorized TRICARE provider. Such hospital-based intensive outpatient programs are not required to be separately authorized by TRICARE.

(ii) To qualify as a TRICARE authorized provider, the IOP 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 capacity) and operate in substantial compliance with state and federal regulations.

(iii) The IOP is currently accredited by an accrediting organization approved by the Director. Each IOP authorized to treat substance use disorder must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The facility has a written participation agreement with TRICARE. The IOP is not considered a TRICARE authorized provider and TRICARE benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) *Participation agreement requirements.* In addition to other requirements set forth in paragraph (b)(4)(xii) of this section, in order for the services of an IOP to be authorized, the IOP shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility granted that all programs meet the requirements of this part. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by DHA authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

(1) Render intensive outpatient program services to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.

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

(3) Collect from the TRICARE beneficiary or the family of the TRICARE 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 TRICARE;

(4) Make all reasonable efforts acceptable to the Director 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 TRICARE;

(6) Submit claims for services provided to TRICARE 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 IOP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;

(7) Free-standing intensive outpatient programs shall 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 and SUD IOPs;

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

(iii) It will maintain compliance with the TRICARE standards for IOPs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or a designee that it is not in compliance.

(8) Designate an individual who will act as liaison for TRICARE inquiries. The IOP shall inform TRICARE, or a designee 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.

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

(11) Grant the Director, 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 included, but is not limited to:

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

(ii) Conducting such audits of center 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 inspection conducted by federal, state and local government, and private agencies and organizations;

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

(v) Audits conducted by the United States Government Accountability Office.

(C) Other requirements applicable to Intensive Outpatient Programs (IOP).

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

(2) The IOP 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 IOP shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that is 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 IOP will be ineligible for consideration for authorized provider status for a two year period.

(xix) *Opioid Treatment Programs (OTP).* This paragraph (b)(4)(xix) establishes standards and requirements for Opioid Treatment Programs.

(A) *Organization and administration.*

(1) *Definition.* Opioid Treatment Programs (OTP) are defined in § 199.2. Opioid Treatment Programs (OTP) are organized, ambulatory, addiction treatment services for patients with an opioid use disorder. OTPs have the capacity to provide daily direct administration of medications without the prescribing of medications.

Medication supplies for patients to take outside of the OTP originate from within the OTP. OTP services offer medication assisted treatment, patient-centered, recovery-oriented individualized treatment through addiction counseling, mental health therapy, case management, and health education.

(2) *Eligibility.* (i) Every free-standing Opioid Treatment Program must be accredited by an accrediting organization recognized by Director, under the current standards of an accrediting organization, as well as meet additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. OTPs adhere to requirements of the Department of Health and Human Services' 42 CFR part 8, the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment, and the Drug Enforcement Agency. Each OTP must be either a distinct part of an otherwise authorized institutional provider or a free-standing program. Approval of a hospital by TRICARE is sufficient for its OTP to be an authorized TRICARE provider. Such hospital-based OTPs, if certified under 42 CFR 8, are not required to be separately authorized by TRICARE.

(ii) To qualify as a TRICARE authorized provider, the OTP 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 capacity) and operate in substantial compliance with state and federal regulations.

(iii) The OTP has a written participation agreement with OCHAMPUS. The OTP is not considered a TRICARE authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in paragraph (b)(4)(xix) of this section, in order for the services of an OTP to be authorized, the OTP shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of a TRICARE authorized facility. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by DHA authorized personnel may be required prior to signing a participation agreement. The Participation Agreement

shall include at least the following requirements:

(1) Render OTP services to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.

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

(3) Collect from the TRICARE beneficiary or the family of the TRICARE 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 TRICARE;

(4) Make all reasonable efforts acceptable to the Director 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 TRICARE;

(6) Submit claims for services provided to TRICARE 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 OTP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;

(7) Free-standing opioid treatment programs shall certify that:

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

(ii) It will maintain compliance with the TRICARE standards for OTPs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or a designee, that it is not in compliance.

(8) Designate an individual who will act as liaison for TRICARE inquiries. The OTP shall inform TRICARE, or a designee, in writing of the designated individual;

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

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

(11) Grant the Director, 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 TRICARE 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 OTP which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(ii) Conducting such audits of OTP 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 TRICARE beneficiaries;

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

(C) *Other requirements applicable to OTPs.* (1) Even though an OTP may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the OTP also meeting all conditions set forth in § 199.4.

(2) The OTP may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices or provisions of special or limited treatment.

(3) The OTP shall assure that all certifications and information provided to the Director 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 OTP will be ineligible for consideration for authorized provider status for a two year period.

* * * * *

§ 199.7 [Amended]

■ 5. Section 199.7 is amended by removing and reserving paragraph (e)(2).

■ 6. Section 199.14 is amended by revising paragraphs (a)(2)(iv)(C)(2) and (4) and (a)(2)(ix) to read as follows:

§ 199.14 Provider reimbursement methods.

- (a) * * *
 (2) * * *
 (iv) * * *
 (C) * * *

(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 Inpatient Prospective Payment System update factor.

* * * * *

(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 amount of each regional per diem that will apply in any Federal fiscal year shall be posted to the Agency's official Web site at the start of that fiscal year.

* * * * *

(ix) *Payment for psychiatric and substance use disorder rehabilitation partial hospitalization services, intensive outpatient psychiatric and substance use disorder services and opioid treatment services*—(A) *Per diem payments.* Psychiatric and substance use disorder partial hospitalization services, intensive outpatient psychiatric and substance use disorder services and opioid treatment services authorized by § 199.4(b)(9), (b)(10), and (b)(11), respectively, and provided by institutional providers authorized under § 199.6(b)(4)(xii), (b)(4)(xviii) and (b)(4)(xix), respectively, are reimbursed on the basis of prospectively determined, all-inclusive per diem rates pursuant to the provisions of paragraphs (a)(2)(ix)(A)(1) through (3) of this section, with the exception of hospital-based psychiatric and substance use disorder and opioid services which are reimbursed in accordance with provisions of paragraph (a)(6)(ii) of this section and freestanding opioid treatment programs when reimbursed on a fee-for-service basis as specified in paragraph (a)(2)(ix)(A)(3)(ii) of this section. The per diem payment amount must be accepted as payment in full, subject to the outpatient cost-sharing provisions under § 199.4(f), for institutional services provided, including board, routine nursing services, group therapy, ancillary services (e.g., music, dance, and occupational and other such therapies), psychological testing and assessment, overhead and any other services for which the customary practice among similar providers is included in the institutional charges, except for those services which may be billed separately

under paragraph (a)(2)(ix)(B) of this section. Per diem payment will not be allowed for leave days during which treatment is not provided.

(1) *Partial hospitalization programs.* For any full-day partial hospitalization program (minimum of 6 hours), the maximum per diem payment amount is 40 percent of the average inpatient per diem amount per case established under the TRICARE mental health per diem reimbursement system during the fiscal year for both high and low volume psychiatric hospitals and units [as defined in paragraph (a)(2) of this section]. Intensive outpatient services provided in a PHP setting lasting less than 6 hours, with a minimum of 2 hours, will be paid as provided in paragraph (a)(2)(ix)(A)(2) of this section. PHP per diem rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(2) *Intensive outpatient programs.* For intensive outpatient programs (IOPs) (minimum of 2 hours), the maximum per diem amount is 75 percent of the rate for a full-day partial hospitalization program as established in paragraph (a)(2)(ix)(A)(1) of this section. IOP per diem rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(3) *Opioid treatment programs.* Opioid treatment programs (OTPs) authorized by § 199.4(b)(11) and provided by providers authorized under § 199.6(b)(4)(xix) will be reimbursed based on the variability in the dosage and frequency of the drug being administered and in related supportive services.

(i) *Weekly all-inclusive per diem rate.* Methadone OTPs will be reimbursed a weekly all-inclusive per diem rate, including the cost of the drug and related services (i.e., the costs related to the initial intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and support services). The bundled weekly per diem payments will be accepted as payment in full, subject to the outpatient cost-sharing provisions under § 199.4(f). The methadone OTP per diem rate will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(ii) *Exceptions to per diem reimbursement.* When providing other medications which are more likely to be prescribed and administered in an office-based opioid treatment setting, but which are still available for treatment of substance use disorders in an outpatient treatment program setting, OTPs will be reimbursed on a fee-for-

service basis (i.e., separate payments will be allowed for both the medication and accompanying support services), subject to the outpatient cost-sharing provisions under § 199.4(f). OTP rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(iii) *Discretionary authority.* The Director, TRICARE, will have discretionary authority in establishing the reimbursement methodologies for new drugs and biologicals that may become available for the treatment of substance use disorders in OTPs. The type of reimbursement (e.g., fee-for-service versus bundled per diem payments) will be dependent on the variability of the dosage and frequency of the medication being administered, as well as the support services.

(B) *Services which may be billed separately.* Psychotherapy sessions and non-mental health related medical services not normally included in the evaluation and assessment of a PHP, IOP or OTP, provided by authorized independent professional providers who are not employed by, or under contract with, a PHP, IOP or OTP for the purposes of providing clinical patient care are not included in the per diem rate and may be billed separately. This includes ambulance services when medically necessary for emergency transport.

* * * * *

§ 199.15 [Amended]

■ 7. Section 199.15 is amended by revising paragraph (a)(6) to delete “, such as inpatient mental health services in excess of 30 days in any year” in the last sentence.

■ 8. Section 199.18 is amended by:

- a. Revising paragraph (d)(2)(ii);
- b. Removing and reserving paragraph (d)(3)(ii); and
- c. Revising paragraphs (e)(2) and (e)(3).

The revisions read as follows:

§ 199.18 Uniform HMO Benefit.

* * * * *

(d) * * *

(2) * * *

(ii) The per visit fee provided in paragraph (d)(2)(i) of this section shall also apply to partial hospitalization services, intensive outpatient treatment, and opioid treatment program services. The per visit fee shall be applied on a per day basis on days services are received, with the exception of opioid treatment program services reimbursed in accordance with § 199.14(a)(2)(ix)(A)(3)(i) which per visit fee will apply on a weekly basis.

* * * * *

(e) * * *

(2) *Structure of cost-sharing.* For inpatient admissions, there is a nominal copayment for retired members, dependents of retired members, and survivors. This nominal copayment shall apply to an inpatient admission to any hospital or other authorized institutional provider, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility.

(3) *Amount of inpatient cost-sharing requirements.* In fiscal year 2001, the inpatient cost-sharing requirements for retirees and their dependents for acute care admissions and other inpatient admissions is a per diem charge of \$11, with a minimum charge of \$25 per admission.

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Dated: January 26, 2016.

Morgan E. Park,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016-01703 Filed 1-29-16; 8:45 am]

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POSTAL REGULATORY COMMISSION**39 CFR Part 3001**

[Docket No. RM2016-6; Order No. 3048]

Procedures Related to Motions**AGENCY:** Postal Regulatory Commission.**ACTION:** Proposed rulemaking.

SUMMARY: The Commission is proposing rules which standardize the procedure and timeframe by which interested parties file motions with the Commission as they relate to mail preparation changes and their compliance with the price cap rules. The Commission invites public comment on the proposed rules.

DATES: *Comments are due:* March 2, 2016. *Reply comments are due:* March 17, 2016.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. Introduction
- II. Background
- III. Proposed Rule
- IV. Comments Requested
- V. Ordering Paragraphs

I. Introduction

The Commission initiates this proposed rulemaking to request

comments on a procedural rule for motions concerning mail preparation changes that require compliance with the price cap rules.

The primary purpose of the rulemaking is to ensure that the Postal Service properly accounts for the rate effects of mail preparation changes under § 3010.23(d)(2) of this chapter in accordance with the Commission's standard articulated in Order No. 3047.¹ The proposed rule is intended to standardize the procedure and timeframe by which interested parties must file a motion with the Commission when they contend that a mail preparation change has a rate effect requiring compliance with the price cap rules.

II. Background

In Docket No. R2013-10R, the Commission issued Order No. 3047 and articulated a clear standard to determine when mail preparation changes require compliance with § 3010.23(d)(2). *Id.* Under § 3010.23(d)(2), a mail preparation change has a rate effect when the change results in the deletion and/or redefinition of a rate cell. *Id.* at 15. The Postal Service is required to comply with § 3010.23(d)(2) where the mail preparation change results in either the deletion of a previously available rate or significantly changes the basic characteristic of the mailing so that the rate cell is effectively "redefined." *Id.* at 16. The Commission determined that the Postal Service has an affirmative burden to decide whether a mail preparation change requires compliance with the price cap rules as set forth under the Commission's standard. *Id.* at 20. Where the Postal Service determines that a mail preparation change has a rate effect, it must comply with the existing rules and procedures governing rate adjustments prior to implementing the change.

However, despite this affirmative burden, the possibility exists that the Postal Service may not recognize or account for all mail preparation changes that have rate effects. In that case, the current regulations do not provide a specific mechanism or timeframe by which interested parties can alert the Commission to mail preparation changes that they conclude have rate effects requiring compliance with § 3010.23(d)(2). Although the Commission's general motion rules would provide an avenue for motions concerning mail preparation changes, the rules do not set a timeframe by which motions must be made and the

Commission believes the proposed rule is better suited to handle the specific issue at hand. In light of the complexity of administering the price cap, the timeframe set forth in the proposed rule is intended to promote certainty for the Postal Service and users of the mail when making operational changes.

In Order No. 3047 setting forth the standard, the Commission indicated that it would propose procedures whereby interested parties could submit motions concerning mail preparation changes that have rate effects. As a result, the proposed rule is intended to clarify and streamline the process by which mail preparation changes that have rate effects may be reviewed by the Commission for compliance with the price cap rules.

III. Proposed Rule

The rule proposed in this notice of proposed rulemaking adds to the current § 3001.21. Proposed § 3001.21(d) requires interested parties to file a motion with the Commission upon actual or constructive notice of a mail preparation change that has a rate effect requiring compliance with § 3010.23(d)(2). This proposed section establishes a 30-day timeframe within which interested parties may file a motion concerning a mail preparation change, after which the Commission will either institute a proceeding or consider the motion within an ongoing matter.

The Commission proposes permitting interested parties to file a motion concerning a mail preparation change if the parties, in good faith, demonstrate that the change has a rate effect and requires compliance with the price cap rules. The proposed procedure is triggered by actual or constructive notice of the mail preparation change. Actual or constructive notice will occur when an interested party becomes aware of or should have reasonably become aware of the mail preparation change. The Commission intends for actual or constructive notice to occur when the Postal Service publishes written notice of the implementation of the mail preparation change. For example, the Postal Service commonly publishes notice of mail preparation changes in the **Federal Register**, Postal Bulletin, and on the RIBBS Web site.

The proposed procedure also ties notice to the "implementation date of the change." The Commission intends this provision to cover changes where the Postal Service either immediately implements a mail preparation change or provides published notice that it intends to implement a mail preparation change on a date certain. For example,

¹ Docket No. R2013-10R, Order Resolving Issues on Remand, January 22, 2016 (Order No. 3047).