

positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

91-25-03. McDonnell Douglas: Amendment 39-8104. Docket No. 91-NM-78-AD.

Applicability: Model DC-9 series, including C-9 (military), airplanes equipped with Aircraft Braking System (ABS) brake part numbers identified in paragraph (a), of this AD, certificated in any category.

Compliance: Required as indicated, unless previously accomplished.

To prevent the loss of main landing gear braking effectiveness, accomplish the following:

(a) Within 270 days after the effective date of this AD, inspect the landing gear brakes, having brake numbers listed below, for wear. Any brake worn more than the maximum wear limit specified below must be replaced, prior to further flight, with a brake within these limits.

Series airplane	ABS brake part No.	Maximum wear limit (inches)
DC-9-10	9560746A	0.3
	B9560746A	0.3
	9560743	0.3
	A9560743	0.3
DC-9-20/30	B9560743	0.3
	9560786	0.3
	A9560786	0.3
	B9560786	0.3
DC-9-30	9560955	0.3
	9560788	0.3
	A9560788	0.3
	B9560788	0.3
DC-9-30/40/50	9560788-2/-3/-5/-6	0.3
	9569788-7	0.7
	B9560861	0.3
	9560861-1	0.2
	9560861-2	0.3

Series airplane	ABS brake part No.	Maximum wear limit (inches)
	9560861-3	0.8

(b) Within 270 days after the effective date of this AD, incorporate the maximum brake wear limits specified in paragraph (a) of this AD into the FAA-approved maintenance inspection program.

(c) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles ACO.

(d) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

(e) This amendment (39-8104), AD 91-25-03, becomes effective on December 31, 1991.

Issued in Renton, Washington, on November 14, 1991.

Leroy A. Keith,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 91-28358 Filed 11-25-91; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN-0720-AA11

[DoD 6010.8-R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Drug Benefits; Appropriate Level of Care Provisions

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule amends the DoD Regulation 6010.8-R (32 CFR part 199) by: (1) Establishing the absolute requirement for approval by the Food and Drug Administration (FDA) of all prescription drugs and medicines (drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered under CHAMPUS as if FDA approved); (2) clarifying that medical care related to the use of Group C drugs (approved and distributed by the National Cancer Institute) and Treatment Investigational New Drugs (INDs) will not automatically be considered as experimental when the

patient's medical condition warrants the use of these drugs; and (3) reclarifying a CHAMPUS provision that allows benefits in an acute facility above the appropriate level of care. The above changes are reasonable and necessary for effective and uniform administration of CHAMPUS.

EFFECTIVE DATE: November 26, 1991.

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

FOR FURTHER INFORMATION CONTACT: Marty Maxey, Office of Program Development, OCHAMPUS, telephone (303) 361-4337.

SUPPLEMENTARY INFORMATION: DoD 6010.8-R (Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)) was published in the Federal Register on July 1, 1986 (51 FR 24008).

In FR Doc. 90-13388 appearing in the Federal Register on June 11, 1990 (55 FR 23554), the Office of the Secretary of Defense published for public comment a notice of proposed rule making regarding (1) Establishing the absolute requirement for approval by the Food and Drug Administration (FDA) of all prescription drugs and medicines (drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered under CHAMPUS as if FDA approved); (2) clarifying that medical care related to the use of Group C drugs (approved and distributed by the National Cancer Institute) and Treatment INDs will not automatically be considered as experimental when the patient's medical condition warrants the use of these drugs; and (3) removing a provision that allows benefits in a facility above the appropriate level of care. The following summarizes the comments received and the actions taken based on these comments.

Discussion of Comments

We received three (3) public comments from two (2) nationally recognized associations recommending changes or additions to the proposed rule. We also received three (3) comments from those government agencies which by law CHAMPUS is required to consult with during the rule making process. Two (2) of the three (3) comments were identical to those expressed by the public. A summary of the comments and our responses are listed below.

Comment: We question CHAMPUS coverage and payment for the drug Clozaril, a drug indicated for the

management of severely ill schizophrenic patients who fail to respond adequately to standard antipsychotic treatment. We recommend consideration be given to allowing CHAMPUS coverage of Clozaril for patients requiring the drug as treatment.

Response: Drugs that are FDA approved for marketing are a benefit under the CHAMPUS as long as they are prescribed in accordance with generally accepted standards. CHAMPUS coverage criteria for Clozaril are under development and will be released in the near future.

Comment: We oppose the removal of the current exception to the CHAMPUS requirement for an appropriate level of care, specifically its effects on mental health patients requiring residential treatment center (RTC) care which is not always available in the general locality. We are concerned that these CHAMPUS beneficiaries would be denied access to needed psychiatric care.

Response: We wish to assure this commentator that CHAMPUS beneficiaries will not be denied access to needed psychiatric care. The removal of the current exception will in no way affect the quality of care available to CHAMPUS mental health patients. As stated in the proposed rule, the exception has never been applied to mental health care. Acute inpatient psychiatric hospitalization represents not only a different level of care than that provided in other mental health inpatient settings, but often a different kind of care as well. It is often the case that a beneficiary who would benefit from the less structured environment of an RTC would not benefit as much from the more structured acute care environment. When dealing with mental health patients, care furnished above the appropriate level signifies more than merely that it was too much or too expensive; it may also involve care which was not medically appropriate. This exception has only been applied to patients requiring skilled nursing facility care which as outlined in the proposed rule represents less than 0.02 percent of all CHAMPUS claims. This reclarification will have no impact on the adjudication and review of mental health benefits.

Comment: We oppose the elimination of the exception related to appropriate level of care and what we perceive to be an attempt by CHAMPUS to follow Medicare's lead and establish provisions which would incorporate payment for "administratively necessary days" into prospective payment system rates.

Response: We found this commentator's argument persuasive. As stated in

response to the previous comment, this exception has been primarily applied to patients requiring subsequent skilled nursing care following an acute treatment episode and represents only a small CHAMPUS population. For CHAMPUS to follow Medicare's lead for such a small population group is not administratively feasible. Rather than removing the exception, we have incorporated language which clarifies that this exception applies solely to medical care related to skilled nursing facility care.

Comment: We question CHAMPUS' rationale for including coverage of medical care involving the use of Group C drugs and excluding a similar category, Treatment Investigational New Drugs (INDs).

Response: We found this commentator's argument persuasive. We have incorporated language which clarifies that medical care related to the use of Treatment INDs should be covered in the same manner as medical care related to Group C drugs.

Summary of the Final Rule Provisions

I. Drug Listing in the U.S. Pharmacopeia or the National Formulary

Section 199.4(d)(3)(vi) provides for the prescription drug and insulin benefit under the Basic Program and § 199.5(h)(2)(iii) provides for this benefit under the Program for the Handicapped. Section 199.4(d)(3)(vi)(B) states that "CHAMPUS benefits may not be extended for drugs not approved by the U.S. Food and Drug Administration for general use by humans (even though approved for testing with humans)." Also, § 199.5(h)(2)(iii) limits coverage of drugs "to those approved for general use by humans (other than testing) by the U.S. Food and Drug Administration." But in § 199.2 under the definition of "Experimental," there was a provision which read, "However, if a drug or medicine is listed in the 'U.S. Pharmacopeia' or the 'National Formulary' and requires a prescription, it is not considered experimental even if it is under investigation by the U.S. Food and Drug Administration (FDA) as to its effectiveness." In a recent appeal case, we discovered that this provision could unreasonably result in CHAMPUS payment for a drug that has not been approved for general use by the FDA. The "U.S. Pharmacopeia" and the "National Formulary" are merely the official compendia of standards for drugs which include assays and tests for the determination of their strength, quality, and purity. These compendia do not deal with clinical indications, pharmacology, safety, or effectiveness

of drugs. Since the FDA approval requirement is intended to assure safety and effectiveness of drugs, we believe it is appropriate to delete the above provision related to drug listing in the "U.S. Pharmacopeia" and the "National Formulary" which could unreasonably result in CHAMPUS benefits for unapproved drugs. Accordingly, this final rule revises the definition of "Experimental" in § 199.2 by deleting the above provision. It also revises the language in this definition to clarify that the FDA's approval for general use means the approval for their commercial marketing and that drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938, may be covered under CHAMPUS as if FDA approved. In addition, "Prescription Drugs and Medicines" in § 199.2 and § 199.4(d)(3)(vi) has been revised to coincide with the above information.

II. Group C Drugs and Treatment INDs

Under its Cancer Therapy Evaluation, the Division of Cancer Treatment of the National Cancer Institute (NCI), in cooperation with the FDA, permits and distributes certain drugs for use in treating terminally ill cancer patients. One group of these drugs, designated as Group C drugs, unlike other drugs distributed by the NCI, are not limited to use in clinical trials for the purpose of testing their efficacy. The Group C drugs are distributed to the NCI registered physicians at no cost. Drugs are classified as Group C drugs only if there is sufficient evidence demonstrating their activity against a tumor type and that they can be safely administered.

On May 22, 1987, the FDA issued final procedures under which promising investigational new drugs, known as Treatment INDs, may be made available to desperately ill patients before general marketing begins. The procedures were intended to facilitate the availability of promising new drugs to patients as early in the drug development process as possible, and to obtain additional data on the drug's safety and effectiveness. The procedures apply to patients with serious and immediately life-threatening diseases for which no comparable or satisfactory alternative drug or other therapies exist. The FDA also defined the conditions under which drug manufacturers may charge for investigational new drug products. Medical care related to the use of Group C drugs and Treatment INDs should not automatically be considered as experimental even though these drugs are not covered under CHAMPUS as these are not approved for commercial marketing by the FDA. Medical care

related to the use of Group C drugs and Treatment INDs can be cost-shared under CHAMPUS when the patient's medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice. The definition of "Experimental" in § 199.2 precluded CHAMPUS benefits for such medical care as the Group C drugs and Treatment INDs are not FDA approved for general use or commercial marketing. This final rule revises the above definition clarifying that such medical care cannot automatically be considered as experimental, when the patient's condition warrants the use of these drugs.

III. Appropriate Level of Care

The CHAMPUS law and regulation limit CHAMPUS cost-sharing to care which is determined to be medically necessary and furnished at the appropriate level. However, the CHAMPUS regulation contains the following provision (§ 199.4(b)(1)(iv)) which can allow benefits in a higher than the appropriate level care facility under certain circumstances. The provision now reads:

Inpatient, appropriate level required. For purposes of inpatient care, the level of institutional care for which Basic Program benefits may be extended must be at the appropriate level required to provide the medically necessary treatment. If an appropriate lower level care facility is adequate, but is not available in the general locality, benefits may be continued in the higher level care facility, but CHAMPUS institutional benefit payments shall be limited to the allowable cost that would have been incurred in the appropriate lower level care facility, as determined by the Director, OCHAMPUS, or a designee. If it is determined that the institutional care can be provided reasonably in the home setting, no CHAMPUS institutional benefits are payable.

Based on comments received following publication of the proposed rule regarding the appropriate level of care provision, CHAMPUS has decided to retain the provision (§ 199.4(b)(1)(iv)) and add clarifying language which will specifically state that benefits in a higher than the appropriate level care facility may be permitted only for patients requiring skilled nursing facility care not available in the general locality.

Section 605(b) of the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires that each federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues regulations which would have significant impact on a substantial

number of small entities. The Secretary certifies, pursuant to section 605(b) of title 5, United States Code, enacted by the Regulatory Flexibility Act (Pub. L. 96-354), that this regulation amendment will not have a significant economic impact on a substantial number of small businesses, organizations, or government jurisdictions. The final rule will broaden the scope of CHAMPUS benefits by extending benefits to include coverage for medical care related to the administration of Group C drugs and Treatment INDs, establishes the absolute requirement for FDA approval of all prescription drugs and medicines, and reclarifies the intent of the language on appropriate level of care. It will not involve any significant burden on the CHAMPUS beneficiary or provider population. It is not, therefore, a "major rule" under Executive Order 12291.

This final rule does not impose information collection requirements. Therefore, it does not need to be reviewed by the Executive Office of Management and Budget under authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501-3511).

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health Insurance, and Military Personnel.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199—[AMENDED]

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

Authority: 10 U.S.C 1079, 1086, and 5 U.S.C. 301.

2. § 199.2(b) is amended by revising the definitions of *Experimental* and *Prescription drugs and medicines* to read as follows:

§ 199.2 Definitions.

(b) * * *

Experimental. Medical care that essentially is investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal conditions) that does not meet the generally accepted standards of usual professional medical practice in the general medical community. The conduct of biomedical or behavioral research involving human subjects at risk of physical, psychological, or social injury is experimental medicine. For the purposes of CHAMPUS, any medical services or supplies provided under a scientific research grant, either public or private, are classified as "experimental."

(Financial grants-in-aid to an individual beneficiary are not considered grants for this purpose.) Use of drugs and medicines and devices not approved by the U.S. Food and Drug Administration (FDA) for commercial marketing, that is, for general use by humans (even though permitted for testing on human beings) also is considered experimental. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered under CHAMPUS as if FDA approved. Certain cancer drugs, designated as Group C drugs (approved and distributed by the National Cancer Institute) and Treatment Investigational New Drugs (INDs), cannot be cost-shared under CHAMPUS because they are not approved for commercial marketing by the FDA. However, medical care related to the use of Group C drugs and Treatment INDs can be cost-shared under CHAMPUS when the patient's medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice.

Note: In areas outside the United States, standards comparable to those of the FDA are the CHAMPUS objective.

Prescription drugs and medicines. Drugs and medicines which at the time of use were approved for commercial marketing by the U.S. Food and Drug Administration, and which, by law of the United States, require a physician's or dentist's prescription, except that it includes insulin for known diabetics whether or not a prescription is required. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered under CHAMPUS as if FDA approved.

Note: The fact that the U.S. Food and Drug Administration has approved a drug for testing on humans would not qualify it within this definition.

4. § 199.4 is amended by revising paragraphs (b)(1)(iv), (d)(3)(vi) introductory text and (d)(3)(vi)(B) to read as follows:

§ 199.4 Basic program benefits.

(b) * * *

(1) * * *

(iv) *Inpatient, appropriate level required.* For purposes of inpatient care, the level of institutional care for which Basic Program benefits may be extended must be at the appropriate level required to provide the medically necessary treatment except for patients requiring

skilled nursing facility care. For patients for whom skilled nursing facility care is adequate, but is not available in the general locality, benefits may be continued in the higher level care facility. General locality means an area that includes all the skilled nursing facilities within 50 miles of the higher level facility, unless the higher level facility can demonstrate that the skilled nursing facilities are inaccessible to its patients. The decision as to whether a skilled nursing facility is within the higher level facility's general locality, or the skilled nursing facility is inaccessible to the higher level facility's patients shall be a CHAMPUS contractor initial determination for the purposes of appeal under § 199.10 of this part. CHAMPUS institutional benefit payments shall be limited to the allowable cost that would have been incurred in the skilled nursing facility, as determined by the Director, OCHAMPUS, or a designee. If it is determined that the institutional care can be provided reasonably in the home setting, no CHAMPUS institutional benefits are payable.

(d) * * *

(3) * * *

(vi) *Prescription drugs and medicines.* Prescription drugs and medicines that by United States law require a physician's or other authorized individual professional provider's prescription (acting within the scope of their license) and that are ordered or prescribed by a physician or other authorized individual professional provider (except that insulin is covered for a known diabetic, even though a prescription may not be required for its purchase) in connection with an otherwise covered condition or treatment, including Rh immune globulin.

(B) CHAMPUS benefits may not be extended for drugs not approved by the U.S. Food and Drug Administration for commercial marketing. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered under CHAMPUS as if FDA approved.

Dated: November 19, 1991.

L.M. Bynum,

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

[FR Doc. 91-28180 Filed 11-25-91; 8:45 am]

BILLING CODE 3810-01-M

32 CFR Part 199

[DoD 6010.8-R]

RIN-0720-AA12

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Medical Documentation

AGENCY: Office of the Secretary, DoD.
ACTION: Final rule.

SUMMARY: This final rule amends DoD 6010.8-R (32 CFR part 199) which implements the Civilian Health and Medical Program of the Uniformed Services. The final rule clarifies and strengthens medical documentation requirements under the CHAMPUS. This will assist in the maintenance of an adequate level of quality care and help ensure that payment is made only for services rendered.

EFFECTIVE DATE: December 26, 1991.

FOR FURTHER INFORMATION CONTACT: David E. Bennett, Office of Program Development, OCHAMPUS, Aurora, Colorado 80045-6900, telephone (303) 361-3537.

SUPPLEMENTARY INFORMATION: DoD 6010.8-R (32 CFR part 199) was revised in the Federal Register on July 1, 1986 (51 FR 24008). In FR Doc. 90-26939, appearing in the Federal Register on November 26, 1990 (55 FR 49091), the Office of the Secretary of Defense published for public comment a proposed amendment strengthening medical documentation requirements under CHAMPUS.

Background

The need for thorough medical documentation for verification of services has been dramatically demonstrated through the utilization review of services provided to CHAMPUS beneficiaries, particularly within various mental health settings. The lack of pertinent information has often made it impossible to determine the patient's clinical condition, actual treatment rendered, the quality and effectiveness of the care provided, or the identity and qualifications of the staff providing treatment services.

As a result, appropriate medical documentation has become increasingly important to CHAMPUS in the verification of medical and mental health services, since there are few objective indicators to validate professional opinions about diagnoses, response to treatment, and severity of illness. This has placed more emphasis on the need for complete and timely treatment plans, progress notes, and treatment summaries.

Due to the importance of documentation in assuring quality of care and verification of services, minimum requirements are being required, along with specific time frames for their incorporation into the medical records. For mental health care, these medical record documentation requirements have been in effect under the CHAMPUS Contracted Provider Arrangement (CPA) Norfolk Mental Health Services demonstration project since April 1, 1989, and were published in a Federal Register notice (54 FR 13935) on April 6, 1989.

The effectiveness of the requirements has been established since that date with minimal administrative burden to providers. These documentation requirements are similar to those currently being used by the CHAMPUS mental health review contractor responsible for managing mental health utilization for CHAMPUS beneficiaries nationwide.

Based on existing Regulations, the medical records for psychiatric residential treatment centers (RTCs) for children and adolescents, acute care psychiatric hospitals, psychiatric units within acute care institutions, alcohol rehabilitation facilities, partial hospitalization programs, and outpatient psychotherapy must, at a minimum, be maintained in accordance with applicable JCAHO standards. The new requirements will complement the JCAHO standards, ensuring that specific care was actually and appropriately furnished, was medically or psychologically necessary, and will identify the individuals providing the care.

The final rule will clarify and strengthen CHAMPUS requirements for accurate, legible and timely medical documentation of services provided to its beneficiaries. This will require that contemporaneous medical records are maintained in accordance with generally accepted medical practice and that services are actually being rendered. Maintenance of appropriate medical documentation is an essential ingredient in the overall care of the patient assuring medical necessity and appropriateness of care. It serves as a basis for planning a patient's care and for the ongoing evaluation of the patient's condition and treatment. A provider's failure to comply with these new documentation requirements can result in sanctions being imposed by the Director, OCHAMPUS, or a designee, under § 199.9 of this part.

Review of Comments

As a result of the publication of the proposed rule, the following comments were received from interested facilities, associations, agencies and individuals.

1. Several commentors saw no added benefit, either in terms of assuring quality of patient care or appropriateness of services rendered, to be obtained from additional medical record documentation except as a means of evaluating compliance with paperwork requirements.

The medical record provides a longitudinal case history of significant events available to serve as a basis for future treatment decisions and planning. It serves as the medium through which staff members can convey current information regarding the success or failure of therapeutic interventions.

In order to make a judgment as to the quality of care, third-party payors must depend on audits of medical charts. An assumption must be made that the chart accurately documents the decisions and actions of the provider managing the patient's care and reflects the quantity and quality of care actually delivered. While we realize that good records do not always equate to good treatment, they do tend to complement each other.

Due to the increasing cost of health care, and the concern for quality of care available to the public, clinicians can no longer use nondescriptive phenomenon, such as the "therapeutic relationship" to justify the lack of medical documentation. The documentation must be explicit and focused on the diagnostic and treatment process. Since the measuring of quality services is a difficult task, the need for such measurement and subsequent accountability is being demanded by consumers as well as third-party payors.

2. One commentor felt that the additional documentation requirements for provision of mental health services are intrusive, clinically inappropriate, and in effect, discriminatory.

The American Psychiatric Association's position, which is shared by the American Medical Association and the American Hospital Association, is that there should be no discrimination between medical and mental health benefits. This conceptualization should carry through to medical record requirements.

In the case of acute inpatient medical/surgical care, progress notes are usually written on at least a daily basis, with the attending physician documenting all identifiable physician services. The clinical records are continually updated at the end of each of the nursing shifts, recording the patient's status, behavior

and response to treatment.

Contemporaneous medical documentation has been elevated to its current importance as a result of diagnostic related group (DRG) reimbursement, where the quality of medical documentation is directly related to maximum reimbursement.

The need for continual/periodic recording of the patient's status is even more critical with mental health care where there are few objective indicators that validate medical opinions about diagnosis, response to treatment, and severity of illness. Without adequate medical record documentation, there is little on which to determine medical or psychological necessity or appropriateness of care. This is especially relevant with the multiplicity and overlapping of treatment inherent in mental health care, where communication is a vital link in assuring continual ongoing feedback and monitoring of a patient's condition. Documentation is particularly important when problems are encountered in treatment, or when changes in patient status require any modifications in the treatment plan.

3. One commentor contended that no one has concluded that treatment plans and progress notes are useful in evaluating quality. However, it was agreed that these documents may contain the data necessary to monitor some elements of quality.

As was referenced previously, escalating health care costs and quality concerns have increased pressures for accountability in publicly funded programs. Both private and Federal health care programs have implemented and tested numerous measures in order to ensure that payment is being made for therapy and/or procedures that actually were provided and that they are appropriate, reasonable, necessary and of high quality. Within CHAMPUS these have included the Contracted Provider Arrangement (CPA) Norfolk Mental Health Services demonstration project which has been using medical records over the last four years to evaluate utilization and quality of care; the CHAMPUS Peer Review Organization (PRO) program for utilization and quality reviews for services provided in hospitals covered by diagnosis related group (DRG)-based payment systems; the CAMP-MH program, a national mental health review contract for managing mental health utilization for CHAMPUS and CHAMPVA beneficiaries nationwide. All of these quality review programs rely on medical records for their review and evaluation and have been very successful in increasing quality and

ensuring appropriate utilization of services. Additionally, these programs are consistent with similar initiatives implemented nationwide by most third-party payors, public and private, and clearly demonstrate the need for improvement and consistency in the documentation of medical records.

4. One commentor proposed a 10-14 day time frame for completion of a master treatment plan in an RTC setting. It was felt that this would be more appropriate because of multiple therapies and core issues involved in residential treatment.

The commentor's suggestion has been adopted. The 7-day time frame for completion of the RTC master treatment plan has been changed to 10 days.

5. Several commentors felt that many of the specific time frames and documentation requirements were excessively burdensome and out of step with present standards of practice.

The lack of adequate clinical information has often made it difficult for reviewers to determine the patient's clinical condition, actual treatment rendered, the quality and effectiveness of the care provided, or the identity and qualifications of the staff providing treatment services. Contemporaneous medical documentation is the only way that our reviewers can evaluate the quality and effectiveness of the care provided. It is also the only basis for confirming what care was actually rendered and ultimately the appropriate reimbursement due, and serves as a safeguard against potential fraud or abuse of the program.

These medical documentation requirements have been in effect under the Contracted Provider Arrangement (CPA) Norfolk Mental Health Services demonstration project since April 1, 1989. The effectiveness of the requirements has been established since that date with minimal administrative burden to providers. The documentation requirements are also similar to those currently being used by the CHAMPUS mental health review contractor responsible for managing mental health utilization for CHAMPUS beneficiaries nationwide. The proposed requirements are not new to the CHAMPUS program, and can be maintained with minimal time and effort. The rule simply provides an administrative mechanism for the monitoring and enforcement of already established medical documentation requirements.

6. One commentor felt that the details required within the progress notes and time frames proposed for the master treatment plans, nursing notes, physician notes, and daily therapeutic

milieu notes were not consistent with patterns of practice within an RTC setting.

We disagree with this comment and feel the requirements are fully consistent with the level and intensity of care provided in the RTC setting. This is demonstrated by the fact that contracted residential treatment centers within the CPA demonstration area are currently exceeding the compliance standards (95%) for medical documentation. The requirements are reasonable and within the administrative capability of an RTC facility. The time frames and documentation requirements are also similar to those currently required by the CHAMPUS mental health contractor for RTC admissions and concurrent reviews.

7. Another commentator pointed out that only the assessments used to formulate the preliminary plan of treatment are commonly available within 72 hours. A traditional comprehensive, interdisciplinary individualized treatment plan is usually not available sooner than 10 days after admission.

Since the treatment plan reflects an integrated approach to the overall care of the patient, setting forth specific problems, goals and objectives, treatment modalities and staff responsibilities, it is important that it be completed as soon as possible after admission. This is especially critical in an acute care setting where many admissions do not last as long as 10 days. The agency feels that the 72-hour requirement is reasonable and within the administrative capability of the acute care provider, since it has been in effect in the CHAMPUS demonstration project area since April, 1989, with no noticeable impact on the quality of mental health care.

8. One commentator wanted "preliminary treatment plan" defined.

The preliminary treatment plan should, at a minimum, include: (1) A statement of the diagnosis; (2) who the attending physician is going to be; (3) a statement of symptoms/exhibited problems; (4) what therapies and other treatment are to be instituted; and (5) who the therapists are going to be.

9. One commentator pointed out that Accreditation Manual for Hospitals (AMH) standards have, at a minimum, a dyad approach to planning of treatment; i.e., the physician and nurse (RN) complete a plan of treatment within 24 hours.

It is felt that the dyad approach meets the intent of the standard; i.e., the completion of a preliminary treatment plan within 24 hours of admission.

10. Another commentator felt that pre-"established" treatment goals are not always possible.

Modifications may be made to the treatment plan regarding goals and objectives as the patient brings new problems to the therapy sessions; however, there must be an initial framework from which to work. Preliminary goals and objectives must be developed during the initial assessment process in order to develop an individualized treatment plan, with the realization that modifications may be required during the course of the patient's treatment.

11. One commentator felt that the time frames for several of the requirements were more in keeping with an acute care model than that of a residential treatment center.

There is a differentiation of time frames between acute care and residential treatment facilities based on the type and level of treatment provided in each setting. The time frame for completion of an RTC master treatment plan has been changed from 7 to 14 days, which is more consistent with the patterns of practice within an RTC setting.

12. Several commentators felt that documentation requirements for progress notes were excessive/burdensome, and would needlessly duplicate and clutter the medical record.

Since the maintenance of accurate individual treatment records is an essential ingredient to the treatment delivery process, it is important that progress notes provide a chronological picture of the patient's clinical course; documentation of treatment rendered to the patient; the response and outcome of that treatment; and the person(s) rendering the treatment. While a progress note does not need to repeat all that was said during a therapy session, it must document a patient contact and be sufficiently detailed to allow both peer review and audits to substantiate the content and quantity of care intended. This type of recording is included in the reimbursement of both inpatient and outpatient psychotherapy which allows payment for 60 minute psychotherapy sessions consisting of 50 minutes of actual therapy and 10 minutes of recording the session in the patient's chart.

13. Another commentator felt that progress notes should capture the overall course and progress of treatment but should not have to prescriptively describe each event.

As was stated previously, progress notes do not have to divulge everything that occurred or that was observed during the treatment session, only those

observations felt to be of significance in the ongoing treatment of the patient. A superfluous statement such as, "the patient slept well," would only be significant if it had clinical relevance to the patient's diagnosis/condition, response to therapeutic intervention, and/or the degree of progress toward the treatment goals. Also, the use of extraneous statements, such as "condition fair," "general condition good," and "no complaints," are of no value. The quality of the progress note depends in part on the timeliness, meaningfulness, authentication, and legibility of the information content.

14. Another commentator felt that our requirement that each clinical event be documented as soon as possible after its occurrence would demand interpretation of single-event therapies. It was pointed out that these interpretations could be counter productive and even lead to faulty conclusions since many psychiatric therapies rely on a series of interventions to measure effects on the patients and to reach clinical conclusions.

On the contrary, contemporaneous medical documentation would tend to provide a cohesive integration of a series of therapeutic interventions. This would be especially relevant when a patient is receiving a variety of therapies daily, since communication is a vital link in the team approach assuring continual ongoing feedback and monitoring of a patient's condition. Timely documentation would prevent duplicative efforts and maximize treatment by allowing modification to treatment goals/objectives dictated, at least in part, by the patient's needs, severity of illness, and therapeutic responses.

As was noted previously, contemporaneous medical documentation (progress notes) is an integral part of acute inpatient medical care. In a medical care facility, progress notes are usually written on at least a daily basis, with the attending physician documenting all services. However, this is often not the case with mental health care where providers may see patients 4 to 5 times a week and make weekly or biweekly summary notes in the patients' clinical records. It is difficult to believe a professional in daily contact with 6 to 12 patients could accurately recall all contacts, care and significant events with a progress note prepared once a week.

15. Several commentators felt that the proposed regulation forced all CHAMPUS providers to adhere to standards which are not in accordance

with known JCAHO and Medicare standards for mental health providers.

From a third-party payor perspective, there is a distinction between accreditation standards (JCAHO standards) and specific requirements for claims adjudication. The Consolidated Standards (CS) and Accreditation Manual for Hospitals (AMH) standards relate to the accreditation and oversight of entire programs, while claims adjudication requirements focus exclusively on the patient as an individual. Individual medical records are used to demonstrate whether the care was needed and if it was of such quality to meet the patient's needs. Accreditation standards simply establish minimal requirements for certification by third-party payors/programs. As was stated previously, one is facility directed while the other is based on the individual.

Medicare standards were felt to be inappropriate since the scope and focus of Medicare's mental health benefit was significantly different than that of CHAMPUS; i.e., (1) Medicare has a 120-day lifetime limit on inpatient mental health care while CHAMPUS has none; (2) Medicare does not have the range of patients and diagnoses that CHAMPUS has; and (3) while mental health services only account for two percent of the Medicare budget, they account for over 30 percent of CHAMPUS' budget.

The mental health providers within the CPA demonstration area have adapted to the same documentation standards with minimal administrative disruption. These standards have been tested/evaluated over the last four years and are a part of the current mental health utilization review process.

16. One commentator felt that JCAHO consolidated standards place undue hardship on psychiatric hospitals, as they are now surveyed under the JCAHO AMH standards.

The CPA demonstration project has shown that acute psychiatric hospitals can meet and surpass the JCAHO consolidated standards for medical record documentation with minimal hardship. In this area, the consolidated standards provide the necessary detail for ongoing, periodic recording of information about the patient's status, behavior and response to treatment.

17. One commentator felt that the requirement for nursing notes would cause an undue hardship on RTC facilities if "nursing" was strictly interpreted as professional, psychiatrically trained nurses.

We are aware of the fact that the staffing mix within an RTC may vary from that of a psychiatric hospital; i.e., acute hospitals tend to have a greater

mix of professionals and greater involvement by psychiatric nurses and psychiatrists. RTCs, on the other hand, usually have more Masters of Social Work (MSWs) and clinical psychologists. RTC nurses must be, at a minimum, registered nurses (RNs). There is no requirement that the nursing staff be professional, psychiatrically trained nurses.

18. Another commentator felt that nursing notes should be further defined as requiring shift notes by registered nurses for acute care and detox; partial hospitalization should require registered nursing notes every ten visits; and registered nursing notes should be entered into the medical record at least weekly for RTCs.

This suggestion has been adopted and incorporated into the final rule.

19. Several commentators felt the time frames for family assessment documentation would be ineffective in evaluation and treatment.

Since the family is the number one discharge alternative for children and adolescents, it is extremely critical that a family assessment be conducted as soon as possible after admission. This is especially relevant in an acute care setting, where many of the admissions may be less than 10 days. In these particular cases, the dysfunctional family would be the focus of the treatment.

20. Another commentator felt that the requirement for individual and family therapy documentation within 24 hours was unreasonable and not compatible with current treatment practice.

There is apparently a misunderstanding regarding the intent of this requirement. It does not imply that the individual or family therapy has to happen within 24 hours of admission. It simply requires that documentation for individual and family therapy must be recorded in the medical records within 24 hours after its occurrence for patients in acute care, detoxification and residential programs, and within 48 hours for partial programs.

21. One commentator felt that the requirements to "reveal the issues and pathology addressed in the therapy session, the therapeutic intervention attempted during the session, and the degree of progress toward established treatment goals" would lead to a breach of confidentiality in many situations.

It is not felt that being specific about the problems addressed in a psychotherapy session necessarily implies that confidentiality is being breached any more than a vague, rambling progress note might do. As was referenced previously, the progress note does not have to reveal every intimate

detail of the therapy session, only that information pertinent to the broader goals and objectives outlined in the patient's treatment plan. However, this documentation must be distinguished from anecdotal charting. Generalized statements, such as "condition fair", "general condition good" and "no complaints", are not sufficient to review and evaluate the patient's ongoing course of treatment.

22. Another commentator felt that unless CHAMPUS intends to establish an on-site review process to replace the present mental health review system, then the constant threat in the regulation of payment denial is meaningless except retroactively.

The documentation requirements are not designed to be used as prepayment review criteria, since the FIs do not have access to medical records. Mental health records would only be accessed by the mental health review contractor as a result of concurrent review. A pattern of failure to adequately document medical care could result in retrospective denial of CHAMPUS cost-sharing for an entire episode of care, both institutional and professional claims. A pattern of failure to meet minimum documentation requirements could also result in provider sanctions as prescribed under Section 199.9 of the Regulation.

23. One commentator felt that the proposed changes would have a significant impact on CHAMPUS-approved RTCs and also increase information collection requirements on all CHAMPUS providers substantially. It was recommended that the proposed regulation adhere to the regulatory procedures governed by the "major theory and paperwork reduction act."

Since the recording of acute inpatient medical/surgical documentation generally exceeds the informational requirements and time frames set forth in this rule, we would expect these changes to have a minimal impact on this category of provider; i.e., care associated with acute inpatient hospitalization, both institutional and professional.

With regard to mental health providers, it has been demonstrated through the CPA project that these medical documentation requirements can be initiated with minimal administrative disruption. The proposed time frames and documentation requirements are also similar to those used by the CHAMPUS mental health review contract as part of the utilization review.

RTCs represent less than 0.13 percent (.0013) of CHAMPUS institutional providers and less than 0.04 percent

(.0004) of CHAMPUS professional providers.

24. One commentor requested clarification of which providers qualify as "CHAMPUS authorized mental health professional."

The following are CHAMPUS-authorized mental health professionals: (1) Physicians (psychiatrists); (2) clinical psychologists; (3) certified clinical social workers; (4) certified psychiatric nurse specialists; (5) marriage and family counselors; (6) pastoral counselors; and (7) mental health counselors.

25. Another commentor felt that the reference to partial programs was premature, since CHAMPUS benefits currently exist only for chemical dependency partial programs.

It is the intent of the program to establish a partial program benefit in the near future.

26. One commentor felt that stringent requirements would, in effect, keep providers from accepting CHAMPUS patients.

This occurrence is not anticipated since the new documentation requirements have been in effect in the CPA demonstration area since April of 1989, with minimal reduction in the availability of qualified mental health providers.

27. Another commentor was concerned about the borrowing of medical record documentation requirements from the CPA Norfolk Mental Health Services demonstration project since it did not include a broad number of mental health providers.

The CPA Norfolk Mental Health Services demonstration project was initiated to evaluate alternative mental health delivery systems. It has been the testing ground for managed mental health care since 1986, which includes a continuum of mental health services from acute inpatient hospitalization to partial hospitalization. In fact, the proposed implementation of a partial hospitalization benefit (published as a proposed rule in the *Federal Register* on July 8, 1991, (56 FR 30887)) resulted from this study. The demonstration project provided a sufficient number of admissions and providers to accurately assess various aspects of the managed mental health care system, especially the impact of documentation requirements.

28. Another commentor feared that a system may be put into place where precertification will be meaningless because all care will be subject to retroactive review of the medical record.

On the contrary, these medical documentation requirements will only serve to verify that information provided to the mental health review contractor

during the certification process is supported in the medical records. During the precertification process, the utilization management coordinator reviews the planned care and determines whether the care is medically/psychologically necessary and at the appropriate level. This is followed by post-payment validation in which a copy of the complete medical record is requested. The validation examines medical necessity and appropriateness, quality of care, and adequacy of documentation. The new standards will only assure that the medical records are sufficiently detailed to accurately assess these factors; i.e., medical necessity, appropriateness of care, etc.

29. Another commentor stated that our requirement to complete the master treatment plan within 72 hours of admission was not always possible, particularly for patients admitted on an emergency basis on weekends or holidays.

It is recognized that there may be extraordinary situations which make it impossible to meet one of the specific standards/criteria; i.e., emergency admissions on weekends or holidays. The contractor will take this into consideration on an individual basis. Mainly, the contractor will be looking for patterns of inadequate documentation rather than isolated incidences.

30. Several commentors felt that the requirement for daily "milieu" notes was ambiguous and inappropriate. It was pointed out that some programs did not use milieu as an integral part of the treatment focus, but rather as part of an environment that is being fostered.

The requirement was removed because of its apparent ambiguity.

Summary of Regulatory Modifications

The following modifications were made as a result of suggestions received during the public comment period:

(1) The 7-day time frame for completion of the RTC master treatment plan was changed to 10 days; (2) the time frames for nursing notes were further expanded; and (3) the requirements for daily therapeutic milieu notes were removed.

Regulatory Procedures

Executive Order 12291 requires that a regulatory impact analysis be performed on any major rule. A "major rule" is defined as one which would result in an annual effect on the national economy of \$100 million or more or have other substantial impacts.

The Regulatory Flexibility Act (RFA) requires that each federal agency

prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities.

This final rule is not a major rule under Order 12291. The changes set forth in this final rule are minor revisions to existing regulation. In addition, this final rule will have very minor impact and not significantly affect a substantial number of small entities. In light of the above, no regulatory impact analysis is required.

This final rule does not impose information collection requirements. Therefore, it does not need to be reviewed by the Executive Office of Management and Budget under authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501-3511.)

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health insurance, and Military personnel.

PART 199—[AMENDED]

Accordingly, 32 CFR, part 199, is amended as follows:

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

Authority: 5 U.S.C. 301; 10 U.S.C. 1079, 1086.

2. Section 199.2(b) is amended by adding the definition for "Progress Notes" in alphabetical order to read as follows:

§ 199.2 Definitions.

(b) Specific definitions.

Progress notes. Progress notes are an essential component of the medical record wherein health care personnel provide written evidence of ordered and supervised diagnostic tests, treatments, medical procedures, therapeutic behavior and outcomes. In the case of mental health care, progress notes must include: the date of the therapy session; length of the therapy session; a notation of the patient's signs and symptoms; the issues, pathology and specific behaviors addressed in the therapy session; a statement summarizing the therapeutic interventions attempted during the therapy session; descriptions of the response to treatment, the outcome of the treatment, and the response to significant others; and a statement summarizing the patient's degree of progress toward the treatment goals. Progress notes do not need to repeat all that was said during a therapy session but must document a patient contact and be sufficiently detailed to allow for

both peer review and audits to substantiate the quality and quantity of care rendered.

3. Section 199.6 is amended by adding new paragraph (b)(1)(iii), by revising paragraph (b)(4)(iv)(B), by adding new paragraphs (b)(4)(iv)(D), (b)(4)(vii)(E), (b)(4)(x)(B)(3)(viii), and (c)(1)(v) to read as follows:

§ 199.6 Authorized providers.

(b) * * *

(1) * * *

(iii) *Medical records.* Institutional providers must provide adequate contemporaneous clinical records to substantiate that specific care was actually furnished, was medically necessary, and appropriate, and to identify the individual(s) who provided the care. The minimum requirements for medical record documentation are set forth by the following:

(A) The cognizant state licensing authority;

(B) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or other health care accreditation organizations as may be appropriate;

(C) Standards of practice established by national medical organizations; and

(D) This part.

(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 the JCAHO Accreditation Manual for Hospitals (AMH) standards in order for their services to be cost-shared under CHAMPUS. In the case of those psychiatric hospitals that are not JCAHO-accredited because they have not been in operation a sufficient period of time to be eligible to request an accreditation survey by the JCAHO, the Director, OCHAMPUS, 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 the JCAHO.

(D) Although psychiatric hospitals are accredited under the JCAHO AMH standards, their medical records must be maintained in accordance with the JCAHO Consolidated Standard Manual

for Child, Adolescent, and Adult Psychiatric, Alcoholism, and Drug Abuse Facilities and Facilities Serving the Mentally Retarded, 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) * * *

(E) At a minimum, medical records will be maintained in accordance with the JCAHO Consolidated Standard Manual for Child, Adolescent, and Adult Psychiatric, Alcoholism, and Drug Abuse Facilities and Facilities Serving the Mentally Retarded, along with the requirements set forth in § 199.7(b)(3). The residential treatment center is responsible for assuring that patient services and all treatment are accurately documented and completed in a timely manner.

(x) * * *

(B) * * *

(3) * * *

(viii) At a minimum, medical records will be maintained in accordance with the JCAHO Consolidated Standard Manual for Child, Adolescent, and Adult Psychiatric, Alcoholism, and Drug Abuse Facilities and Facilities Serving the Mentally Retarded, along with the requirements set forth in § 199.7(b)(3). The alcohol rehabilitation facility is responsible for assuring that patient services and all treatment are accurately documented and completed in a timely manner.

(c) * * *

(1) * * *

(v) *Medical records:* Individual professional providers must maintain adequate clinical records to substantiate that specific care was actually furnished, was medically necessary, and appropriate, and identify(ies) the individual(s) who provided the care. This applies whether the care is inpatient or outpatient. The minimum requirements for medical record documentation are set forth by the following:

(A) The cognizant state licensing authority;

(B) The Joint Commission on Accreditation of Healthcare Organizations, or other health care accreditation organizations as may be appropriate;

(C) Standards of practice established by national medical organizations; and

(D) This part.

4. Section 199.7 is amended by revising paragraph (a) introductory text, by revising paragraphs (b)(2)(ix) introductory text and (b)(2)(ix)(A), by adding new paragraph (b)(2)(x)(D), by redesignating paragraphs (b)(3) and (b)(4) as paragraphs (b)(4) and (b)(5), by adding new paragraph (b)(3), by revising newly redesignated paragraphs (b)(5)(i) introductory text and (b)(5)(iii), by adding new paragraph (b)(5)(iii), by adding a note immediately following paragraph (c)(1)(iii), by revising paragraph (c)(2)(i)(A), and by adding new paragraph (i)(3) to read as follows:

§ 199.7 Claims submissions, review, and payment.

(a) *General.* The Director, OCHAMPUS, or a designee, is responsible for ensuring that benefits under CHAMPUS are paid only to the extent described in this Part. Before benefits can be paid, an appropriate claim must be submitted that includes sufficient information as to beneficiary identification, the medical services and supplies provided, and double coverage information, to permit proper, accurate, and timely adjudication of the claim by the CHAMPUS contractor or OCHAMPUS. Providers must be able to document that the care or service shown on the claim was rendered. This section sets forth minimum medical record requirements for verification of services. Subject to such definitions, conditions, limitations, exclusions, and requirements as may be set forth in this Part, the following are the CHAMPUS claim filing requirements:

(b) * * *

(2) * * *

(ix) *Physicians or other authorized individual professional providers.* The claims must give the name of the individual actually rendering the care, along with the individual's professional status (e.g., M.D., Ph.D., R.N., etc.) and provider number, if the individual signing the claim is not the provider who actually rendered the service. The following information must also be included:

(A) Date each service was rendered.

(x) * * *

(D) Claims submitted by hospitals (or other authorized institutional providers) must include the name of the individual actually rendering the care, along with the individual's professional status (e.g., M.D., Ph.D., R.N., etc.).

(3) *Medical records/medical documentation.* Medical records are of vital importance in the care and treatment of the patient. Medical records serve as a basis for planning of patient care and for the ongoing evaluation of the patient's treatment and progress. Accurate and timely completion of orders, notes, etc., enable different members of a health care team and subsequent health care providers to have access to relevant data concerning the patient. Appropriate medical records must be maintained in order to accommodate utilization review and to substantiate that billed services were actually rendered.

(i) All care rendered and billed must be appropriately documented in writing. Failure to document the care billed will result in the claim or specific services on the claim being denied CHAMPUS cost-sharing.

(ii) A pattern of failure to adequately document medical care will result in episodes of care being denied CHAMPUS cost-sharing.

(iii) Cursory notes of a generalized nature that do not identify the specific treatment and the patient's response to the treatment are not acceptable.

(iv) The documentation of medical records must be legible and prepared as soon as possible after the care is rendered. Entries should be made when the treatment described is given or the observations to be documented are made. The following are documentation requirements and specific time frames for entry into the medical records:

(A) General requirements for acute medical/surgical services:

(1) Admission evaluation report within 24 hours of admission.

(2) Completed history and physical examination report within 72 hours of admission.

(3) Registered nursing notes at the end of each shift.

(4) Daily physician notes.

(B) Requirements specific to mental health services:

(1) Psychiatric admission evaluation report within 24 hours of admission.

(2) History and physical examination within 24 hours of admission; complete report documented within 72 hours for acute and residential programs and within 3 working days for partial programs.

(3) Individual and family therapy notes within 24 hours of procedure for acute, detoxification and Residential Treatment Center (RTC) programs and within 48 hours for partial programs.

(4) Preliminary treatment plan within 24 hours of admission.

(5) Master treatment plan within 72 hours of admission for acute care, 10

days for RTC care, 7 days for full-day partial programs and within 5 days for half-day partial programs.

(6) Family assessment report within 72 hours of admission for acute care and 7 days for RTC and partial programs.

(7) Nursing assessment report within 24 hours of admission.

(8) Nursing notes at the end of each shift for acute and detoxification programs; every ten visits for partial hospitalization; and at least once a week for RTCs.

(9) Daily physician notes for intensive treatment, detoxification, and rapid stabilization programs; twice per week for acute programs; and once per week for RTC and partial programs.

(10) Group therapy notes once per week.

(11) Ancillary service notes once per week.

Note: A pattern of failure to meet the above criteria may result in provider sanctions prescribed under § 199.9.

* * *

(5) * * *

(i) As a condition precedent to the cost-sharing of benefits under this part or pursuant to a review or audit, whether the review or audit is prospective, concurrent, or retroactive, OCHAMPUS or CHAMPUS contractors may request, and shall be entitled to receive, information from a physician or hospital or other person, institution, or organization (including a local, state, or Federal Government agency) providing services or supplies to the beneficiary for whom claims or requests for approval for benefits are submitted. Such information and records may relate to the attendance, testing, monitoring, examination, diagnosis, treatment, or services and supplies furnished to a beneficiary and, as such, shall be necessary for the accurate and efficient administration of CHAMPUS benefits. This may include requests for copies of all medical records or documentation related to the episode of care. In addition, before a determination on a request for preauthorization or claim of benefits is made, a beneficiary, or sponsor, shall provide additional information relevant to the requested determination, when necessary. The recipient of such information shall hold such records confidential except when:

* * *

(ii) For the purposes of determining the applicability of and implementing the provisions of §§ 199.8 and 199.9, or any provision of similar purpose of any other medical benefits coverage or entitlement, OCHAMPUS or CHAMPUS fiscal intermediaries, without consent or notice to any beneficiary or sponsor,

may release to or obtain from any insurance company or other organization, governmental agency, provider, or person, any information with respect to any beneficiary when such release constitutes a routine use duly published in the **Federal Register** in accordance with the Privacy Act.

(iii) Before a beneficiary's claim of benefits is adjudicated, the beneficiary or the provider(s) must furnish to CHAMPUS that information which is necessary to make the benefit determination. Failure to provide the requested information will result in denial of the claim. A beneficiary, by submitting a CHAMPUS claim(s) (either a participating or nonparticipating claim), is deemed to have given consent to the release of any and all medical records or documentation pertaining to the claims and the episode of care.

(c) * * *

(1) * * *

(iii) * * *

Note: If the care was rendered to a minor and a custodial parent or legal guardian requests information prior to the minor turning 18 years of age, medical records may still be released pursuant to the signature of the parent or guardian, and claims information may still be released to the parent or guardian in response to the request, even though the beneficiary has turned 18 between the time of the request and the response. However, any follow-up request or subsequent request from the parent or guardian, after the beneficiary turns 18 years of age, will necessitate the authorization of the beneficiary (or the beneficiary's legal guardian as appointed by a cognizant court), before records and information can be released to the parent or guardian.

* * *

(2) * * *

(i) * * *

(A) Certifies that the specific medical care listed on the claim form was, in fact, rendered to the specific beneficiary for which benefits are being claimed, on the specific date or dates indicated, at the level indicated and by the provider signing the claim unless the claim otherwise indicates another individual provided the care. For example, if the claim is signed by a psychiatrist and the care billed was rendered by a psychologist or licensed social worker, the claim must indicate both the name and profession of the individual who rendered the care.

* * *

(i) * * *

(3) *Fraudulent billing.* Claims that are submitted to CHAMPUS that include a billing for services, supplies, or equipment not furnished, or used by, CHAMPUS beneficiaries will be denied in their entirety, regardless of the

relative amount of the fraudulent billing compared to the total billings. Claims that have been CHAMPUS cost-shared that are retroactively audited or reviewed and are found to include fraudulent billings may be denied in part or in total based on the discretion of the Director, OCHAMPUS, or a designee.

5. Section 199.10 is amended by revising paragraph (a)(2)(ii) introductory text to read as follows:

§ 199.10 Appeal and hearing procedures.

(a) * * *

(2) * * *

(ii) *Representative.* Any party to the initial determination may appoint a representative to act on behalf of the party in connection with an appeal. Generally, the parent of a minor beneficiary and the legally appointed guardian of an incompetent beneficiary shall be presumed to have been appointed representative without specific designation by the beneficiary. The custodial parent or legal guardian (appointed by a cognizant court) of a minor beneficiary may initiate an appeal based on the above presumption. However, should a minor beneficiary turn 18 years of age during the course of an appeal, then any further requests to appeal on behalf of the beneficiary must be from the beneficiary or pursuant to the written authorization of the beneficiary appointing a representative. For example, if the beneficiary is 17 years of age and the sponsor (who is a custodial parent) requests a formal review, absent written objection by the minor beneficiary, the sponsor is presumed to be acting on behalf of the minor beneficiary. Following the issuance of the formal review, the sponsor requests a hearing; however if, at the time of the request for a hearing, the beneficiary is 18 years of age or older, the request must either be by the beneficiary or the beneficiary must appoint a representative. The sponsor, in this example, could not pursue the request for hearing without being appointed by the beneficiary as the beneficiary's representative.

Dated: November 19, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD-90-064c]

Drawbridge Operation Regulations; Potomac River, District of Columbia

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule with request for comments.

SUMMARY: The Coast Guard has been petitioned by the Federal Highway Administration, the Maryland and Virginia Departments of Transportation, and the District of Columbia Department of Public Works to permanently amend the regulations governing operation of the Woodrow Wilson Memorial Bridge across the Potomac River, mile 103.8, at Alexandria, Virginia. As part of the rulemaking process, the Coast Guard is considering several alternative opening schedules as well as the schedule proposed by the petitioners. This temporary rule is being issued to evaluate the impacts of a variation of one of the other alternatives previously evaluated under an earlier temporary rule for its impact on both marine and highway traffic.

DATES: This temporary rule is effective from November 28, 1991, through January 27, 1992, unless sooner terminated. Comments must be received on or before January 13, 1992.

ADDRESSES: Comments should be mailed to Commander (ob), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004. The comments received will be available for inspection and copying at room 507 at the above address between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, Fifth Coast Guard District, at 804-398-6222.

SUPPLEMENTARY INFORMATION:

Drafting Information

The drafters of this notice are Ann B. Deaton, Project Officer, and CAPT M. K. Cain, Project Attorney.

Discussion of Temporary Rule

This temporary rule is being issued to evaluate a variation of one of the alternative opening schedules that was previously evaluated by the Coast Guard in response to a request from the Federal Highway Administration, the Virginia and Maryland Departments of Transportation, and the District of

Columbia Department of Public Works, to permanently change the regulations for the Woodrow Wilson Memorial Bridge by further restricting the hours during which the bridge may open for vessel traffic. This variation makes a distinction between deep-draft commercial vessels and other commercial vessels. It slightly extends the hours in the early morning and evening during which deep-draft vessels may request an opening of the drawbridge. This change is being considered because commercial shipping interests and the Virginia Pilots Association have stated deep-draft vessels require more leeway for requesting openings than other vessels because they must plan their transits of the river to coincide with high tide stages. Due to shoaling in portions of the river, these vessels require high tide to safely transit these portions of the river. Deep draft vessels are those with a draft of over 20 feet.

This temporary rule is for evaluation purposes only and will be effective for a 60 day period beginning on November 28, 1991. The impact of this proposal on highway and marine traffic during this period will be evaluated to determine if it will result in substantial improvements in vehicular traffic flow without unreasonably restricting marine traffic. Data will be collected during the period to document the time and duration of draw openings and length of any resulting vehicle backups. If this rule results in an unforeseen disruption of traffic it may be withdrawn sooner than 60 days.

The Woodrow Wilson Bridge operated under temporary rules from August 2, 1990, through May 31, 1991, to facilitate repairs to the bridge. Repairs were completed by May 31, 1991. Normally, operation of the bridge would revert to the permanent rule in 33 CFR 117.255. However, it is apparent that these will not provide a satisfactory balance between the needs of today's vehicular traffic and the needs of vessels. Therefore, the Coast Guard issued a temporary deviation from the permanent rules under the provisions of 33 CFR 117.43. That temporary rule with request for comments was issued to evaluate one of the alternative opening schedules being considered for a permanent change in the regulations. The rule was published in the *Federal Register* (56 FR 25369) on June 4, 1991. It was effective from June 1, 1991, through July 30, 1991. Comments were accepted through July 15, 1991. On July 9, 1991, the Coast Guard issued a second temporary rule with request for comments under the provisions of 33 CFR 117.43 to

evaluate another of the alternative opening schedules being considered for a permanent change in regulations. That rule was published in the *Federal Register* (56 FR 35816) on July 29, 1991. It was effective from July 31, 1991, through September 28, 1991. Comments were accepted through September 13, 1991. On September 23, 1991, the Coast Guard issued a third temporary rule with request for comments under the provisions of 33 CFR 117.43 to evaluate another alternative opening schedule being considered. That rule was published in the *Federal Register* (56 FR 49145) on September 27, 1991. It was effective from September 29, 1991, through November 27, 1991. Comments were accepted through November 12, 1991.

Before any permanent changes are made in the operating rule for the Woodrow Wilson Bridge, a notice of proposed rulemaking will be published and comments on all alternatives under consideration will be solicited.

Comments are also invited concerning any particular problems experienced with this temporary schedule. These comments will be evaluated and modifications may be made or an alternate temporary schedule of openings may be established for the purpose of further evaluation. All comments received will also be considered along with those received in connection with the permanent operating schedule rule change being considered. Persons submitting comments should include their name and address, identify the bridge, and give reasons for any recommended changes to the temporary rules. Persons desiring acknowledgment that their comments have been received should enclose a stamped, self-addressed postcard or envelope.

This temporary rule serves the immediate interests of highway traffic with no expected significant adverse impacts on marine traffic. It is a variation of one of the alternative opening schedules previously evaluated and is the fourth in a series of temporary rules being evaluated to gather information for drafting a new permanent rule. For these reasons, pursuant to 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for publishing this temporary rule without publication of a notice of proposed rulemaking. Further, because the Coast Guard agrees that it is not acceptable to revert to the existing permanent rule on the expiration of the current temporary deviation on November 27, 1991, it finds, pursuant to 5 U.S.C. 553(d), that good cause exists for making this rule

effective in less than 30 days after the date of publication in the *Federal Register*.

Regulatory Evaluation

This temporary rule is considered to be non major under Executive Order 12291 and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034, February 26, 1979). The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary. This conclusion is based on the fact that these regulations are temporary and may be withdrawn earlier than scheduled. They are not expected to have any substantial effect on commercial navigation or on any businesses that depend on waterborne transportation for successful operations.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the U.S. Coast Guard must consider whether proposed rules will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632). The Coast Guard will accept comments on the economic impact on small entities, in connection with the proposal for permanent regulations, and consider them at that time.

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the temporary rule does not raise sufficient federalism implications to warrant preparation of a Federalism Assessment.

Environment

This rulemaking has been thoroughly reviewed by the Coast Guard and it has been determined to be categorically excluded from further environmental documentation in accordance with section 2.B.2.g.(5) of Commandant Instruction M16475.1B. A Categorical Exclusion Determination statement has been prepared and placed in the rulemaking docket.

List of Subjects in 33 CFR Part 117

Bridges.

In consideration of the foregoing, part 117 of title 33, Code of Federal Regulations, is temporarily amended as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05-1(g); 33 CFR 117.42.

2. Section 117.255 is temporarily amended by revising paragraph (a)(2) to read as follows: (This is a temporary rule and will not appear in the Code of Federal Regulations).

§ 117.255 Potomac River.

(a) * * *

(2) Need not open:

(i) Except as provided in paragraph (a)(1) of this section, for the passage of any vessel unless at least 2 hours advance notice is given to the bridgetender at (202) 727-5522.

(ii) For the passage of any vessel from 5 a.m. to 9 a.m. and from 2 p.m. to 6 p.m., on Mondays through Fridays other than Federal holidays.

(iii) For the passage of any vessel from 2 p.m. to 7 p.m. on Saturdays, Sundays, and Federal holidays.

(iv) For the passage of any vessel other than a commercial vessel with a draft of over 20 feet from 4 a.m. to 5 a.m., from 9 a.m. to 10 a.m., and from 6 p.m. to 8 p.m., on Mondays through Fridays other than Federal holidays.

(v) For the passage of recreational vessels from 4 a.m. to 12 midnight with the exception of one opening at 12 noon, if requested, on Mondays through Fridays other than Federal holidays.

(vi) For the passage of recreational vessels from 6 a.m. to 12 midnight with the exception of one opening at 12 noon, if requested, and one opening at 9 p.m., if requested, on Saturdays, Sundays, and Federal holidays.

(vii) This temporary rule is effective from November 28, 1991, through January 27, 1992.

* * * * *

Dated: November 20, 1991.

W.T. Leland,

Rear Admiral, U.S. Coast Guard Commander,
Fifth Coast Guard District.

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PANAMA CANAL COMMISSION

35 CFR Part 60

RIN 3207-AA 29

Classified Information

AGENCY: Panama Canal Commission.

ACTION: Final rule.