§ 354.6 Authority of Federal Reserve Banks.

(a) Each Federal Reserve Bank is hereby authorized as fiscal agent of Sallie Mae to perform functions with respect to the issuance of Book-entry Sallie Mae Securities offered and sold by Sallie Mae, in accordance with the Securities Documentation, and Federal Reserve Bank Operating Circulars; to service and maintain Book-entry Sallie Mae Securities in accounts established for such purposes; to make payments of principal and interest with respect to such Book-entry Sallie Mae Securities as directed by Sallie Mae; to effect transfer of Book-entry Sallie Mae Securities between Participants' Securities Account as directed by the Participants; to effect conversions between Book-entry Sallie Mae securities and Definitive Sallie Mae Securities with respect to those securities as to which conversion rights are available pursuant to the applicable Securities Documentation; and to perform such other duties as fiscal agent as may be requested by Sallie Mae.

(b) Each Federal Reserve Bank may issue Operating Circulars not inconsistent with this Part, governing the details of its handling of Book-entry Sallie Mae Securities, Security Entitlements, and the operation of the Book-entry System under this Part.

§ 354.7 Withdrawal of eligible Book-entry Sallie Mae Securities for conversion to definitive form.

(a) Eligible Book-entry Sallie Mae Securities may be withdrawn from the Book-entry System by requesting delivery of like Definitive Sallie Mae Securities.

(b) A Federal Reserve Bank shall, upon receipt of appropriate instructions to withdraw Eligible Book-entry Sallie Mae Securities from book-entry in the Book-entry System, convert such securities into Definitive Sallie Mae Securities and deliver them in accordance with such instructions. No such conversion shall affect existing interests in such Sallie Mae Securities.

(c) All requests for withdrawal of Eligible Book-entry Sallie Mae Securities must be made prior to the maturity or date of call of such securities.

(d) Sallie Mae Securities which are to be delivered upon withdrawal may be issued in either registered or bearer form, to the extent permitted by the applicable Securities Documentation.

§ 354.8 Waiver of regulations.

The Secretary reserves the right, in the Secretary's discretion, to waive any provision(s) of the regulations in this Part in any case or class of cases for the convenience of Sallie Mae, or in order to relieve any person or entity of unnecessary hardship, if such action is not inconsistent with law, does not adversely affect substantial existing rights, and the Secretary is satisfied that such action will not subject Sallie Mae to any substantial expense or liability.

§ 354.9 Liability of Sallie Mae and Federal Reserve Banks.

Sallie Mae and the Federal Reserve Banks may rely on the information provided in a Transfer Message, and are not required to verify the information. Sallie Mae and the Federal Reserve Banks shall not be liable for any action taken in accordance with the information set out in a Transfer Message or evidence submitted in support thereof.

§ 354.10 Additional provisions.

(a) *Additional requirements.* In any case or any class of cases arising under these regulations, Sallie Mae may require such additional evidence and a bond of indemnity, with or without surety, as may in the judgment of Sallie Mae be necessary for the protection of the interests of Sallie Mae.

(b) *Notice of attachment for Sallie Mae Securities in Book-entry System.* The interest of a debtor in a Security Entitlement may be reached by a creditor only by legal process upon the Securities Intermediary with whom the debtor's securities account is maintained, except where a Security Entitlement is maintained in the name of a secured party, in which case the debtor's interest may be reached by legal process upon the secured party. The regulations in this part do not purport to establish whether a Federal Reserve Bank is required to honor an order or other notice of attachment in any particular case or class of cases.

Dated: December 29, 1996.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 97–129 Filed 1–3–97; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8–R]

RIN 0720–AA29

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Clarification of the CHAMPUS Exclusion of Unproven Drugs, Devices and Medical Treatments and Procedures

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule clarifies the CHAMPUS exclusion of unproven drugs, devices and medical treatments and procedures and describes the process that the Office of CHAMPUS follows in determining when such drugs, devices, treatments and procedures have moved from the status of unproven to the position of proven medical effectiveness. This clarification is necessary to ensure the CHAMPUS beneficiary and provider population understand the process the Office of CHAMPUS (OCHAMPUS) follows prior to endorsement by CHAMPUS of a new emerging medical technology, drug, or device for which the safety and efficacy have been proven.

DATES: This final rule is effective February 5, 1996.

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

FOR FURTHER INFORMATION CONTACT: Rene Morrell, Program Development Branch, OCHAMPUS, telephone (303) 361–1218.

SUPPLEMENTARY INFORMATION:

A. Discussion of Champus Policy

Under statutes governing CHAMPUS, including 10 U.S.C. 1079, CHAMPUS payments are prohibited for health care services that are ''not medically or psychologically necessary.'' The purpose of this provision, common in health care payment programs, is to prevent CHAMPUS beneficiaries from being exposed to less than fully developed and tested medical procedures and to avoid the associated risk of unnecessary or unproven treatment. CHAMPUS regulations and program policies restrict benefits to those procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. In general, the CHAMPUS

regulations and program policies exclude cost-sharing of procedures which are unproven, including those that remain in a developmental status. The evolution of any medical technology or procedure from unproven status to one of national acceptance is often controversial, with those members of the medical community who are using and promoting the procedure arguing that the procedure has national acceptance. In determining whether a procedure has proven medical effectiveness, CHAMPUS uses the following hierarchy of assessment sources:

1. Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature.

2. Formal technology assessments from nationally recognized technology assessment groups, such as the:

—Food and Drug Administration (FDA);
—Agency for Health Care Policy and Research (AHCPR);
—Emergency Care Research Institute (ECRI).

3. National medical policy organization positions such as the:

—Medical Advisory Panel of the National Blue Cross/Blue Shield Association.

4. National professional medical association positions such as those promulgated by the:

—American College of Obstetricians and Gynecologists.

5. National expert opinion organizations such as the:

—Diagnostic and Therapeutic Technology Assessment (DATTA) group of the American Medical Association;
—Health Care Financing Administration.

CHAMPUS policy and benefit structure are never based solely on coverage offered by other third party payers, including Medicare, since each operates under different rules and requirements.

B. Need for the Regulation

This final rule does not present new agency policy. Rather, it reaffirms and clarifies existing CHAMPUS policy in the body of the CHAMPUS regulation. We revise the regulation primarily in response to a series of U.S. district court decisions concerning one particular unproven treatment, high dose chemotherapy (HDC) with stem cell rescue (SCR) as a treatment for breast cancer (discussed more below), in which the courts held that the CHAMPUS determination regarding this treatment was not sufficiently established to be accepted by the courts. For example, in *Hawkins* v. *Mail Handlers Benefit Plan and CHAMPUS,* Civil No. 1:94CV6, W.D.N.C. (Jan. 28, 1994), the court ruled on a motion for a preliminary injunction filed by a beneficiary of both the Mail Handlers Benefit Plan and CHAMPUS, seeking a court order overruling the exclusion in both plans of coverage for HDC/SCR as a treatment for breast cancer. The court ruled in favor of the Mail Handlers Benefit Plan, but against CHAMPUS based on judgment that the determination that this procedure was experimental was not clearly established by CHAMPUS and was not supported by the evidence submitted to the court.

Similarly, in *Wheeler* v. *Dynamic Engineering Inc., and CHAMPUS,* No. 4.94CV16, E.D.Va (April 4, 1994), another case of a beneficiary covered by both an employer plan and CHAMPUS who sought a judgment that both should cover HDC/SCR for breast cancer treatment, the court made a distinction between a new company plan that specifically excluded the procedure and the former company plan and CHAMPUS, both of which did not expressly do so. After determining that the former plan was applicable (based on the date the treatment began), the court ruled that neither the plan nor CHAMPUS could properly exclude coverage of the procedure.

Two Circuit Courts of Appeals have recently addressed this issue, and reached conflicting results. In *Smith* v. *OCHAMPUS,* No. 94–3744, 7th Cir., Sept. 26, 1995, the Seventh Circuit Court of Appeals ruled that the CHAMPUS exclusion for HDC/SCR for breast cancer was justified, but the opposite answer was reached by the Fourth Circuit Court of Appeals in *Wilson* v. *OCHAMPUS,* No. 95–1016, 4th Cir., Sept. 15, 1995. The Seventh Circuit recently granted a motion for rehearing in the *Smith* case.

OCHAMPUS has carefully reviewed the evidence on HDC/SCR as a treatment for breast cancer. It is our conclusion that it continues to be an unproven treatment because the chemotherapy regimen is not approved by FDA, no well-controlled clinical trials have proven the effectiveness of HDC/SCR for breast cancer (and certain other cancers as well), and because formal technology assessment studies have concluded similarly. The CHAMPUS policy regarding the unproven nature of HDC/SCR for breast cancer is based upon a series of reports from four primary sources:

1. The 1988 study entitled ''Public Health Service Reassessment: Autologous Bone Marrow Transplantation'' prepared by the Office of Health Technology Assessment, Agency for Health Care Policy and Research (OHTA/AHCPR) of the Public Health Service, and authored by Harry Handelsman, D.O.;

2. The American Medical Association Diagnostic and Therapeutic Technology Assessment (AMA DATTA) evaluation of January 1990 entitled ''Autologous Bone Marrow Transplantation 0 Reassessment'' by Elizabeth Brown, M.D.;

3. The June 1993 study entitled ''Autologous Bone Marrow Transplant and Peripheral Blood Stem Cell Rescue for the Treatment of Breast Cancer'' copyright by the Emergency Care Research Institute (ECRI) 5200 Butler Pike, Plymouth Meeting, Pa 19462; and

4. The February 1995 ECRI assessment of ''Autologous Bone Marrow Transplant and Peripheral Blood Stem Cell Rescue for the Treatment of Breast Cancer.''

Since the time the 1988 and 1990 reports mentioned above were initially prepared, OCHAMPUS has performed a continuous review of the refereed medical literature on this topic, and has had numerous confirming discussions with the Office of Health Technology Assessment (OHTA) of the Public Health Service regarding their position. The latest of these discussions confirmed the lack of refereed medical literature that would support CHAMPUS coverage of this procedure for treatment of breast carcinoma. Therefore, although the initial policy classifying HDC/SCR as investigational under CHAMPUS was based upon literature and technical assessments dating from the 1988–1990 time-frame, OCHAMPUS continually monitored development of the literature and the status of ongoing well-controlled clinical trials regarding the effectiveness of this form of treatment for breast carcinoma and other carcinomas for which it is not currently authorized as a CHAMPUS benefit. The June 1993 formal assessment by ECRI provided independent reconfirmation of the CHAMPUS position. This independent reconfirmation has been substantially bolstered by the 1995 ECRI studies which indicated that ''results from the experimental procedure are not any better than published results for conventional therapy to treat breast cancer,'' and that ''the impetus for this (treatment) is more political than scientific * * * (It) is a treatment that's becoming mandated by popular opinion.'' This most recent information reconfirms, in even stronger terms and with new studies and literature, the earlier conclusions of previous

technology assessments that HDC/SCR has not been proven to be effective in the treatment of breast cancer. To date there has been no new evidence which would warrant a departure from the original coverage determination to exclude CHAMPUS cost-sharing of this procedure for the treatment of breast carcinoma. The CHAMPUS position is further supported by the Consensus Conference on Intensive Chemotherapy Plus Hematopietic Stem Cell Transplantation in Malignancies [(Journal of Clinical Oncology, Volume 12, Number 1, (January 1994); pages 226–231; (Attachment 5)] which states in part:

* * * Although there is currently insufficient evidence to justify the use of HDC/plus HSC (Hematopietic Stem Cell) transplantation outside the setting of clinical trial for any stage of breast cancer, there is amply scientific background for vigorous clinical investigation in this important area * * *

Based on the evidence regarding this procedure, which demonstrates that it continues to be unproven, and the series of recent court rulings declining to follow an exclusion not clearly established in the governing instruments of the program, we believe this rule is necessary to reaffirm and clarify CHAMPUS policy on unproven drugs, devices, and medical treatments and procedures and to specifically list a number of procedures we have determined are unproven.

The Department shares public and scientific concern about disappointing cure rates under standard cancer therapies. In emphasizing refereed medical literature as the primary source of reliable evidence that a particular treatment or procedure has proven medical effectiveness, we also underscore our support for committed efforts to advance medical research. We have an interest and a responsibility to participate in the appropriate evaluation of improved therapeutic approaches for our patients. A number of military medical centers are engaged in such research protocols. In November 1994, under authority of 10 U.S.C. 1092, the Department of Defense undertook a demonstration project to authorize payment for breast cancer treatment under certain government approved clinical protocols. Initially, the demonstration project applied only to phase III clinical trials under approved National Cancer Institute protocols for high dose chemotherapy with stem cell rescue for breast cancer treatment. It was expanded in January of this year to include a broad range of National Cancer Institute sponsored Phase II and III clinical trials for other cancers. The Department has worked closely with the National Cancer Institute to establish a formal program for interagency cooperation which will provide an important contribution to the continued development of promising new cancer therapies.

C. Provisions of the Final Rule

The final rule describes the criteria we use to identify the proven medical necessity of procedures, treatments, drugs, or devices, includes a partial list of unproven drugs, devices, treatments, and procedures, and makes provision for promptly treating a drug, device, treatment or procedure as no longer unproven when reliable scientific evidence supports that conclusion. Any changes to the partial list will be published periodically as a notice in the Federal Register.

D. Public Comments

This final rule is based on a proposed rule published May 18, 1995 (60 FR 26705–26709). We received seven public comments. Many of the comments were quite similar in wording and content. Some were very detailed and provided helpful insight and analysis. We thank those who provided input on this important issue. Significant items raised by commenters and our analysis of the comments are summarized below:

1. *Definitions of ''Experimental.''* We received a significant number of comments expressing concerns about terminology used in the proposed rule, particularly the use of the term ''experimental'' to describe treatments that had not yet established proven medical effectiveness.

Response: We agree that use of this term causes more confusion than clarification, and have modified the final rule to delete the use of the term ''experimental.''

2. *Effect of CHAMPUS policy on other government agencies or other health care programs.* We wish to underscore that this final rule relates to the CHAMPUS program. It does not directly affect Medicare, Medicaid or other payers. Each program has its own set of rules, requirements, and procedures. Thus, determinations by the Office of CHAMPUS concerning medical treatments that have established proven medical effectiveness and those that have not should be understood as representing the best judgment of the Department of Defense, but not necessarily reflecting the views of any other government agency or other health care program. In addition CHAMPUS policy and benefit structure are never based solely on coverage offered by other third party payers, including Medicare, since each operates under different rules and requirements. In the interest of minimizing regulatory burden and confusion, CHAMPUS seeks to harmonize its coverage policy with other federal programs and the private sector to the extent appropriate.

3. *Discretionary waiver authority.* One commenter suggested this rule provide discretionary waiver authority to the Director, OCHAMPUS, based on coordination at the professional level between the military medical services and OCHAMPUS, to ensure that individuals who might otherwise benefit, would not be unduly penalized by the inflexibility of the rule. Such a provision would be consistent with implementation of the managed care concept, current research protocols at military facilities, and the Department of Defense demonstration programs.

Response: The CHAMPUS Regulation already allows for discretionary waiver authority for rare and unusual cases, consistent with applicable law. However, by law, CHAMPUS can only cost-share medically necessary supplies and services. Any drug, device or medical treatment or procedure whose safety and efficacy have not been established, is unproven and cannot be cost-shared by CHAMPUS.

4. *Definition of Reliable Evidence.* We received several comments expressing concern about the use of the term ''reliable evidence'' in the proposed rule. Many of the types of evidence demanded by the proposed regulation do not exist for many surgical and other procedures. Also, simply stating that randomized controlled trials constitute a form of reliable evidence, does not address the question whether the trial demonstrates efficacy or lack thereof. The commenter believed that CHAMPUS needs to define more clearly how it will determine the boundaries of experimental, i.e., the ''gray zone'' between effective and ineffective treatment.

Response: We agree that the use of this term was easily misunderstood and have modified the definition for clarity. The term ''reliable evidence'' means well controlled studies of clinically meaningful endpoints, published in refereed medical literature; published formal technology assessments; published reports of national professional medical associations; published national medical policy organizations positions; and published reports of national expert opinion organizations. We have also included specific examples of resources *not* included in the meaning of reliable evidence. As stated previously, the

definition of ''experimental'' has been deleted from the rule.

5. *Benefit Limitations.* We received several comments on the denial of payment for a procedure that uses FDA-approved products, and coverage of off-label uses of approved drugs in clinical trials. It was recommended that CHAMPUS cover the patient's care costs associated with any clinical trial (including all ''phases'' of evaluation) involving a life-threatening or other serious condition.

Response: Some procedures, even though the procedure uses an FDA-approved product, do not meet CHAMPUS' criteria for medically necessary treatment. The purpose of this provision is to prevent CHAMPUS beneficiaries from being exposed to less than fully developed and tested medical procedures and to avoid the associated risk of unnecessary or unproven treatment. In addition, services or supplies for which the beneficiary or sponsor has no legal obligation to pay; or for which no charge would be made if the beneficiary or sponsor was not eligible under CHAMPUS, as may be the case in clinical trials, are not covered by CHAMPUS. One of the provisions of this rule allows coverage for a device with an FDA-approved IDE categorized by the FDA as non-experimental/ investigation (FDA Category B) for CHAMPUS beneficiaries participating in FDA-approved clinical trials.

6. *Off-Label Uses of Drugs.* Several commenters were concerned that the proposed regulation does not give automatic coverage to many well-recognized off-label uses. It was recommended that CHAMPUS adopt the approach that Congress utilized in the Medicaid program for all drugs and in the Medicare program for cancer chemotherapy. Under those statutes, off-label drug uses listed in the three major drug-use compendia—U.S. Pharmacopoeia Drug Information, the American Medical Association's Drug Evaluations, and the American Hospital Formulary Service—are automatically covered.

Response: The above listed compendia do not meet the CHAMPUS criteria for ''reliable evidence.'' CHAMPUS can consider coverage of unlabeled or off-label uses of drugs that are otherwise approved by the FDA for use in humans. Approval for reimbursement of unlabeled or off-label uses requires review for medical necessity, and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the unlabeled or off-label use of the drug is safe, effective and in accordance with nationally accepted standards of practice in the medical community.

7. *List of Excluded Procedures.* We received several comments objecting to several of the items listed. Some comments state that the descriptions used in many of the items were too vague to define accurately which procedures are being excluded for payment and some are of procedures independent of the diseases or conditions that they may treat or mitigate. Several commenters submitted literature regarding intraoperative radiation therapy; single and dual photon absorptiomentry (DEXA); videofluroscopy, herniography, percutaneous balloon valvuloplasty (PBV); interoperative monitoring of sensory evoked potentials (SEP); radioimmunoguided surgery in the detection of cancer; quantitative computed tomography (QCT); percutaneous transluminal angioplasty (PBA); light therapy for seasonal depression; immunotherapy for malignant diseases; intracavity administration of cisplatin; palladium (103Pd) seed brachytherapy; cryosurgery for liver metastases; HLA–DNA typing; and home uterine activity monitoring. The greatest disagreement involved high-dose chemotherapy with stem-cell rescue for breast cancer, ovarian cancer, testicular cancer and multiple myeloma.

Response: The issue of high-dose chemotherapy with stem-cell rescue (HSC/SCR) is addressed extensively in the preamble. The most recent information reconfirms, in even stronger terms and with new studies and literature, the earlier conclusions of previous technology assessments that HSC/SCR is unproven in the treatment of breast cancer. To date there has been no new evidence which would warrant a departure from the original coverage determination.

Since the proposed rule was published, OCHAMPUS has removed herniography, HLA–DNA typing, cryosurgery for liver metastases, bone density studies [single and dual photon absorptiometry and quantitated computed tomography (QCT)], Contigen Bard ® collagen implant, transurethral laser incision of the prostate (TULIP) and intraventricular administration of narcotics from the list of unproven procedures. We will continually monitor the development of the literature and the status of ongoing well-controlled clinical trails regarding the effectiveness of the remaining procedures on the list. If and when the Director, OCHAMPUS determines that, based on reliable evidence, a procedure has proven medical effectiveness, the Director OCHAMPUS will initiate action to remove the procedure from the partial list of unproven drugs, devices or medical treatment or procedures.

E. Regulatory Procedures

Executive Order 12866 requires certain regulatory assessments for any ''significant regulatory action,'' defined as one which would result in an annual effect on the 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 regulations which would have significant impact on a substantial number of small entities. This proposed rule is not a significant regulatory action under Executive Order 12866. This rule will not involve any significant burden on the CHAMPUS beneficiary or provider population. This rule only clarifies the CHAMPUS exclusion of unproven drugs, devices, treatments and procedures and describes the process that the Office of CHAMPUS follows in determining for purposes of benefit coverage when a procedure, treatment, drug, or device has moved from the status of unproven to the position of nationally accepted medical practice. This rule does not impose information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*)

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health Insurance, and Military personnel.

Accordingly, 32 CFR Part 199 is amended as follows:

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

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

2. Section 199.2 is amended in paragraph (b) by removing the definition of ''Experimental'' and adding the definitions for ''Clinically Meaningful Endpoints'', ''Rare Diseases'', ''Reliable Evidence'', and ''Unlabeled or Off-Labeled Drugs'' and placing them in alphabetical order to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Clinically Meaningful Endpoints. As used the definition of *reliable evidence* in this paragraph (b) and § 199.4(g)(15), the term clinically meaningful endpoints means objectively measurable outcomes of clinical interventions or other medical procedures, expressed in

terms of survival, severity of illness or condition, extent of adverse side effects, diagnostic capability, or other effect on bodily functions directly associated with such results.

* * * * *

Rare Diseases. CHAMPUS defines a rare disease as one which affects fewer than one in 200,000 Americans.

* * * * *

Reliable evidence. (1) As used in § 199.4(g)(15), the term reliable evidence means only:

(i) Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.

(ii) Published formal technology assessments.

(iii) The published reports of national professional medical associations.

(iv) Published national medical policy organization positions; and

(v) The published reports of national expert opinion organizations.

(2) The hierarchy of reliable evidence of proven medical effectiveness, established by (1) through (5) of this paragraph, is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

* * * * *

Unlabeled or Off-Label Drugs. Food and Drug Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. The drug must be medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice.

* * * * *

3. Section 199.4 is amended by revising paragraph (g)(15) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(g) *Exclusions and limitations.* * * *

(15) *Unproven drugs, devices, and medical treatments or procedures.* By law, CHAMPUS can only cost-share medically necessary supplies and services. Any drug, device or medical treatment or procedure, the safety and efficacy of which have not been established, as described in this paragraph (g)(15), is unproven and cannot be cost-shared by CHAMPUS.

(i) A drug, device, or medical treatment or procedure is unproven:

(A) If the drug or device cannot be lawfully marketed without the approval or clearance of the United States Food and Drug Administration (FDA) and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient.

Note: Although the use of drugs and medicines not approved by the FDA for commercial marketing, that is for use by humans, (even though permitted for testing on humans) is excluded from coverage as unproven, drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered by 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), are not covered 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.

CHAMPUS can also consider coverage of *unlabeled* or *off-label* uses of drugs that are Food and Drug Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. Approval for reimbursement of *unlabeled* or *off-label* uses requires review for medical necessity, and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the *unlabeled* or *off-label* use of the drug is safe, effective and in accordance with nationally accepted standards of practice in the medical community.

(B) If a medical device (as defined by 21 U.S.C. 321(h)) with an Investigational Device Exemption (IDE) approved by the Food and Drug Administration is categorized by the FDA as experimental/investigational (FDA Category A).

Note: CHAMPUS will consider for coverage a device with an FDA-approved IDE categorized by the FDA as non-experimental/investigational (FDA Category B) for CHAMPUS beneficiaries participating in FDA approved clinical trials. Coverage of any such Category B device is dependent on its meeting all other requirements of the laws and rules governing CHAMPUS and upon the beneficiary involved meeting the FDA-approved IDE study protocols.

(C) Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis. (See the definition of *reliable evidence* in § 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

(D) If the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated doses, its toxicity, its safety, or its effectiveness as compared with the standard means of treatment or diagnosis. (See the definition of *reliable evidence* in § 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

(ii) CHAMPUS benefits for rare diseases are reviewed on a case-by-case basis by the Director, Office of CHAMPUS, or a designee. In reviewing the case, the Director, or a designee, may consult with any or all of the following sources to determine if the proposed therapy is considered safe and effective:

(A) Trials published in refereed medical literature.

(B) Formal technology assessments.

(C) National medical policy organization positions.

(D) National professional associations.

(E) National expert opinion organizations.

(iii) *Care excluded.* This exclusion from benefits includes all services directly related to the unproven drug, device, or medical treatment or procedure. However, CHAMPUS may cover services or supplies when there is no logical or causal relationship between the unproven drug, device or medical treatment or procedure and the treatment at issue or where such a logical or causal relationship cannot be established with a sufficient degree of certainty. This CHAMPUS coverage is authorized in the following circumstances:

(A) Treatment that is not related to the unproven drug, device or medical treatment or procedure; e.g., medically necessary in the absence of the unproven treatment.

(B) Treatment which is necessary follow-up to the unproven drug, device or medical treatment or procedure but which might have been necessary in the absence of the unproven treatment.

(iv) *Examples of unproven drugs, devices or medical treatments or*

procedures. This paragraph (g)(15)(iv) consists of a partial list of unproven drugs, devices or medical treatment or procedures. These are excluded from CHAMPUS program benefits. This list is not all inclusive. Other unproven drugs, devices or medical treatments or procedures, are similarly excluded, although they do not appear on this partial list. This partial list will be reviewed and updated periodically as new information becomes available. With respect to any procedure included on this partial list, if and when the Director, OCHAMPUS determines that based on reliable evidence (as defined in section 199.2) such procedure has proven medical effectiveness, the Director will initiate action to remove the procedure from this partial list of unproven drugs, devices or medical treatment or procedures. From the date established by the Director as the date the procedure has established proven medical effectiveness until the date the regulatory change is made to remove the procedures from the partial list of unproven drugs, devices or medical treatment or procedures the Director, OCHAMPUS will suspend treatment of the procedure as unproven drugs, devices, or medical treatments or procedures. Following is the non-inclusive, partial list of unproven drugs, devices or medical treatment or procedures, all of which are excluded from CHAMPUS benefits:

(A) Radial keratotomy (refractive keratoplasty).

(B) Cellular therapy.

(C) Histamine therapy.

(D) Stem cell assay, a laboratory procedure which allows a determination to be made of the type and dose of cancer chemotherapy drugs to be used, based on in vitro analysis of their effects on cancer cells taken from an individual.

(E) Topical application of oxygen.

(F) Immunotherapy for malignant disease, except when using drugs approved by the FDA for this purpose.

(G) Prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents.

(H) Transcervical block silicone plug.

(I) Whole body hyperthermia in the treatment of cancer.

(J) Portable nocturnal hypoglycemia detectors.

(K) Testosterone pellet implants in the treatment of females.

(L) Estradiol pellet implants.

(M) Epikeratophakia for treatment of aphakia and myopia.

(N) Bladder stimulators.

(O) Ligament replacement with absorbable copolymer carbon fiber scaffold.

(P) Intraoperative radiation therapy.

(Q) Gastric bubble or balloon.

(R) Dorsal root entry zone (DREZ) thermocoagulation or micorcoagulation neurosurgical procedure.

(S) Brain electrical activity mapping (BEAM).

(T) Topographic brain mapping (TBM) procedure.

(U) Ambulatory blood pressure monitoring.

(V) Bilateral carotoid body resection to relieve pulmonary system.

(W) Intracavitary administration of cisplatin for malignant disease.

(X) Cervicography.

(Y) In-home uterine activity monitoring for the purpose of preventing preterm labor and/or delivery.

(Z) Sperm evaluation, hamster penetration test.

(AA) Transfer factor (TF).

(BB) Continuous ambulatory esophageal pH monitoring (CAEpHM) is considered unproven for patients under age 12 for all indications, and for patients over age 12 for sleep apnea.

(CC) Adrenal-to-brain transplantation for Parkinson's disease.

(DD) Videofluoroscopy evaluation in speech pathology.

(EE) Applied kinesiology.

(FF) Hair analysis to identify mineral deficiencies from the chemical composition of the hair. Hair analysis testing may be reimbursed when necessary to determine lead poisoning.

(GG) Iridology (links flaws in eye coloration with disease elsewhere in the body).

(HH) Small intestinal bypass (jejunoileal bypass) for treatment of morbid obesity.

(II) Biliopancreatic bypass.

(JJ) Gastric wrapping/gastric banding.

(KK) Calcium EAP/calcium orotate and selenium (also known as Nieper therapy)—Involves inpatient care and use of calcium compounds and other non-FDA approved drugs and special diets. Used for cancer, heart disease, diabetes, and multiple sclerosis.

(LL) Percutaneous balloon valvuloplasty for mitral and tricuspid valve stenosis.

(MM) Amniocentesis performed for ISO immunization to the ABO blood antigens.

(NN) Balloon dilatation of the prostate.

(OO) Helium in radiosurgery.

(PP) Electrostimulation of salivary production in the treatment of xerostomia secondary to Sjogren's syndrome.

(QQ) Intraoperative monitoring of sensory evoked potentials (SEP). To include visually evoked potentials, brainstem auditory evoked response, somatosensory evoked potentials during spinal and orthopedic surgery, and sensory evoked potentials monitoring of the sciatic nerve during total hip replacement. Recording SEPs in unconscious head injured patients to assess the status of the somatosensory system. The use of SEPs to define conceptional or gestational age in preterm infants.

(RR) Autolymphocyte therapy (ALT) (immunotherapy used for treating metastatic kidney cancer patients).

(SS) Radioimmunoguided surgery in the detection of cancer.

(TT) Gait analysis (also known as a walk study or electrodynogram)

(UU) Use of cerebellar stimulators/pacemakers for the treatment of neurologic disorders.

(VV) Signal-averaged ECG.

(WW) Peri-urethal Teflon injections to manage urinary incontinence.

(XX) Extraoperative electrocorticography for stimulation and recording

(YY) Quantitative computed tomography (QCT) for the detection and monitoring of osteoporosis.

(ZZ) [Reserved]

(AAA) Percutaneous transluminal angioplasty in the treatment of obstructive lesions of the carotoid, vertebral and cerebral arteries.

(BBB) Endoscopic third ventriculostomy.

(CCC) Holding therapy—Involves holding the patient in an attempt to achieve interpersonal contact, and to improve the patient's ability to concentrate on learning tasks.

(DDD) In utero fetal surgery.

(EEE) Light therapy for seasonal depression (also known as seasonal affective disorder (SAD)).

(FFF) Dorsal column and deep brain electrical stimulation of treatment of motor function disorder.

(GGG) Chelation therapy, except with products and for indications approved by the FDA.

(HHH) All organ transplants *except* heart, heart-lung, lung, kidney, some bone marrow, liver, liver-kidney, corneal, heart-valve, and kidney-pancreas transplants for Type I diabetics with chronic renal failure who require kidney transplants.

(III) Implantable infusion pumps, *except* for treatment of spasticity, chronic intractable pain, and hepatic artery perfusion chemotherapy for the treatment of primary liver cancer or metastic colorectal liver cancer.

(JJJ) Services related to the candidiasis hypersensitivity syndrome, yeast syndrome, or gastrointestinal candidiasis (i.e., allergenic extracts of

Candida albicans for immunotherapy and/or provocation/neutralization).

(KKK) Treatment of chronic fatigue syndrome.

(LLL) Extracorporeal immunoadsorption using protein A columns for conditions other than acute idopathic thrombocytopenia purpura.

(MMM) Dynamic posturography (both static and computerized).

(NNN) Laparoscopic myomectomy.

(OOO) Growth factor, including platelet-derived growth factors, for treating non-healing wounds. This includes Procurene®, a platelet-derived wound-healing formula.

(PPP) High dose chemotherapy with stem cell rescue (HDC/SCR) for any of the following malignancies:

(1) Breast cancer, except for metastic breast cancer that has relapsed after responding to a first line treatment.

(2) Ovarian cancer.

(3) Testicular cancer.

Dated: December 30, 1996.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–101 Filed 1–6–97; 8:45 am]

BILLING CODE 5000–04–M

Department of the Air Force

32 CFR Part 813

Schedule of Fees for Copying, Certifying and Searching Records and Other Documentary Material

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Final rule; removal.

SUMMARY: The Department of the Air Force is amending Title 32, Chapter VII of the CFR by removing Part 813, Schedule of Fees for Copying, Certifying and Searching Records and Other Documentary Material. This rule is removed because the source document has been rescinded.

EFFECTIVE DATE: January 6, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Patsy J. Conner, Air Force Federal Register Liaison Officer, SAF/AAX, 1720 Air Force Pentagon, Washington DC 20330–1720, telephone (703) 697–4191.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 813

Freedom of information.

Authority: 10 U.S.C. 8013.

PART 813—[REMOVED]

Accordingly, 32 CFR, Chapter VII, is amended by removing part 813.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 97–88 Filed 1–3–97; 8:45 am]

BILLING CODE 3910–01–P

32 CFR Part 818b

Legal Assistance Program

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Final rule; removal.

SUMMARY: The Department of the Air Force is amending Title 32, Chapter VII of the CFR by removing Part 818b, Legal Assistance Program. This rule is removed because it has limited applicability to the general public. This action is the result of departmental review. The intended effect is to ensure that only regulations which substantially affect the public are maintained in the Air Force portion of the Code of Federal Regulations.

EFFECTIVE DATE: January 6, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Patsy J. Conner, Air Force Federal Register Liaison Officer, SAF/AAX, 1720 Air Force Pentagon, Washington DC 20330–1720, telephone (703) 697–4191.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 818b

Legal services, Military law, Military personnel.

Authority: 10 U.S.C. 8013.

PART 818b—[REMOVED]

Accordingly, 32 CFR, Chapter VII, is amended by removing part 818b.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 97–87 Filed 1–3–97; 8:45 am]

BILLING CODE 3910–01–P

32 CFR Part 844

Distribution of Literature and Protest and Dissident Activities

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Final rule; removal.

SUMMARY: The Department of the Air Force is amending Title 32, Chapter VII of the CFR by removing Part 844, Distribution of Literature and Protest and Dissident Activities. This rule is removed because it has limited applicability to the general public. This action is the result of departmental review. The intended effect is to ensure that only regulations which substantially affect the public are maintained in the Air Force portion of the Code of Federal Regulations.

EFFECTIVE DATE: January 6, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Patsy J. Conner, Air Force Federal Register Liaison Officer, SAF/AAX, 1720 Air Force Pentagon, Washington DC 20330–1720, telephone (703) 697–4191.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 844

Civil disorders, Military academies, Military personnel.

Authority: 10 U.S.C. 8013.

PART 844—[REMOVED]

Accordingly, 32 CFR, Chapter VII, is amended by removing part 844.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 97–89 Filed 1–3–97; 8:45 am]

BILLING CODE 3910–01–P

POSTAL SERVICE

39 CFR Part 20

Global Package Link (Formerly International Package Consignment Service)

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service, after considering the comments submitted in response to its requests in 59 FR 65961 (December 22, 1994) for comments on interim regulations implementing International Package Consignment (IPCS) service, and in 60 FR 61660 (December 1, 1995) on an amendment of the interim regulations implementing International Package Consignment Service, hereby gives notice that it is adopting the interim regulations as amended on a permanent basis, without modification. The Postal Service also announces that the name of the service has been changed to Global Package Link (GPL) service.

EFFECTIVE DATE: 12:01, a.m., January 6, 1997.

FOR FURTHER INFORMATION CONTACT: Robert E. Michelson, (202) 268–5731.

SUPPLEMENTARY INFORMATION: On December 22, 1994, the Postal Service published in the Federal Register interim regulations implementing Global Package Link (GPL) to Japan and