



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
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TRICARE
MANAGEMENT ACTIVITY

MB&RB

**CHANGE 43
32 CFR 199
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**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
TITLE 32 - CODE OF FEDERAL REGULATIONS - PART 199
(TMA VERSION)**

FINAL RULE

The Department of Defense, Office of the Secretary, has authorized the following addition(s)/revision(s) to 32 CFR Part 199, reissued April 2005.

**CHANGE TITLE: CHAMPUS/TRICARE: INCLUSION OF RETAIL NETWORK PHARMACIES
AS AUTHORIZED TRICARE PROVIDERS FOR THE ADMINISTRATION OF
TRICARE COVERED VACCINES**

FEDERAL REGISTER: Vol 76, No 134 (Pages 41063 - 41065)

PAGE CHANGE(S): See page 2.

**ATTACHMENT(S): 10 PAGES
DISTRIBUTION: 32 CFR 199**

WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

REMOVE PAGE(S)

INSERT PAGE(S)

CHAPTER 6

Chapter pages 49, 50, 53, and 54

Chapter pages 49, 50, 53, and 54

CHAPTER 21

Chapter pages 5 through 8, 13, and 14

Chapter pages 5 through 8, 13, and 14

determined allowable charge as payment in full, except for applicable deductibles and cost-shares (i.e., balance billing of a beneficiary above the allowable charge is prohibited; may not bill beneficiary for noncovered care). The pastoral counselor must also agree to enter into the same participation agreement as a certified marriage and family therapist with the Office of CHAMPUS within which the pastoral counselor agrees to all provisions including licensure, national association membership and conditions upon termination, outlined above for certified marriage and family therapist.

NOTE: No dual status will be recognized by the Office of CHAMPUS. Pastoral counselors must elect to become one of the categories of extramedical CHAMPUS provides specified above. Once authorized as either a pastoral counselor, or a certified marriage and family therapist, claims review and reimbursement will be in accordance with the criteria established for the elected provider category.

(C) Mental health counselor. For the purposes of CHAMPUS, a mental health counselor is an individual who meets the following requirements:

- (1) Minimum of a master's degree in mental health counseling or allied mental health field from a regionally accredited institution; and
- (2) Two years of post-masters experience which includes 3000 hours of clinical work and 100 hours of face-to-face supervision; and
- (3) Is licensed or certified to practice as a mental health counselor by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information); and
- (4) May only be reimbursed when:
 - (i) The CHAMPUS beneficiary is referred for therapy by a physician; and
 - (ii) A physician is providing ongoing oversight and supervision of the therapy being provided; and
 - (iii) The mental health counselor certifies on each claim for reimbursement that a written communication has been made or will be made to the referring physician of the results of the treatment. Such communication will be made at the end of the treatment, or more frequently, as required by the referring physician (refer to Sec. 199.7).

(D) The following additional information applies to each of the above categories of extramedical individual providers:

- (1) These providers must also be licensed or certified to practice as a certified marriage and family therapist, pastoral counselor or mental health counselor by the jurisdiction where practicing. In jurisdictions that do not provide for licensure or certification, the provider must be certified by or eligible for full clinical membership in the appropriate national professional association that sets standards for the specific profession.
- (2) Grace period for therapists or counselors in states where licensure/certification is optional. CHAMPUS is providing a grace period for those therapists or counselors who did not obtain optional licensure/certification in their jurisdiction, not realizing it was a

TMA Version - April 2005

CHAMPUS requirement for authorization. The exemption by state law for pastoral counselors may have misled this group into thinking licensure was not required. The same situation may have occurred with the other therapist or counselor categories where licensure was either not mandated by the state or was provided under a more general category such as "professional counselors." This grace period pertains only to the licensure/certification requirement, applies only to therapists or counselors who are already approved as of October 29, 1990, and only in those areas where the licensure/certification is optional. Any therapist or counselor who is not licensed/certified in the state in which he/she is practicing by August 1, 1991, will be terminated under the provisions of Sec. 199.9. This grace period does not change any of the other existing requirements which remain in effect. During this grace period, membership or proof of eligibility for full clinical membership in a recognized professional association is required for those therapists or counselors who are not licensed or certified by the state. The following organizations are recognized for therapists or counselors at the level indicated: Full clinical member of the American Association of Marriage and Family Therapy; membership at the fellow or diplomate level of the American Association of Pastoral Counselors; and membership in the National Academy of Certified Clinical Mental Health Counselors. Acceptable proof of eligibility for membership is a letter from the appropriate certifying organization. This opportunity for delayed certification/licensure is limited to the counselor or therapist category only as the language in all of the other provider categories has been consistent and unmodified from the time each of the other provider categories were added. The grace period does not apply in those states where licensure is mandatory.

(E) Christian Science practitioners and Christian Science nurses. CHAMPUS cost-shares the services of Christian Science practitioners and nurses. In order to bill as such, practitioners or nurses must be listed or be eligible for listing in the Christian Science Journal² at the time the service is provided.

(d) Other providers. Certain medical supplies and services of an ancillary or supplemental nature are coverable by CHAMPUS, subject to certain controls. This category of provider includes the following:

(1) Independent laboratory. Laboratory services of independent laboratories may be cost-shared if the laboratory is approved for participation under Medicare and certified by the Medicare Bureau, Health Care Financing Administration.

(2) Suppliers of portable x-ray services. Such suppliers must meet the conditions of coverage of the Medicare program, set forth in the Medicare regulations, or the Medicaid program in that state in which the covered service is provided.

(3) **Pharmacies.** Pharmacies must meet the applicable requirements of state law in the state in which the pharmacy is located. In addition to being subject to the policies and procedures for authorized providers established by this section, additional policies and procedures may be established for authorized pharmacies under Sec. 199.21 of this part implementing the Pharmacy Benefits Program.

² Copies of this journal can be obtained through the Christian Science Publishing Company, 1 Norway Street, Boston, MA 02115-3122 or the Christian Science Publishing Society, P.O. Box 11369, Des Moines, IA 50340.

- (B) Surgical treatment procedures;
- (C) Maternity management procedures;
- (D) Rehabilitation and/or habilitation procedures; or
- (E) Diagnostic technical procedures.

(viii) The Director, OCHAMPUS, or designee, shall determine the appropriate procedural category of a qualified organization and may change the category based upon the provider's CHAMPUS claim characteristics. The category determination of the Director, OCHAMPUS, designee, is conclusive and may not be appealed.

(2) Conditions of authorization. An applicant must meet the following conditions to be eligible for authorization as a CHAMPUS corporate services provider:

- (i) Be a corporation or a foundation, but not a professional corporation or professional association; and
- (ii) Be institution-affiliated or freestanding as defined in Sec. 199.2; and
- (iii) Provide:

(A) Services and related supplies of a type rendered by CHAMPUS individual professional providers or diagnostic technical services and related supplies of a type which requires direct patient contact and a technologist who is licensed by the state in which the procedure is rendered or who is certified by a Qualified Accreditation Organization as defined in Sec. 199.2; and

(B) A level of care which does not necessitate that the beneficiary be provided with on-site sleeping accommodations and food in conjunction with the delivery of services; and

(iv) Complies with all applicable organizational and individual licensing or certification requirements that are extant in the state, county, municipality, or other political jurisdiction in which the provider renders services; and

(v) Be approved for Medicare payment when determined to be substantially comparable under the provisions of paragraph (f)(1)(iv)(D) of this section or, when Medicare approved status is not required, be accredited by a qualified accreditation organization, as defined in Sec. 199.2; and

(vi) Has entered into a participation agreement approved by the Director, OCHAMPUS, or designee, which at least complies with the minimum participation agreement requirements of this section.

(3) Transfer of participation agreement. In order to provide continuity of care for beneficiaries when there is a change of provider ownership, the provider agreement is automatically assigned to the new owner, subject to all the terms and conditions under which the original agreement was made.

TMA Version - April 2005

(i) The merger of the provider corporation or foundation into another corporation or foundation, or the consolidation of two or more corporations or foundations resulting in the creation of a new corporation or foundation, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation or foundation into the provider corporation or foundation does not constitute change of ownership.

(iii) The surviving corporation or foundation shall notify the Director, OCHAMPUS, or designee, in writing of the change of ownership promptly after the effective date of the transfer or change in ownership.

(4) Pricing and payment methodology: The pricing and payment of procedures rendered by a provider authorized under this paragraph (f) shall be limited to those methods for pricing and payment allowed by this part which the Director, OCHAMPUS, or designee, determines contribute to the efficient management of CHAMPUS.

(5) Termination of participation agreement. A provider may terminate a participation agreement upon 45 days written notice to the Director, OCHAMPUS, or designee, and to the public.

[51 FR 24008, Jul 1, 1986; 67 FR 40602, Jun 13, 2002; 67 FR 42720, Jun 25, 2002; 68 FR 65174, Nov 19, 2003; 69 FR 29229, May 21, 2004; 69 FR 44591, Jul 28, 2004; 69 FR 51568, Aug 20, 2004; 69 FR 55359, Sep 14, 2004; 70 FR 61378, Oct 24, 2005; 72 FR 63988, Nov 14, 2007; 74 FR 44755, Aug 31, 2009; 74 FR 55777, Oct 29, 2009; 74 FR 65438, Dec 10, 2009; 75 FR 47460, Aug 6, 2010; 75 FR 50882, Aug. 18, 2010; 76 FR 41065, Jul 13, 2011]

EDITORIAL NOTE: For Federal Register citations affecting Sec. 199.6, see the List of Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

- (2) Approval of a new indication for an existing pharmaceutical agent;
- (3) Changes in the clinical use of existing pharmaceutical agents;
- (4) New information concerning the safety, effectiveness or clinical outcomes of existing pharmaceutical agents;
- (5) Price changes;
- (6) Shifts in market share;
- (7) Scheduled review of a therapeutic class; and
- (8) Requests from Pharmacy and Therapeutics Committee members, military treatment facilities, or other Military Health System officials.

(g) Administrative procedures for establishing and maintaining the uniform formulary--(1) Pharmacy and Therapeutics Committee determinations. Determinations of the Pharmacy and Therapeutics Committee are by majority vote and recorded in minutes of Committee meetings. The minutes set forth the determinations of the committee regarding the pharmaceutical agents selected for inclusion in the uniform formulary and summarize the reasons for those determinations. For any pharmaceutical agent (including maintenance medications) for which a recommendation is made that the status of the agent be changed from the formulary tier to the non-formulary tier of the uniform formulary, or that the agent requires a pre-authorization, the Committee shall also make a recommendation as to effective date of such change that will not be longer than 180 days from the final decision date but may be less. The minutes will include a record of the number of members voting for and against the Committee's action.

(2) Beneficiary Advisory Panel. Comments and recommendations of the Beneficiary Advisory Panel are recorded in minutes of Panel meetings. The minutes set forth the comments and recommendations of the Panel and summarize the reasons for those comments and recommendations. The minutes will include a record of the number of members voting for or against the Panel's comments and recommendations.

(3) Uniform formulary final decisions. The Director of the TRICARE Management Activity makes the final DoD decisions regarding the uniform formulary. Those decisions are based on the Director's review of the final determinations of the Pharmacy and Therapeutics Committee and the comments and recommendations of the Beneficiary Advisory Panel. No pharmaceutical agent may be designated as non-formulary on the uniform formulary unless it is preceded by such recommendation by the Pharmacy and Therapeutics Committee. The decisions of the Director of the TRICARE Management Activity are in writing and establish the effective date(s) of the uniform formulary actions.

(4) Transition to the Uniform Formulary. Beginning in Fiscal Year 2005, under an updated charter for the DoD P&T Committee, the committee shall meet at least quarterly to review therapeutic classes of pharmaceutical agents and make recommendations concerning which pharmaceutical agents should be on the Uniform Formulary, the Basic Care Formulary (BCF), and Extended Core Formulary (ECF). The P&T Committee will review the classes in a methodical, but expeditious manner. During the transition period from the previous

TMA Version - April 2005

methodology of formulary management involving only the MTFs and the TMOP Program, previous decisions by the predecessor DoD P&T Committee concerning MTF and Mail Order Pharmacy Program formularies shall continue in effect. As therapeutic classes are reviewed under the new formulary management process, the processes established by this section shall apply.

(h) Obtaining pharmacy services under the retail network pharmacy benefits program. (1) Points of service. There are four outpatient pharmacy points of service:

- (i) Military Treatment Facilities (MTFs);
- (ii) Retail network pharmacies: Those are non-MTF pharmacies that are a part of the network established for TRICARE retail pharmacy services;
- (iii) Retail non-network pharmacies: Those are non-MTF pharmacies that are not part of the network established for TRICARE retail pharmacy services, and
- (iv) the TRICARE Mail Order Pharmacy (TMOP).

(2) Availability of formulary pharmaceutical agents--(i) General. Subject to paragraph (h)(2)(ii) of this section, formulary pharmaceutical agents are available under the Pharmacy Benefits Program from all of the points of service identified in paragraph (h)(1) of this section.

(ii) Availability of formulary pharmaceutical agents at military treatment facilities (MTF). Pharmaceutical agents included on the uniform formulary are available through facilities of uniformed services, consistent with the scope of health care services offered in such facilities and additional determinations by the P&T Committee of the relative clinical effectiveness and cost effectiveness, based on costs to the Program associated with providing the agents to beneficiaries. The BCF is a subset of the uniform formulary and is a mandatory component of formularies at all full-service MTF pharmacies. The BCF contains the minimum set of pharmaceutical agents that each full-service MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care Manager enrollment sites. Limited-service MTF pharmacies (e.g., specialty pharmacies within an MTF or pharmacies servicing only active duty military members) are not required to include the entire BCF on their formularies, but may limit their formularies to those BCF agents appropriate to the needs of the patients they serve. An ECF may list preferred agents in drug classes other than those covered by the BCF. Among BCF and ECF agents, individual MTF formularies are determined by local P&T Committees based on the scope of health care services provided at the respective MTFs. All pharmaceutical agents on the local formulary of full-service MTF pharmacies must be available to all categories of beneficiaries.

(3) Availability of non-formulary pharmaceutical agents--(i) General. Non-formulary pharmaceutical agents are generally available under the pharmacy benefits program from the retail network pharmacies, retail non-network pharmacies, and the TRICARE Mail Order Pharmacy (TMOP) at the non-formulary cost-share.

(ii) Availability of non-formulary pharmaceutical agents at military treatment facilities. Although not a beneficiary entitlement, non-formulary pharmaceutical agents may be made available to eligible covered beneficiaries through the MTF pharmacies for

TMA Version - April 2005

prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary pharmaceutical agent.

(iii) Availability of clinically appropriate non-formulary pharmaceutical agents to members of the Uniformed Services. The pharmacy benefits program is required to assure the availability of clinically appropriate pharmaceutical agents to members of the uniformed services, including, where appropriate, agents not included on the uniform formulary. Clinically appropriate pharmaceutical agents will be made available to members of the Uniformed Services, including, where medical necessity has been validated, agents not included on the uniform formulary. MTFs shall establish procedures to evaluate the clinical necessity of prescriptions written for members of the uniformed services for pharmaceutical agents not included on the uniform formulary. If it is determined that the prescription is clinically necessary, the MTF will provide the pharmaceutical agent to the member.

(iv) Availability of clinically appropriate pharmaceutical agents to other eligible beneficiaries at retail pharmacies or the TMOP. Eligible beneficiaries will receive non-formulary pharmaceutical agents at the formulary cost-share when medical necessity has been established by the beneficiary and/or his/her provider. The peer review provisions of Sec. 199.15 shall apply to the clinical necessity pre-authorization determinations. TRICARE may require that the time for review be expedited under the pharmacy benefits program.

(4) Availability of vaccines/immunizations. A retail network pharmacy may be an authorized provider under the Pharmacy Benefits Program when functioning within the scope of its state laws to provide authorized vaccines/immunizations to an eligible beneficiary. The Pharmacy Benefits Program will cover the vaccine and its administration by the retail network pharmacy, including administration by pharmacists who meet the applicable requirements of state law to administer the vaccine. A TRICARE authorized vaccine/immunization includes only vaccines/immunizations authorized as preventive care under the basic program benefits of Sec. 199.4 of this part, as well as such care authorized for Prime enrollees under the uniform HMO benefit of Sec. 199.18. For Prime enrollees under the uniform HMO benefit, a referral is not required under paragraph (n)(2) of Sec. 199.18 for preventive care vaccines/immunizations received from a retail network pharmacy that is a TRICARE authorized provider. Any additional policies, instructions, procedures, and guidelines appropriate for implementation of this benefit may be issued by the TMA Director.

(i) **Cost-sharing requirements under the pharmacy benefits program--**(1) General. Under 10 U.S.C. 1074g(a)(6), cost-sharing requirements are established in this section for the pharmacy benefits program independent of those established under other provisions of this Part. Cost-shares under this section partially defray government costs of administering the pharmacy benefits program when collected by the government for prescriptions dispensed through the retail network pharmacies or the TRICARE Mail Order Pharmacy. The higher cost-share paid for prescriptions dispensed by a non-network retail pharmacy is established to encourage the use of the most economical venue to the government. Cost-sharing requirements are based on the classification of a pharmaceutical agent as generic, formulary, or non-formulary, in conjunction with the point of service from which the agent is acquired.

TMA Version - April 2005

(2) Cost-sharing amounts. Active duty members of the uniformed services do not pay cost-shares. For other categories of beneficiaries, cost-sharing amounts are as follows:

(i) For pharmaceutical agents obtained from a military treatment facility, there is no co-payment.

(ii) For pharmaceutical agents obtained from a retail network pharmacy there is a:

(A) \$9.00 co-payment per prescription required for up to a 30-day supply of a formulary pharmaceutical agent.

(B) \$3.00 co-payment per prescription for up to a 30-day supply of a generic pharmaceutical agent.

(C) \$22.00 co-payment per prescription for up to a 30-day supply of a non-formulary pharmaceutical agent.

(D) \$0.00 co-payment for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

(iii) For formulary and generic pharmaceutical agents obtained from a retail non-network pharmacy there is a 20 percent or \$9.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(iv) For non-formulary pharmaceutical agents obtained at a retail non-network pharmacy there is a 20 percent or \$22.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(v) For pharmaceutical agents obtained under the TMOP program there is a:

(A) \$9.00 co-payment per prescription for up to a 90-day supply of a formulary pharmaceutical agent.

(B) \$3.00 co-payment for up to a 90-day supply of a generic pharmaceutical agent.

(C) \$22.00 co-payment for up to a 90-day supply of a non-formulary pharmaceutical agent.

(vi) For TRICARE Prime beneficiaries who obtain prescriptions from retail non-network pharmacies, the enrollment year deductible for outpatient claims is \$300 per individual; \$600 per family; and a point of service cost-share of 50 percent thereafter applies in lieu of the 20 percent co-payment.

(vii) Except as provided in paragraph (h)(2)(viii) of this section, for pharmaceutical agents acquired by TRICARE Standard beneficiaries from retail non-network pharmacies, beneficiaries are subject to the \$150.00 per individual or \$300.00 maximum per family annual fiscal year deductible.

(viii) Under TRICARE Standard, dependents of members of the uniformed services whose pay grade is E-4 or below are subject to the \$50.00 per individual or \$100.00 maximum per family annual fiscal year deductible.

TMA Version - April 2005

(iii) For purposes of this paragraph (q)(2), a covered drug is a drug that is a covered drug under 38 U.S.C. 8126, but does not include:

- (A) A drug that is not a covered drug under 38 U.S.C. 8126;
- (B) A drug provided under a prescription that is not covered by 10 U.S.C. 1074g(f);
- (C) A drug that is not provided through a retail network pharmacy under this section;
- (D) A drug provided under a prescription which the TRICARE Pharmacy Benefits Program is the second payer under paragraph (m) of this section;
- (E) A drug provided under a prescription and dispensed by a pharmacy under section 340B of the Public Health Service Act; or
- (F) Any other exception for a drug, consistent with law, established by the Director, TMA.

(iv) The requirement of this paragraph (q)(2) may, upon the recommendation of the Pharmacy and Therapeutics Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement referred to in paragraph (q)(1) that all covered TRICARE retail network pharmacy prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements under this paragraph (q)(2).

(3) Refund procedures. (i) Refund procedures to ensure that pharmaceuticals paid for by the DoD that are provided by retail network pharmacies under the pharmacy benefits program are subject to the pricing standards referred to in paragraph (q)(1) of this section shall be established. Such procedures may be established as part of the agreement referred to in paragraph (q)(2), or in a separate agreement, or pursuant to Sec. 199.11.

(ii) The refund procedures referred to in paragraph (q)(3)(i) of this section shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures shall provide the manufacturer at least 70 days from the date of the submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing. The current annual FCP and the annual non-FAMP from which it was derived will be applicable to all prescriptions filled during the calendar year.

(iii) A refund due under this paragraph (q) is subject to Sec. 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under section 199.11 of this part request waiver or compromise of a refund amount due under 10 U.S.C. 1074g(f) and this paragraph (q).

(B) During the pendency of any request for waiver or compromise under paragraph (q)(3)(iii)(A) of this section, a manufacturer's written agreement under paragraph (q)(2) shall be deemed to exclude the matter that is the subject of the request for waiver or compromise. In such cases the agreement, if otherwise sufficient for the purpose of the condition referred to in paragraph (q)(2), will continue to be sufficient for that purpose. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor a requirement or an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in Sec. 199.11, a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.

(iv) In the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, TMA. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under section 199.10 of this part. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge from the date payment of the amount was initially due, consistent with section 199.11 of this part.

(4) Remedies. In the case of the failure of a manufacturer of a covered drug to honor a requirement of this paragraph (q) or to honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law.

(5) Beneficiary transition provisions. In cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization under paragraph (q)(2) of this section, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.

[69 FR 17048, Apr 1, 2004; 74 FR 11292, Mar 17, 2009; 74 FR 55776, Oct 29, 2009; 74 FR 65438, Dec 10, 2009; 75 FR 63397, Oct 15, 2010; 76 FR 41065, Jul 13, 2011]

TMA Version - April 2005