Office of Generic Drugs. This action is being taken to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective October 29, 2009.

FOR FURTHER INFORMATION CONTACT: Peter Chen, Center for Drug Evaluation and Research (HFD–615), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8436.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in part 312 (21 CFR part 312) to clarify where ANDA applicants should submit INDs for in vivo bioavailability and bioequivalence studies in humans. This document adds the address for the Office of Generic Drugs in § 312.140(a)(1).

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to add an address for the submission of INDs related to ANDAs.

List of Subjects in 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

■ 2. Section 312.140 is amended by revising paragraph (a)(1) to read as follows:

§ 312.140 Address for correspondence.

(a) * * *

(1) *For drug products regulated by CDER.* Send the IND submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266; except send an IND submission for an in vivo bioavailability or bioequivalence study in humans to support an abbreviated new drug application to the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II, 7500 Standish Pl., Rockville, MD 20855.

* * * * *

Dated: October 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26095 Filed 10–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

[DOD–2006–HA–0149; RIN 0720–AB01]

32 CFR Part 199

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); TRICARE; Implementation of Changes to the Pharmacy Benefits Program; Double Coverage With Medicare Part D

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: TRICARE eligible beneficiaries, who are entitled to Medicare Part A on the basis of age, disability, or end-stage renal disease, maintain their TRICARE eligibility when they are enrolled in the supplementary medical insurance program under Part B of Medicare. In general, in the case of medical or dental care provided to these individuals for which payment may be made under both Medicare and TRICARE, Medicare is the primary payer and TRICARE will normally pay the actual out-of-pocket costs incurred by the person. This final rule prescribes double coverage payment procedures and makes revisions to TRICARE rules to accommodate beneficiaries who are eligible under both Medicare and TRICARE, and who participate in Medicare's outpatient prescription drug program under Medicare Part D. These revisions are necessary because of the requirements contained in the Centers for Medicare and Medicaid Services (CMS) final rule for the Medicare Prescription Drug Benefit, Part D plans with other prescription drug coverage.

This final rule also establishes requirements and procedures for implementation of the improvements to the TRICARE Pharmacy Benefits Program directed by section 714 of the Ronald W. Reagan National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2005 (NDAA FY 05) (Pub. L.108–365). The rule clarifies that the cost-sharing requirements for Medicare-eligible beneficiaries may not be in excess of the cost-sharing requirements applicable to other retirees, their dependents, former spouses and survivors. Additionally, the rule authorizes the Department of Defense (DoD) Pharmacy and Therapeutics Committee (P&T) to make a separate and additional determination of the relative clinical and cost effectiveness of pharmaceutical agents that provide greater value than other uniform formulary agents in that therapeutic class. This rule also describes the transition process that will occur as the uniform formulary is developed and uniform service facilities move to a uniform formulary, consistent with their scope of practice.

DATES: *Effective Date:* This final rule is effective November 30, 2009.

FOR FURTHER INFORMATION CONTACT: RADM Thomas McGinnis, TRICARE Management Activity, Pharmaceutical Operations Directorate, telephone (703) 681–2890.

SUPPLEMENTARY INFORMATION:

I. Double Coverage With Medicare Part D

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), (Pub. L. 108–173), amended Title XVIII of the Social Security Act by establishing a new Part D: the Voluntary Prescription Drug Benefit Program (henceforth, Medicare Part D). The Department of Health and Human Services, CMS, published their Final Rule on January 28, 2005 (70 FR 4193–4585). The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program, and became available to beneficiaries beginning on January 1, 2006.

The Floyd D. Spence NDAA for FY 2001 (Pub. L. 106–398), established the TRICARE Senior Pharmacy Program under section 711 (which was effective April 1, 2001). The Act, also under section 712 (which was effective October 1, 2001), continued TRICARE eligibility for beneficiaries entitled to Medicare Part A on the basis of age, provided they also are enrolled in Medicare Part B. This program has come to be known as TRICARE for Life (TFL). Under section 701 of the National Defense Authorization Act for Fiscal Year 2000 (Pub. L. 106–65), codified at Title 10, U.S.C., Section 1074g, the Department established its new pharmacy benefits program for all TRICARE beneficiaries (as implemented by 32 CFR 199.21). The full implementation of the pharmacy benefit program was not effective until May 3, 2004; however, changes in pharmacy cost shares were effective with the implementation of TRICARE Senior Pharmacy on April 1, 2001.

In implementing TRICARE Senior Pharmacy, DoD stated that the double

coverage rules in 32 CFR 199.8 are applicable to services provided to all beneficiaries under the retail pharmacy network, retail pharmacy non-network, or TRICARE Mail Order programs. In implementing TFL, DoD explained the double coverage rules under 10 U.S.C. 1086(d)(3). The statute states that if a TRICARE-Medicare dual-eligible beneficiary receives medical or dental care for which payment may be made under Medicare and TRICARE, the amount payable for that care by TRICARE shall be the amount of the actual out-of-pocket costs incurred by the person for that care over the sum of (i) the amount paid for that care under Medicare; and (ii) the total of all amounts paid or payable by third party payers other than Medicare. The amount payable by TRICARE may not exceed the total amount that would be paid under TRICARE, if payment for the care were made solely under TRICARE. TFL did not expand the scope of benefits available to this group of beneficiaries beyond the scope of TRICARE benefits available to other retirees and their families. The critical fact is whether the service or supply is payable by both Medicare and TRICARE. For health care services for which payment may be made under both Medicare and TRICARE, TRICARE will pay, up to the beneficiary's legal liability, the actual out-of-pocket costs incurred by the beneficiary, less any payments made by Medicare or other sources of insurance. Actual out-of-pocket costs incurred by the beneficiary include the initial deductible, which is for services payable by Medicare and TRICARE, but for the fact that the beneficiary has not met the deductible amount, and any subsequent beneficiary cost shares. However, if a health care service or supply is a benefit payable only by Medicare, but not by TRICARE, then Medicare has sole responsibility for payment of the health care service or supply, as defined by Medicare, and the beneficiary has the responsibility to pay any corresponding Medicare cost-share or deductible. Likewise, if a health care service or supply is a benefit payable only by TRICARE, but not Medicare, then TRICARE has sole responsibility for payment of the health care service and supply, and the beneficiary has the responsibility to pay any corresponding TRICARE cost-shares or deductible. Finally, if a health care service or supply is neither a benefit payable by Medicare or TRICARE, the beneficiary pays the total cost.

TRICARE has applied the double coverage rules of 32 CFR 199.8 to the Pharmacy Benefits Program under Sec. 199.21(m), and said to the extent they provide a prescription drug benefit, Medicare supplemental insurance plans or Medicare health maintenance organization (HMO) plans are double coverage plans and will be the primary payer. This rule was written prior to Medicare providing a prescription drug benefit under Medicare Part D, and CMS's final rule on the Medicare Prescription Drug Coverage, Section 423.464(f)(l)(iv), military coverage, including TRICARE coverage under chapter 55 of title 10, U.S.C., qualifies as other prescription drug coverage with which a Part D plan must coordinate benefits.

Medicare Part D plans are offered by private insurance companies that contract with CMS. Part D benefits may be offered by a stand-alone prescription drug plan sponsor, a Medicare Advantage Organization offering qualified prescription drug coverage, a Program for All-Inclusive Care for the Elderly (PACE) organization offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage (collectively referred to as a ''Part D plan sponsor''). Each Part D plan sponsor submits a bid to CMS for plan benefit packages, which results in, among other things, the offering of Part D plans with varying monthly premiums and benefits designs. Part D plan sponsors may offer a defined standard benefit, which is the type of benefit used as an example in this preamble, or an actuarially equivalent standard benefit. Part D plan sponsors may also offer alternative prescription drug coverage, which may consist of basic alternative coverage or enhanced alternative coverage. Therefore depending on the Part D plan that a beneficiary chooses, monthly premiums, coinsurances, co-pays, deductibles and benefit design may vary from plan to plan. Under the Medicare Prescription Drug, Improvement and Modernization Act (MMA), certain low-income beneficiaries may be eligible for reduced premiums and cost-sharing for their drug coverage. In some cases, beneficiaries pay no premium and nominal cost-sharing. Other beneficiaries have a reduced premium and lower cost-sharing.

The standard Medicare Part D plan benefit includes several phases of beneficiary spending, as described below.

Premiums. Statute requires a beneficiary to pay a monthly premium to participate in the plan. A beneficiary who wants to participate in a standard Medicare Part D plan is solely responsible for payment of any premium that is not otherwise subsidized under the program. Beneficiary premiums do not count toward any required beneficiary cost-sharing to reach the deductible, coverage gap, or catastrophic limit (described below).

Deductibles. Under the Medicare Part D defined standard benefit, the beneficiary is responsible for paying an out-of-pocket deductible ($275 in 2008) that adjusts annually according to the annual percentage increase in spending on covered Part D drugs. For purposes of meeting the deductible, both spending by the beneficiary and spending by TRICARE on behalf of the beneficiary (*i.e.*, the TRICARE wraparound coverage) qualify.

Cost-sharing between deductible and coverage gap. After the deductible is met, the standard Part D plan sponsors are responsible for 75 percent of the actual cost of the covered Part D drug, and the beneficiary is responsible for 25 percent of the actual cost of the covered Part D drug, until the beneficiary reaches the coverage gap. TRICARE wraparound coverage qualifies as beneficiary cost-sharing between the deductible and coverage gap.

Coverage gap. To reach the coverage gap, the beneficiary must reach a statutorily-specified amount of total drug spending. Total beneficiary spending needed to meet the coverage gap is defined as beneficiary out-of-pocket spending, or TRICARE spending on behalf of the beneficiary, and spending by the Part D plan sponsor. In 2008, a beneficiary reaches the coverage gap when he has incurred $2,510 in total drug spending and remains in the gap until he has incurred $4,050 in beneficiary out-of-pocket spending. Individuals who qualify for the low-income subsidies pay lower cost-sharing amounts before they reach the coverage gap. In the coverage gap, the beneficiary is responsible for 100 percent of the cost of the drug, although the beneficiary by law is entitled to receive the plan's negotiated price. Individuals who qualify for low-income subsidies do not have a coverage gap.

Catastrophic threshold. To reach the catastrophic threshold defined in the standard benefit, the beneficiary must have incurred total spending defined in statute as true out-of-pocket spending (TrOOP) ($4,050 in 2008). In the catastrophic phase, the beneficiary is responsible for the greater of 5 percent of the cost of the drug, or, in 2008, $2.25 for a generic/preferred multi-source drug or $5.60 for other drugs. In the catastrophic phase of the defined standard benefit, the Part D plan sponsor and Medicare are responsible for what is not paid by the beneficiary

up to the Part D plan sponsor's negotiated price.

Under 42 CFR 423.100, incurred costs means costs incurred by the Part D enrollee for covered Part D drugs: (1) That are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying annual out-of-pocket threshold amount under section 423.104(d)(5)(iii); and, (2) that are paid for by the Part D enrollee or on behalf of the enrollee by another person, and the enrollee or other person is not reimbursed through insurance or otherwise, a group health plan or other third party arrangement. Because TRICARE falls under the definition of ''or otherwise,'' which refers to ''government-funded health programs,'' wraparound payments made by TRICARE for covered Part D drugs on behalf of an enrollee eligible for both Part D and TRICARE do not count towards beneficiary incurred costs. Therefore, for purposes of reaching the catastrophic limit, only TrOOP counts as beneficiary spending. Although TRICARE supplementary coverage counts toward meeting the deductible and the initial coverage limit, it does not count toward meeting the catastrophic threshold.

Generally, a Part D plan is primary payer under 42 CFR 423.464, coordination of benefits with other providers of prescription drug coverage, which includes military coverage (including TRICARE) under chapter 55 of title 10, U.S.C. A Part D plan under section 423.464(f)(2) must exclude expenditures for covered Part D drugs made by TRICARE for purposes of determining whether a Part D enrollee has satisfied the out-of-pocket threshold, which for 2008 is $4,050.

As a result of these provisions implementing Medicare Part D, TRICARE double coverage rules must be modified. If a TRICARE-Medicare beneficiary enrolls in a Part D plan that adds prescription coverage to their Medicare plan, the Medicare Part D plan is generally primary payer and TRICARE is secondary payer. TRICARE will pay the beneficiary's out-of-pocket costs for Medicare and TRICARE covered medications, including the initial deductible and Medicare Part D cost-share. TRICARE will not pay the beneficiary's out-of-pocket cost associated with any monthly premium required to enroll in and participate in the Medicare Part D plan.

In the coverage gap, the Part D plan is generally still the primary payer. Thus, assuming the beneficiary is accessing a pharmacy under contract with his or her Part D plan, the pharmacy would bill the Part D plan, which would respond by indicating that it is responsible for $0, at which point the pharmacy would bill TRICARE. When the beneficiary becomes responsible for 100 percent of the drug costs in the coverage gap, the beneficiary may use the TRICARE pharmacy benefit as the secondary payer. TRICARE will cost share during the coverage gap to the same extent as it does under Section 199.21 for beneficiaries not enrolled in a Medicare Part D plan. The beneficiary is responsible for the applicable TRICARE pharmacy cost-sharing amounts (and deductible if using a retail non-network pharmacy). During the coverage gap, TRICARE is incurring the cost of the drugs during the Medicare Part D coverage gap and not the beneficiary. Thus none of the costs of drugs borne by TRICARE will be applied to meeting the beneficiary's annual Medicare Part D TrOOP threshold. Generally, however the beneficiary's own TRICARE pharmacy benefit cost-share will accrue to meeting his annual Medicare Part D TrOOP spending because this cost-sharing is an actual out-of-pocket expense to the beneficiary. Any actual out-of-pocket expense incurred by the beneficiary also will apply toward the TRICARE fiscal year catastrophic cap.

Similarly, if the TRICARE-Medicare dual-eligible beneficiary enrolls in a Medicare Advantage drug plan, the beneficiary has to pay the plan's monthly premiums and obtain all medical care and prescription drugs through the Medicare Advantage plan. The Medicare Advantage plan will generally be the primary payer, and TRICARE will be the secondary payer. If the Medicare Advantage plan has a Part D drug benefit, TRICARE will pay secondary described above.

II. Legislative Changes for TRICARE-Medicare Dual-Eligible Beneficiaries

Section 701 of the NDAA for FY 2000 (Pub. L. 106–65), codified at Title 10, U.S.C., Section 1074g, directs the Department to establish an effective, efficient, integrated pharmacy benefits program. The Department published the final rule on the Pharmacy Benefits Program on April 1, 2004 (69 FR 17035–17052) implementing the pharmacy benefits program, effective May 3, 2004. Congress in section 714 of the Ronald W. Reagan NDAA for FY05 has directed certain improvements to the TRICARE pharmacy benefits program.

Section 714(a) directs that for a TRICARE-Medicare dual-eligible beneficiary, the cost-sharing requirements under the pharmacy benefits program may not be greater than the cost-sharing requirements applicable to all other beneficiaries covered by 10 U.S.C. 1086, which are beneficiaries who are retirees, their authorized dependents, survivors, and certain former spouses. Under 10 U.S.C. 1074g(a)(6), the Department may establish cost-sharing requirements for the pharmacy benefits program, which may be established as a percentage or fixed dollar amount, for generic, formulary, and non-formulary pharmaceutical agents. For non-formulary agents, cost-sharing shall be consistent with common industry practice and not in excess of amounts generally comparable to 20 percent for beneficiaries who are dependents of active duty members of the uniformed services, and 25 percent for beneficiaries who are retirees, their authorized dependents, survivors, and certain former spouses.

In the TRICARE Pharmacy Benefits Program final rule, the Department published the cost share amounts for pharmaceutical agents based upon two factors: (1) The agent's status as generic, formulary, or non-formulary; and (2) the venue in which the agent was obtained, that is, military treatment facility (MTF), TRICARE Mail Order Program (TMOP), retail network pharmacy, or retail non-network pharmacy. The Department is authorized under 10 U.S.C. 1074g(a)(6) to have two non-formulary cost-shares based upon the status of the beneficiary, no more than 20 percent for active duty family members and no more than 25 percent for all others (other than active duty members who have no cost share). The Department chose to have one non-formulary cost-share equal to no more than 20 percent of the anticipated aggregated cost of non-formulary agents that is $22 for non-formulary agents obtained in the TMOP or retail network pharmacies, and $22 or 20 percent (whichever is greater) for non-formulary agents obtained in retail non-network pharmacies. *(For more information on TRICARE Pharmacy Benefit Program cost shares, see Section 199.21(i)).* Section 714(a) emphasizes that if the Department were to move to a two-tier non-formulary cost-share based upon the status of the beneficiary, the Department may not have a higher cost-share for TRICARE–Medicare dual-eligible beneficiaries than for other retirees, their authorized dependents, survivors, and certain former spouses.

This final rule adds to section 199.21 a provision incorporating into the regulation the new statutory requirement.

III. Legislative Changes To Improve the Uniform Formulary Process

Under 10 U.S.C. 1074g(a)(2)(E)(i), pharmaceutical agents included on the uniform formulary on the basis of relative clinical effectiveness and cost effectiveness are required to be available to beneficiaries through facilities of the uniformed services, consistent with the scope of health care services offered in such facilities. Section 714(b) of the Ronald Reagan NDAA for FY05 directs the Department to allow the DoD Pharmacy and Therapeutics (P&T) Committee to make additional relative clinical and cost effectiveness determinations for MTFs. This change in the law means that MTFs are not required to include on their formularies every pharmaceutical agent in a therapeutic class that is on the uniform formulary that is consistent with the scope of health care services offered in the MTF. This final rule incorporates into section 199.21 a provision reflecting the change in the statute.

IV. Transition to the Uniform Formulary

The DoD P&T Committee is required under section 199.21 to make recommendations concerning which pharmaceutical agents should be on the uniform formulary and the Basic Core Formulary (BCF), and may now make recommendations concerning which agents should be on the Extended Core Formulary (ECF). The BCF contains the minimum set of pharmaceutical agents that each MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care Manager (PCM) enrollment sites. The ECF contains the minimum set of pharmaceutical agents that each MTF pharmacy must have on it formulary to support an extended care scope of practice if the MTF P&T Committee has authorized agents in that class based upon the scope of practice at that facility.

The DoD P&T Committee will review the classes in a methodical but expeditious manner, taking into consideration circumstances that may include, but are not limited to: DoD national contracting, or DoD and the Department of Veterans Affairs (VA) national joint contracting or other agreements with pharmaceutical manufacturers; approval of a new drug by the FDA; approval of a new indication for an existing drug; changes in the clinical use of existing drugs; new information concerning the safety, effectiveness or clinical outcomes of existing drugs; price changes; shifts in market share; scheduled review of a therapeutic class; and requests from DoD P&T Committee members, MTF, or other Military Health System (MHS) officials. During the transition period from the previous methodology of formulary management involving only the MTFs and the TMOP, previous decisions by the DoD P&T Committee or committed use requirements contracts executed by DoD, or jointly by DoD and VA, shall continue in effect. This is necessary to comply with the statutory requirements of 38 U.S.C. 8111 and 10 U.S.C. 1104 relating to resource sharing between DoD and VA, and allow time to incorporate the impact of uniform formulary management into those agreements. As therapeutic classes are reviewed under the new formulary management process and pharmaceutical agents are designated for formulary or non-formulary status, this transition methodology shall apply.

The P&T Committee will meet at least quarterly to review new and existing drugs and drug classes, and recommended pharmaceutical agents for inclusion on or exclusion from the uniform formulary after evaluating their relative clinical and cost effectiveness. Pending review of a pharmaceutical agent or class, previous decisions by the predecessor to the P&T Committee regarding national contracts, agreements, formulary status, BCF status, pre-authorization requirements and quantity limits shall remain in effect. The P&T Committee will eventually evaluate all applicable drug classes at which time the transition period will be complete.

During this transition period, pharmaceutical agents in drug classes not yet evaluated by the P&T Committee will continue to be available from the TMOP and the TRICARE Retail Pharmacy (TRRx) network at either the generic or formulary (brand) cost share. MTFs may evaluate for inclusion on the MTF formulary pharmaceutical agents in drug classes that do not already have BCF status, or have not yet been evaluated by the P&T Committee. BCF listed agents must be on the formulary at all full-service MTF pharmacies at all times.

Public Comments

A proposed rule (71 FR 78110–78115) was published on December 28, 2006, and provided a 60-day comment period. Only one comment related to the rule was received and is responsed to below. Other comments unrelated to this rule were submitted by a national association representing retail drugstores. These comments were directed toward suggested overall program changes that would favor use of retail pharmacies.

Comment: Limiting Military Treatment Facility (MTF) Formularies

A pharmaceutical manufacturer commented that it understood DoD to be limiting MTF formularies to only those drugs on the basic core formulary (BCF) or the extended core formulary (ECF), and if so, this action would limit other uniform formulary items availability at MTFs, drive up government costs, and increase beneficiary costs.

Point of Clarification and Response

DoD does not intend to change the current process by which MTFs create local formularies. MTFs must carry BCF items, and may augment those items based on the scope of health care services provided at the respective MTF. Therapeutic classes reviewed by the DoD P&T Committee will contain pharmaceutical agents that carry either a BCF or ECF designation. All pharmaceutical agents in therapeutic classes that the Committee has not reviewed have the presumption of inclusion on the Uniform Formulary and are available to augment local MTF formularies. These pharmaceutical agents remain available options for MTF Commanders to add to their formularies in accordance with their local MTF P&T Committee process.

Comment: A national association representing retail drugstores offered comments unrelated to this rule regarding co-payments, recommendations for DoD to adopt electronic coordination of benefits, and stated that DoD should more diligently pursue it's authority to purchase pharmaceuticals at Federal discounts for dispensing in the retail network pharmacies.

Response: None of these comments are related to this rule. DoD's copay structure is defined in law and is not affected by this rule. DoD implemented electronic coordination of benefits in 2007 and has successfully adjudicated millions of third party claims through this process. Regarding comments toward pursuit of Federal discounts for retail prescriptions, the FY08 National Defense Authorization Act included new legislative authority for DoD to access Federal discounts for retail prescriptions. A Final Rule implementing the legislation has been issued.

V. Regulatory Procedures

Executive Order (EO) 12866 directs agencies to assess all costs and benefits available, regulatory alternatives and, when regulation is necessary, to select

regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Order classifies a rule as a significant regulatory action requiring review by the Office of Management and Budget (OMB) if it meets any one of a number of specified conditions, including: having an annual effect on the national economy of $100 million or more, creating a serious inconsistency or interfering with an action of another agency, materially altering the budgetary impact of entitlements or the rights of entitlement recipients, or raising novel legal or policy issues. DoD has examined the economic, legal, and policy implications of this final rule and has concluded that it is a significant regulatory action as it addresses novel policy issues relating to implementation of coordination of medical benefits programs for covered beneficiaries of the uniformed services under TRICARE and the Medicare Prescription Drug Benefit.

The double coverage payment procedures will implement the statutory designation of Medicare as primarily responsible for payment of prescription drug costs for TRICARE-Medicare dual-eligible beneficiaries who have prescription drug coverage under Medicare Part D during the double coverage period described in this rule. It is estimated that the cost avoidance for the DoD Medicare Eligible Retiree Health Care Fund will be approximately $1800 per beneficiary. As of January 2008, approximately 123,000 dual-eligible beneficiaries were enrolled in the Medicare Part D program, resulting in a decrease in the Medicare-Eligible Retiree Health Care (MERHC) fund liability of $22,140,000. Benefits of the final rule include implementation of the Congressional requirement for primary payment responsibility between the two programs. The rule has been determined not to be major under the Congressional Review Act.

This final rule does not contain a Federal mandate that may result in the expenditure by State, local or tribunal governments, in aggregate, or by the private sector of $100 million or more in any one year.

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 rule does not require a regulatory flexibility analysis as it would have no significant economic impact on a substantial number of small entities.

This final rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 55). In order to determine which dual-eligible beneficiaries are participating in Medicare Part D, TRICARE will rely on the Defense Eligibility Enrollment Reporting System (DEERS) to identify which beneficiaries are enrolled in Medicare Part D through existing data sharing agreements with CMS and will not need to collect additional information from them.

We have examined the impact(s) of the final rule under EO 13132 and it does not have policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, health care, health insurance, military personnel, pharmacy benefits.

■ Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—[AMENDED]

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

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

■ 2. Section 199.8 is amended by adding paragraph (d)(1)(iii)(C) and revising paragraph (d)(1)(vi) to read as follows:

§ 199.8 Double coverage.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(C) For Medicare beneficiaries who enroll in Medicare Part D, the Part D plan is primary and TRICARE is secondary payer. TRICARE will pay the beneficiary's out-of-pocket costs for Medicare and TRICARE covered medications, including the initial deductible and Medicare Part D cost-sharing amounts up to the initial coverage limit of the Medicare Part D plan. The Medicare Part D plan, although the primary plan, pays nothing during any coverage gap period. When the beneficiary becomes responsible for 100 percent of the drug costs under a Part D coverage gap period, the beneficiary may use the TRICARE pharmacy benefit as the secondary payer. TRICARE will cost share during the coverage gap to the same extent as it does under Section 199.21 for beneficiaries not enrolled in Medicare Part D plan. The beneficiary is responsible for the applicable TRICARE pharmacy cost-sharing amounts (and deductible if using a retail non-network pharmacy). Part D plan sponsors may offer a defined standard benefit, or an actuarially equivalent standard benefit. Part D plan sponsors may also offer alternative prescription drug coverage, which may consist of basic alternative coverage or enhanced alternative coverage. Therefore depending on the Part D plan that a beneficiary chooses, monthly premiums, coinsurances, co-pays, deductibles and benefit design may vary from plan to plan. TRICARE payment of the beneficiary's initial deductible, if any, along with payment of any beneficiary cost share count towards total spending on drugs, and may have the effect of moving the beneficiary more quickly through the initial phase of coverage to the coverage gap. Irrespective of the phase of the benefit in which a beneficiary may be, if a beneficiary is accessing a pharmacy under contract with his or her Part D plan, the provider will bill the Part D plan first, then TRICARE. If the beneficiary chooses to use his or her TRICARE pharmacy benefit during a coverage gap under Part D, the beneficiary may do so, but the beneficiary is responsible for the TRICARE cost-shares.

* * * * *

(vi) Effect on enrollment in Medicare Advantage Prescription Drug (MA–PD) plan. In the case of a beneficiary enrolled in a MA–PD plan who receives items or services for which payment may be made under both the MA–PD plan and CHAMPUS/TRICARE, a claim for the beneficiary's normal out-of-pocket costs under the MA–PD plan may be submitted for CHAMPUS/TRICARE payment. However, consistent with paragraph (c)(4) of this section, out-of-pocket costs do not include costs associated with unauthorized out-of-system care or care otherwise obtained under circumstances that result in a denial or limitation of coverage for care that would have been covered or fully covered had the beneficiary met applicable requirements and procedures. In such cases, the CHAMPUS/TRICARE amount payable is limited to the amount that would have been paid if the beneficiary had received care covered by the Medicare Advantage plan. If the TRICARE-Medicare beneficiary enrolls in a MA–PD drug plan, it generally will be governed by Medicare Part C, although

plans that offer a prescription drug benefit must comply with Medicare Part D rules. The beneficiary has to pay the plan's monthly premiums and obtain all medical care and prescription drugs through the Medicare Advantage plan before seeking CHAMPUS/TRICARE payment. CHAMPUS/TRICARE payment for such beneficiaries may not exceed that which would be payable for a beneficiary under paragraph (d)(1)(iii)(C) of this section.

* * * * *

■ 3. Section 199.21 is amended by adding new paragraphs (g)(4) and (i)(2)(xi), and by revising paragraphs (h)(2)(ii) and (m), to read as follows:

§ 199.21 Pharmacy benefits program.

* * * * *

(g) * * *

(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 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) * * *

(2) * * *

(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.

* * * * *

(i) * * *

(2) * * *

(xi) For a Medicare-eligible beneficiary, the cost-sharing requirements may not be in excess of the cost-sharing requirements applicable to all other beneficiaries covered by 10 U.S.C. 1086.

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(m) *Effect of other health insurance.* The double coverage rules of section 199.8 of this part are applicable to services provided under the pharmacy benefits program. For this purpose, the Medicare prescription drug benefit under Medicare Part D, prescription drug benefits provided under Medicare Part D plans are double coverage plans and such plans will be the primary payer, to the extent described in section 199.8 of this part. Beneficiaries who elect to use these pharmacy benefits shall provide DoD with other health insurance information.

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Dated: October 23, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF DEFENSE

Office of the Secretary

RIN 0720–AB28; DoD–2008–HA–0073

32 CFR Part 199

TRICARE; Hospital-Based Psychiatric Partial Hospitalization Programs

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule will provide that TRICARE approval of a hospital is sufficient for its psychiatric partial hospitalization program (PHP) to be an authorized TRICARE provider. Upon implementation of this provision, separate TRICARE certification of hospital-based psychiatric PHPs would no longer be required. This rule will establish uniform requirements for recognizing a hospital-based PHP as an authorized TRICARE provider.

DATES: *Effective Date:* This rule is effective November 30, 2009.

FOR FURTHER INFORMATION CONTACT: Ann N. Fazzini, Medical Benefits and Reimbursement Branch, TRICARE Management Activity, telephone, (303) 676–3803. Questions regarding payment of specific claims should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 30, 2008, (73 FR 79726), the Office of the Secretary of Defense published for public comment a proposed rule regarding TRICARE certification standards for psychiatric PHPs. The rule proposed that TRICARE no longer impose its unique certification standards upon hospital-based psychiatric PHPs. Rather, TRICARE approval of a hospital shall be sufficient to establish the hospital as an authorized provider of its PHP services to TRICARE beneficiaries.

II. Review of Public Comments

We received two comments on the proposed rule. One commenter applauded the agency for its decision to find that TRICARE approval of a hospital is sufficient for its psychiatric partial hospitalization program to be an authorized provider. We appreciate the comment.

A second commenter recommended that DoD eliminate TRICARE's unique requirements for hospital-based PHPs. We note that the proposed rule put forward eliminating the unique requirements for hospital based PHPs and recognizing a hospital-based PHP as