name] or other pain relievers. [Product name] may increase your risk of liver damage and stomach bleeding.''

(b) *Requirements to supplement approved application*. Holders of approved applications for OTC drug products that contain internal analgesic/antipyretic active ingredients that are subject to the requirements of paragraph (a) of this section must submit supplements under § 314.70(c) of this chapter to include the required warning in the product's labeling. Such labeling may be put into use without advance approval of FDA provided it includes at least the information included in paragraph (a) of this section.

(c) Any drug product subject to this section that is not labeled as required and that is initially introduced or initially delivered for introduction into interstate commerce after (date 6 months after
date of publication of the final rule in the **Federal Register**), is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and is subject to regulatory action.

Dated: August 20, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–30035 Filed 11–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 11

RIN 1076–AD76

Law and Order on Indian Reservations; Correction

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Correction to proposed regulations.

SUMMARY: This document contains corrections to the proposed regulations which were published Friday, July 5, 1996 (61 FR 35158) and corrections to the proposed regulations which were published Wednesday, February 26, 1997 (62 FR 8665). The proposed rule amends regulations governing Courts of Indian Offenses.

DATES: Comments must be received on or before December 15, 1997.

ADDRESSES: Comments are to be mailed to Bettie Rushing, Office of Tribal Services, Bureau of Indian Affairs, 1849 C Street, NW, MS 4641–MIB, Washington, DC 20240; or, hand delivered to Room 4641 at the same address.

FOR FURTHER INFORMATION CONTACT: Bettie Rushing, Bureau of Indian Affairs (202) 208–4400.

SUPPLEMENTARY INFORMATION:

Background

The proposed rule that is the subject of these corrections supersedes 25 CFR 11.100(a) and affects those tribes that have exercised their inherent sovereignty by removing the names of those tribes from the list of Courts of Indian Offenses.

The Assistant Secretary-Indian Affairs, or her designee, has received law and order code adopted by the Confederated Tribes of the Goshute Reservation of Nevada in accordance with their constitutions and by-laws and approved by the appropriate bureau official. The Assistant Secretary-Indian Affairs recognizes that this court was established in accordance with the tribe's constitutions and by-laws. Also, the list of Courts of Indian Offenses has been corrected to include tribes inadvertently omitted from the correction and to reflect the decision of the Court in *Fletcher* v. *United States*, No. 95–5208 (10th Cir. Dec. June 10, 1997, reh. den. Aug. 18, 1997).

Inclusion in § 11.100, *Where are Courts of Indian Offenses established?,* does not defeat the inherent sovereignty of a tribe to establish tribal courts and exercise jurisdiction under tribal law. *Tillett* v. *Lujan*, 931 F.2d 636, 640 (10th Cir. 1991) (CFR courts ''retain some characteristics of an agency of the federal government'' but they ''also function as tribal courts''); *Combrink* v. *Allen*, 20 Indian L. Rep. 6029, 6030 (Ct. Ind. App., Tonkawa, Mar. 5, 1993) (CFR court is a ''federally administered tribal court''); *Ponca Tribal Election Board* v. *Snake*, 17 Indian L. Rep. 6085, 6088 (Ct. Ind. App., Ponca, Nov. 10, 1988) (''The Courts of Indian Offenses act as tribal courts since they are exercising the sovereign authority of the tribe for which the court sits.''). Such exercise of inherent sovereignty and the establishment of tribal courts shall comply with the requirements in 25 CFR 11.100(c).

Need for Correction

As published, the proposed rule and the correction to the proposed rule contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication on July 5, 1996 (61 FR 35158), of the proposed regulations, which were the subject of FR Doc. 96–16039, and the publication of February 26, 1997 (62 FR 8664), corrections to the proposed regulations, which were the subject of FR Doc. 97–4686, are corrected as follows:

§ 11.100 [Corrected]

In the **Federal Register** published July 5, 1996 on page 35159, and corrected on February 26, 1997 on 1997 on page 8665, in § 11.100, paragraph (a) is, corrected to read as follows:

§ 11.100 Where are Courts of Indian Offenses established?

(a) Unless indicated otherwise in this part, the regulations in this part apply to the Indian country (as defined in 18 U.S.C. 1151) occupied by the tribes listed below:

(1) Red Lake Band of Chippewa Indians (Minnesota).

(2) Te-Moak Band of Western Shoshone Indians (Nevada).

(3) Yomba Shoshone Tribe (Nevada).

(4) Kootenai Tribe (Idaho).

(5) Shoalwater Bay Tribe (Washington).

(6) Eastern Band of Cherokee Indians (North Carolina).

(7) Ute Mountain Ute Tribe (Colorado).

(8) Quechan Indian Tribe (Arizona) (except resident members).

(9) Hoopa Valley Tribe, Yurok Tribe and Coast Indian Community of California (California jurisdiction limited to special fishing regulations).

(10) Louisiana Area (includes Coushatta and other tribes located in the State of Louisiana which occupy Indian country and which accept the application of this part); *Provided,* that this part shall not apply to any Louisiana tribe other than the Coushatta Tribe until notice of such application has been published in the **Federal Register**.

(11) For the following tribes located in the former Oklahoma Territory (Oklahoma):

(i) Absentee Shawnee Tribe of Indians of Oklahoma.

(ii) Apache Tribe of Oklahoma.

(iii) Caddo Tribe of Oklahoma.

(iv) Cheyenne-Arapaho Tribe of Oklahoma.

(v) Citizen Band of Potawatomi Indians of Oklahoma.

(vi) Comanche Tribe of Oklahoma (Except Comanche Children's Court).

(vii) Delaware Tribe of Western Oklahoma.

(viii) Fort Sill Apache Tribe of Oklahoma.

(ix) Iowa Tribe of Oklahoma.

(x) Kaw Tribe of Oklahoma.

(xi) Kickapoo Tribe of Oklahoma.

(xii) Kiowa Tribe of Oklahoma.

(xiii) Otoe-Missouria Tribe of Oklahoma.

(xiv) Pawnee Tribe of Oklahoma.
(xv) Ponca Tribe of Oklahoma.
(xvi) Tonkawa Tribe of Oklahoma.
(xvii) Wichita and Affiliated Tribes of Oklahoma.
(12) For the following tribes located in the former Indian Territory (Oklahoma):
(i) Chickasaw Nation.
(ii) Choctaw Nation.
(iii) Thlopthlocco Tribal Town.
(iv) Seminole Nation.
(v) Eastern Shawnee Tribe.
(vi) Miami Tribe.
(vii) Modoc Tribe.
(viii) Ottawa Tribe.
(ix) Peoria Tribe.
(x) Quapaw Tribe.
(xi) Wyandotte Tribe.
(xii) Seneca-Cayuga Tribe.
(xiii) Osage Tribe.

Dated: October 29, 1997.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 97–29938 Filed 11–13–97; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN–0720–AA37

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

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This rule proposes to revise certain requirements and procedures for reimbursement under the TRICARE program, the purpose of which is to implement a comprehensive managed health care delivery system composed of military medical treatment facilities and CHAMPUS. Issues addressed in this proposed rule include: implementation of changes made to the Medicare Prospective Payment System (PPS) upon which the CHAMPUS DRG-based payment system is modeled and required by law to follow wherever practicable, along with changes to make our DRG-based payment system operate better; extension of the balance billing limitations currently in place for individual and professional providers to non-institutional, non-professional providers; adjusting the CHAMPUS maximum allowable charge (CMAC) rate in the small number of cases where the CMAC rate is less than the Medicare rate; and implementing the government-wide debarment rule where any provider excluded or suspended form CHAMPUS shall be excluded from all other programs and activities involving Federal financial assistance, such as Medicare or Medicaid, and adding violations of our balance billing or claims filing requirements to the list of provider actions considered violations of the TRICARE/CHAMPUS program.

DATES: Comments must be received on or before January 13, 1998.

ADDRESSES: Tricare Support Office (TSO), Program Development Branch, Aurora, CO 80045–6900.

FOR FURTHER INFORMATION CONTACT: Kathleen Larkin, Office of the Assistant Secretary of Defense (Health Affairs), telephone (703) 695–3350.

Questions regarding payment of specific claims under the CHAMPUS allowable charge method should be addressed to the appropriate TRICARE/CHAMPUS contractor.

SUPPLEMENTARY INFORMATION:

I. Proposed Changes Regarding The Champus DRG-Based Payment System

The final rule published on September 1, 1987, (52 FR 32992) set forth the basic procedures used under the CHAMPUS DRG-based payment system. This was subsequently amended by final rules published on August 31, 1988 (53 FR 33461), October 21, 1988 (53 FR 41331), December 16, 1988 (53 FR 50515), May 30, 1990 (55 FR 21863), and October 22, 1990 (55 FR 42560). This rule proposes to amend 32 CFR 199 to conform to changes made to the Medicare Prospective Payment System (PPS) upon which the CHAMPUS DRG-based payment system is modeled and required by law to follow whenever practicable. In addition, the rule proposes to: eliminate the requirement for the physician attestation form and change the requirement for physician acknowledgment statements; clarify authorized payment reductions by managed care support contractors for noncompliance with required utilization review procedures and; limit the ambulatory surgery group payment rate to the amount that would be allowed if the services were provided on an inpatient basis.

A. Heart and Liver Transplants

When we first implemented the CHAMPUS DRG-based payment system in 1987, we exempted all services related to heart and liver transplantation. Although both of these types of transplants are subject to the Medicare PPS, we initially exempted them because at that time we had limited experience and claims data for them. We believed these limitations could significantly skew the relative weights we would calculate for such transplants.

Since 1987 we have continued to collect data on these services. From the beginning, heart transplants were grouped to DRG 103 and exempted. For Fiscal Year 1991 the Health Care Financing Administration (HCFA) created DRG 480 for liver transplants, but we continued to exempt them.

In our notice of updated rates and weights for Fiscal Year 1991, which was published on November 5, 1990 (55 FR 46545), we noted that we intended to consider including both heart and liver transplants in our DRG system in the future, and we invited any comments in that regard. We received none.

Since we have enough claims data to calculate accurate weights for these transplants, we are proposing to end the DRG exemption for all CHAMPUS covered solid organ transplants for which there is an assigned DRG and enough data to calculate the DRG weight. Just as Medicare does, we will continue to exempt acquisition costs for all CHAMPUS covered solid organ transplants.

B. Payment Requests for Capital and Direct Medical Education Costs

Initially we required that hospitals submit their request for payment of capital and direct medical education costs within three months of the end of the hospital's Medicare cost-reporting period. However, some hospitals encountered difficulties in meeting this deadline, because HCFA implemented changes which resulted in extensions to the filing deadline. Therefore, we often did not enforce our deadline, and as of October 1988 we eliminated the requirement entirely.

We eliminated the requirement because we believed hospitals would submit their requests at the earliest possible time anyway. Also, we believed there would be no adverse impact on TRICARE/CHAMPUS. Neither of these has proven to be correct. We continually receive these requests well after the end of the Medicare cost-reporting period—in some cases several years later. As a result, it is necessary for our contractors to retain claims data in their systems indefinitely, so that they can verify the reported amounts when the requests are submitted. This is proving to be a very burdensome and costly requirement for our contractors.

On June 27, 1995, HCFA published a final rule (60 FR 33137) extending the time frame providers have to file cost reports from no later than 3 months after the close of the period covered by the report to no later than 5 months after the close of that period. The rule also