(*Pearson* v. *Shalala*, 14 F. Supp. 2d 10 (D.D.C. 1998)); however, the U.S. Court of Appeals for the D.C. Circuit reversed the district court's decision. The court of appeals held the regulations codifying FDA's decision not to authorize the four health claims invalid and instructed FDA to reconsider the four health claims (*Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).

In the Nutrition Labeling and Education Act of 1990, Congress made health claims for dietary supplements subject to a procedure and standard to be established by FDA (see section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(5)(D)). FDA adopted the same procedure for health claims in dietary supplement labeling that Congress had prescribed for health claims in the labeling of conventional foods (see section 403(r)(3) and (r)(4) of the act). This procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling. Unless and until FDA adopts a regulation authorizing the claim, a dietary supplement bearing the claim is subject to regulatory action as a misbranded food (see section 403(r)(1)(B) of the act, a misbranded drug (see section 502(f)(1) of the act (21 U.S.C. 352(f)(1)), and as an unapproved new drug (see section 505(a) of the act (21 U.S.C. 355(a)).

Recently, the U.S. District Court for the District of Columbia denied the *Pearson* plaintiffs' motion for a preliminary injunction granting them immediate permission to make the four health claims that FDA is reconsidering. In their motion, the plaintiffs argued that because the court of appeals had invalidated the regulations codifying FDA's decision not to authorize the four claims, the claims should be permitted in dietary supplement labeling if accompanied by disclaimers suggested by the court of appeals. The district court rejected this argument. The court's decision said in part that a preliminary injunction was not in order because the plaintiffs may not bypass FDA's pre-clearance process for health claims. ''Plaintiffs' fatal assumption is that the Court of Appeals' invalidation of the regulations allows them to now make their health claims with disclaimers, without any further pre-clearance by FDA. It does not. Invalidation of the regulations merely puts plaintiffs back at square one, which means they must again go through the pre-clearance process * * *.'' (*Pearson* v. *Shalala*, No. Civ. A. 95–1865, 2000 WL 767584, at *2 (D.D.C. May 24, 2000)).

Thus, while FDA is revoking the regulations codifying its original decision not to authorize the four health claims that were challenged in *Pearson*, such claims still may not be used in labeling pending reconsideration of these claims by FDA. FDA expects to complete its reconsideration of the four claims and issue a decision on each claim by October 10, 2000.

II. Effective Date

The Administrative Procedure Act and FDA regulations provide that an agency may dispense with notice-and-comment rulemaking procedures when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(3)(B); § 10.40(e)(1) (21 CFR 10.40(e)(1))). Because this final rule is being issued in response to a court order, FDA finds that notice and comment are unnecessary. In addition, the Commissioner of Food and Drugs finds good cause under 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii) to make this final rule effective upon publication.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

§ 101.71 [Amended]

2. Section 101.71 *Health claims: claims not authorized* is amended by removing paragraphs (a), (c), and (e); and by redesignating paragraph (b) as paragraph (a), and paragraph (d) as paragraph (b).

§ 101.79 [Amended]

3. Section 101.79 *Health claims: Folate and neural tube defects* is amended by removing paragraph (c)(2)(i)(G), and by redesignating paragraph (c)(2)(i)(H) as (c)(2)(i)(G).

Dated: September 25, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–25352 Filed 10–2–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 36

Contracts Under the Indian Self-Determination Act; Removal of Regulations

AGENCY: Indian Health Service, HHS.

ACTION: Final rule.

SUMMARY: The Indian Health Service (IHS) is eliminating regulations on contracts under the Indian Self-Determination Act as mandated by Executive Order 12866 to streamline the regulatory process and enhance the planning and coordination of new and existing regulations.

EFFECTIVE DATE: October 3, 2000.

FOR FURTHER INFORMATION CONTACT: Leslie M. Morris, Director, Division of Regulatory and Legal Affairs, Indian Health Service, Suite 450, 12300 Twinbrook Parkway, Rockville, MD 20852; telephone (301) 443–1116. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On June 24, 1996, The Department of Health and Human Services (HHS) and the Department of the Interior (DOI) issued joint regulations authorized by section 107 of the Indian Self-Determination and Education Assistance Act (ISDA), Public Law 93–638, as amended, 25 U.S.C. 450k. These joint regulations, published in the **Federal Register** on June 24, 1996, and codified at 25 CFR part 900, replaced Department regulations codified at 42 CFR part 36, subpart I, ''Contracts under the ISDA''; 48 CFR section 352.280–4, ''Contracts awarded under the ISDA''; 48 CFR section 352.380–4, ''Contracts awarded under the ISDA''; and 48 CFR subpart 380.4, ''Contracts awarded under the ISDA''; because they are no longer necessary for the Administration of the IHS Program.

Section 107(b) of the ISDA provides in pertinent part that ''the secretary is authorized to repeal any regulation inconsistent with the provisions of this act.'' The HHS has proposed at 64 FR 1344 to revise 48 CFR, Chapter 3, to streamline and simplify its acquisition regulations (HHSRA) in accordance with the directions of the National Performance Review. In so doing, the sections of 48 CFR liminated by the joint rule (25 CFR part 900) issued by the HHS and the DOI would be removed. Therefore, the IHS proposed at 65 FR 4797 the elimination of only Subpart I of 42 CFR part 36. No comments were received in response to the proposed rule. The proposed rule is converted to a final rule without change.

Executive Order 12866

This rule is not a significant regulatory action under Executive Order 12866 and has not been reviewed by the Office of Management and Budget. It removes obsolete regulations.

Regulatory Flexibility Act

The HHS certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act since it only removes obsolete regulations.

Executive Order 12612

The Department has determined that this rule does not have significant Federalism effects because it pertains solely to Federal-Tribal relations and will not interfere with the roles, rights, and responsibilities of States.

Paperwork Reduction Act of 1995

This regulation contains no information collection requirement that would require notification of the Office of Management and Budget.

The authority to eliminate these regulations is 42 U.S.C. 2003 and 25 U.S.C. 13.

List of Subjects in 42 CFR Part 36

American Indians, Alaska Natives, Government health care, Indians—business and finance, property.

Dated: September 12, 2000.

Michel E. Lincoln,

Deputy Director, Indian Health Service.

Approved: September 26, 2000.

Donna E. Shalala,

Secretary of Health and Human Services.

For the reasons set out in the preamble, and under the authority of 42 U.S.C. 2003 and 25 U.S.C. 13, subpart I of 42 CFR part 36 is removed and reserved.

[FR Doc. 00–25292 Filed 10–2–00; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 413, 489, and 498

[HCFA–1005–CN4]

RIN 0938–AI56

Medicare Program; Prospective Payment System for Hospital Outpatient Services: Provider-Based Criteria; Delay of Effective Date and Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of delay of effective date and correction.

SUMMARY: In the April 7, 2000 **Federal Register** (65 FR 18434), we published a final rule with comment period entitled, ''Prospective Payment System for Hospital Outpatient Services.'' New §§ 413.24(d)(6) and 413.65 and revisions to §§ 489.24, 498.2, and 498.3 established requirements for facilities or organizations seeking provider-based status. This document delays the effective date of these provider-based regulations from October 10, 2000 to January 10, 2001, applicable for provider cost reporting periods beginning on or after January 10, 2001. In this document, we are also making a conforming change in the regulations text at § 413.65(i) concerning enforcement.

DATES: *Effective date:* The effective date of new §§ 413.24(d)(6) and 413.65 and revised §§ 489.24, 498.2, and 498.3 is delayed until January 10, 2001.

Applicability date: New §§ 413.24(d)(6) and 413.65 and revised §§ 489.24, 498.2, and 498.3 are applicable for provider cost reporting periods beginning on or after January 10, 2001.

FOR FURTHER INFORMATION CONTACT: George Morey, (410) 786–4653.

SUPPLEMENTARY INFORMATION:

I. Background

On April 7, 2000, we published in the **Federal Register** (65 FR 18434), a final rule with comment period entitled ''Prospective Payment System for Hospital Outpatient Services.'' Among the regulatory provisions included were new §§ 413.24(d)(6) and 413.65 and revisions to §§ 489.24, 498.2, and 498.3. These regulations established requirements for facilities or organizations that seek provider-based status (departments, provider-based entities, satellite facilities, and remote locations of hospitals). The effective date of the provider-based regulations, as stated in the April 2000 rule, is October 10, 2000.

New § 413.65(i) states that we will recover any overpayments resulting from inappropriate treatment of a facility or organization as provided-based. However, this provision states that no recovery will be made for any period prior to October 10, 2000, if the management of the facility or organization made a ''good faith'' effort to operate it as provided-based (as described in § 413.65(i)(3)). The reference to October 10, 2000 was included to limit the ''good faith'' exception to periods before the effective date of the new requirements.

II. Provisions of This Notice

Based on the following concerns, we have decided to delay the effective date of the provider-based portions of the April 2000 final rule until January 10, 2001, applicable for provider cost reporting periods beginning on or after January 10, 2001. For example, a provider whose cost reporting periods begins on April 1 will not be affected by these provider-based regulations until its cost reporting period beginning on April 1, 2001.

To provide for smooth implementation of the provider-based regulations, we must clarify a number of administrative, procedural, and technical issues and provide our regional offices, which are charged with responsibility for making provider-based determinations, and hospitals with further training and guidance. We have completed a variety of training and informational activities, developed responses to ''Frequently Asked Questions,'' and held numerous meetings with individual providers and provider associations in order to communicate our policies and plans for implementing the new regulations. In the course of these activities, the need for additional guidance interpreting the regulations and addressing procedural and administrative concerns has become apparent. Given the time needed to complete and disseminate this material, we have concluded that implementation of the new provider-based regulations on October 10, 2000 would be imprudent.

A delay in the effective date of the provider-based regulations will allow for dissemination of the additional material described above, and will give hospitals and other providers additional time to fully assess the potential impact of both the new hospital outpatient prospective payment system and the new provider-based regulations on their facilities and organizations. A delay in