and, therefore, will be exempt from premarket notification under section 510(l) of the act.

FDA, however, disagrees that the lice detector kit and infusion stand should be exempt from the CGMP requirements (section 520(f) of the act). FDA's believes that the CGMP requirements are necessary to ensure product quality. FDA believes, however, that the Apgar timer is a very simple device that may be exempted from the CGMP regulations

Consistent with the purpose of the act, class I (general controls), as defined by section 513(a)(1) of the act, would provide the least amount of regulation necessary to reasonably ensure that current and future Apgar timers, lice removal kits, and infusion stands are safe and effective.

The agency, therefore, proposes to classify the Apgar timer, lice removal kit, and infusion stand into class I in 21 CFR part 880 (general hospital and personal use devices).

VIII. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. General Hospital and Personal Use Devices Panel, 30th meeting, meeting and transcript minutes, July 18, 1995.

IX. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of 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 agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. For these three devices, FDA is proposing that they be classified into class I, the lowest level of control allowed. Therefore, the agency certifies that the proposed rule will not have a significant economic impact on a substantial economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

XI. Comments

Interested persons may, on or before June 8, 1998 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 880 be amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 880.2930 is added to subpart C to read as follows:

§ 880.2930 Apgar timer.

(a) *Identification*. The Apgar timer is a device intended to alert a health care provider that the Apgar score of an new born infant should be taken.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

3. Section 880.5960 is added to subpart F to read as follows:

§ 880.5960 Lice removal kit.

(a) *Identification*. The lice removal kit is a comb or comb-like device intended to kill and/or remove lice and nits from head and body hair. It may or may not be battery operated.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

4. Section 880.6990 is added to subpart G to read as follows:

§ 880.6990 Infusion stand.

(a) *Identification*. The infusion stand is a stationary or movable stand designed to hold infusion fluids, infusion accessories, and related devices. The infusion stand may be used to hold other medical devices.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: February 27, 1998.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–6150 Filed 3–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 243, 250, and 290, and 43 CFR Part 4

RIN 1010–AC21 and AC08

Administrative Appeals Process and Policy for Release of Third-Party Proprietary Information

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of a public workshop.

SUMMARY: The Minerals Management Service (MMS) is announcing a second public workshop to discuss plans to revise its regulations governing MMS's administrative appeals and alternative dispute resolution processes, including authority for disclosure of third-party proprietary information. The revisions are based in large part on a report and recommendations from the Royalty Policy Committee, which provides advice to the Secretary of the Interior under the authority of the Federal Advisory Committee Act. Interested

parties are invited to attend and participate in the workshop and are requested to register in advance.

DATES: The public workshop will be held on Monday, March 30, 1998, 10:30 a.m.–5:00 p.m., Mountain Standard Time.

ADDRESSES: The workshop will be held in the Building 85 Auditorium at the Denver Federal Center, Denver, Colorado. You also may mail comments to Hugh Hilliard, as listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT: Mr. Hugh Hilliard, Chief, Appeals Division (MS 4230), or Ms. Charlotte Bennett, Appeals Division, (MS 4230), Minerals Management Service, 1849 C Street, NW, Washington, D.C., 20240, telephone number (202) 208–2622, fax number (202) 219–5565, e:mail: Hugh.Hilliard@mms.gov or Charlotte.Bennett@mms.gov.

SUPPLEMENTARY INFORMATION: In response to the notice of proposed rule to amend regulations governing the administrative appeals process, published in the **Federal Register** on October 28, 1996 (61 FR 55607), MMS received as a comment a comprehensive report from the Royalty Policy Committee (RPC), which adopted a recommendation from its Appeals and Alternative Dispute Resolution Subcommittee. The RPC, which is composed of representatives from states, Indian tribes and allottees, the mineral industries, other Federal agencies, and the public, advises the Secretary of the Interior under a charter authorized by the Federal Advisory Committee Act. On March 27, 1997, the RPC sent its report to the Secretary and requested adoption of its proposal in lieu of the October 28, 1996, proposed rule.

The Secretary sent a response to the RPC on September 22, 1997, stating that the Department planned to prepare revised proposed regulations to implement the RPC proposal, with several changes. The Secretary also stated that the public would have the opportunity to comment on these proposed regulations, which could change before they become final. MMS held its first public workshop on this matter on January 27, 1998 (see **Federal Register** notice at 62 FR 68244, December 31, 1997, for additional background provided before the first meeting).

The revised notice of proposed rule will affect not only appeals involving actions taken by officials of the MMS's Royalty Management Program, but also will affect appeals involving actions taken by the Offshore Minerals Management Program of MMS under the regulations at 30 CFR Part 250. In addition, the rule will affect activities of the Office of Hearings and Appeals, Interior Board of Land Appeals, as set out at 43 CFR Part 4 (though these effects are expected to be limited to appeals generated by actions of the Minerals Management Service).

We invite participation at the workshop by representatives of states, Indian tribes and allottees, the minerals industries, and the general public. We plan to present our initial views as to what will be in the revised proposed rule and to engage in open discussion with participants about any suggestions for improvement.

In order to help us plan for a successful workshop, we would appreciate your pre-registration by March 16. If you plan to attend, please contact Ms. Charlotte Bennett, using the methods provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice, and provide your name, address, and telephone and fax numbers. This will help us to ensure sufficient space for all and to provide you with any relevant information available in advance of the meeting. In particular, we intend to distribute in advance a draft version of the revised notice of proposed rule.

Dated: March 3, 1998.

Walter D. Cruickshank,

Associate Director for Policy and Management Improvement.

[FR Doc. 98–6062 Filed 3–9–98; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 220

[RIN 0790–AG51]

Collection From Third Party Payers of Reasonable Costs of Healthcare Services

AGENCY: Office of the Assistant Secretary of Defense (Health Affairs), DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule implements several recent statutory changes and makes other revisions to the Third Party Collection Program. The primary matter include implementation of new statutory authority to include workers' compensation programs under the Third Party Collection Program; the addition of special rules for collections from preferred provider organizations; and other program revisions.

DATES: Comments are requested by May 11, 1998.

ADDRESSES: Forward comments to: Third Party Collection Program, Office of the Assistant Secretary of Defense (Health Affairs), Health Services Operations and Readiness, 1200 Defense Pentagon, Washington, DC 20301–1200.

FOR FURTHER INFORMATION CONTACT: LTC Michael Montgomery, 703–681–8910.

SUPPLEMENTARY INFORMATION: This proposes rule implements several recent statutory changes and makes other revisions to the Third Party Collection Program under 10 U.S.C. 1095, as discussed below.

1. Preferred Provider Organizations

Section 713(b)(1) of the National Defense Authorization Act for Fiscal Year 1994, Pub. L. 103–160, amended the Third Party Collection Program's definition of ''insurance, medical service, or health plan'' to clarify that any ''preferred provider organization'' (PPO) is included in the definition. This amendment codified DoD's previous interpretation. Experience in applying the statutory authority to the context of preferred provider organizations has indicated a need to establish some special rules for plans with PPO provisions or options so that all parties will have a clear understanding of their obligations and rights under the statute. We propose to do this by amending § 220.12.

It is our interpretation of 10 U.S.C. 1095 that a plan with a PPO provision or option generally has an obligation to pay the United States the reasonable costs of health care services provided through any facility of the Uniformed Services to a Uniformed Services beneficiary who is also a beneficiary under the plan. No provision of any PPO plan having the effect of excluding from coverage or limiting payment for certain care if that care is provided through a facility of the Uniformed Services shall operate to prevent collection under this part.

10 U.S.C. 1095 strikes a careful balance. On the one hand, it disallows third party payer rules that would have the effect of excluding from coverage or limiting payment because the care was provided in a DoD facility. The law renders inoperative numerous administrative procedures and payments rules of third party payers that would defeat the purpose of 10 U.S.C. 1095 or result in a windfall for a third party payer who has collected premiums but then avoided payments. On the other hand, the statute does not require third party payers to maker