

and departments to conduct a comprehensive review of the regulations they administer and, by June 1, 1995, to identify those rules that are obsolete or unduly burdensome. EPA has conducted a review of its rules, including rules issued under the Resource Conservation and Recovery Act (RCRA). Based on the review, EPA is today proposing to remove from the Code of Federal Regulations (CFR) two guidelines pertaining to solid waste management which are obsolete. The activities addressed in these 1976 guidelines have been included in numerous state and local statutes and regulations and other Federal rules, or have been superseded by such Presidential actions as Executive Order 12873, "Federal Acquisition, Recycling, and Waste Prevention." These guidelines are now obsolete because: the need for Part 244 guidelines for Federal facilities on beverage containers has passed with the implementation of state and local recycling mandates and requirements, RCRA Section 6001 requirements, and Executive Order 12873, and Part 245 requirements are incorporated into state and local laws and Part 256, which addresses the requirements for facility planning and implementation of resource recovery programs.

Therefore, deleting these guidelines from the CFR will have no measurable impact on solid waste management.

In the rules and regulations section of today's Federal Register, EPA is also promulgating a direct final rule to withdraw Parts 244 and 245 from Title 40 of the Code of Federal Regulations (CFR). A detailed rationale for the removal of these guidelines is set forth in the direct final rule and is incorporated herein. Potential commenters should consult that notice. If no adverse comments are received in response to this notice, no further activity is contemplated in relation to this proposed rule and Parts 244 and 245 will be withdrawn. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

**DATES:** Written comments on this proposed rule must be received by January 30, 1997.

**ADDRESSES:** Written comments (one original and two copies) should reference docket number F-96-MRBP-FFFFF and be addressed to: RCRA Docket and Information Center (RIC),

Office of Solid Waste (5305W), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. Supporting docket materials can be viewed at and hand deliveries of comments can be made to the following address: Crystal Gateway I, first floor, 1235 Jefferson Davis Highway, Arlington, VA. The RIC is open from 9 a.m. to 4 p.m. Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling 703 603-9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost \$0.15/page.

**FOR FURTHER INFORMATION CONTACT:** Deborah Gallman (703) 308-7276, U.S. EPA, Office of Solid Waste and Emergency Response, 401 M Street, S.W., (5306W), Washington, D.C. 20460, or the RCRA Hotline, phone (800) 424-9346 or TDD (800) 553-7672 hearing impaired or (703) 412-9810 or TDD (703) 412-3323 in the Washington, D.C., metropolitan area.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Authority**

This rule is being proposed under the authority of sections 1008, 2002, 6001, and 6004 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 and the Hazardous and Solid Waste Amendments of 1984; 42 U.S.C. 6961.

##### **II. Additional Information**

For additional information, see the corresponding direct final rule published in the rules and regulations section of this Federal Register.

##### **III. Analysis under Executive Order (E.O.) 12866, the Unfunded Mandates Reform Act of 1995, and the Paperwork Reduction Act**

Because the withdrawal of these guidelines from the CFR reflects their current obsolescence and has no regulatory impact, this action is not a "significant" regulatory action within the meaning of E.O. 12866, and does not impose any Federal mandate on state, local, or tribal governments or the private sector within the meaning of the Unfunded Mandates Reform Act of 1995. For the same reasons, their deletion from the CFR does not affect requirements under the Paperwork Reduction Act.

##### **IV. Regulatory Flexibility Act**

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally requires

an agency to prepare, and make available for public comment, a regulatory flexibility analysis that describes the impact of a proposed or final rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant adverse economic impact on a substantial number of small entities. This proposed rule is deregulatory in nature. The effect of the proposed rule is to remove obsolete guidelines which are mandatory only for Federal facilities. Therefore, I certify that this proposed rule will not have a significant economic impact on a substantial number of small entities. As a result, no Regulatory Flexibility Analysis is needed.

#### **List of Subjects**

##### **40 CFR Part 244**

Environmental protection, Beverages, Government property, Recycling.

##### **40 CFR Part 245**

Government property, Recycling.

Dated: December 20, 1996.

Carol M. Browner,  
Administrator.

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Office of Inspector General**

#### **42 CFR Part 1001**

#### **Solicitation of New Safe Harbors and Modifications to Existing Safe Harbors**

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice of intent to develop regulations.

**SUMMARY:** In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996, this notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Medicare and State health care programs' anti-kickback statute, as well as developing new OIG Special Fraud Alerts.

**DATES:** To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on March 3, 1997.

**ADDRESSES:** Please mail or deliver your written comments to the following

address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-11-N, Room 5246, Cohen Building, 330 Independence Avenue, S.W., Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commencing, please refer to file code OIG-11-N. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C., on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m.

**FOR FURTHER INFORMATION CONTACT:** Joel Schaer, (202) 619-0089, OIG Regulations Officer.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

###### **A. The OIG Safe Harbor Provisions**

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or relieve remuneration in order to induce business reimbursed under the Medicare or State health care programs. The offense is classified as a felony, and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years.

The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, or in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State health care programs.

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution. As a response to the above concern, the Medicare and Medicaid Patient and Program Protection Act of 1987, section 14 of Public Law 100-93, specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, designed to specify various payment and business practices which, although potentially capable of inducing referrals of business under the Medicare and State health care programs, would not

be treated as criminal offenses under the anti-kickback statute (section 1128B(b) of the Social Security Act; 42 U.S.C. 1320a-7b(b)) and would not serve as a basis for a program exclusion under section 1128(b)(7) of the Social Security Act; 42 U.S.C. 1320a-7(b)(7). The OIG safe harbor provisions have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements" (56 FR 35952, July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the anti-kickback statute or program exclusion authority.

To date, the OIG has developed and codified in 42 CFR 1001.952 a total of 13 final safe harbors that describe practices that are sheltered from liability, and is continuing to finalize 8 additional safe harbor provisions (see the OIG notice of proposed rulemaking at 58 FR 49008, September 21, 1993).

###### **B. OIG Special Fraud Alerts**

In addition, the OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices the OIG regards as unlawful. These Special Fraud Alerts provide the OIG with a means of notifying the health care industry that we have become aware of certain abusive practices which we plan to pursue and prosecute, or bring civil and administrative action, as appropriate. The Special Fraud Alerts also serve as a tool to encourage industry compliance by giving providers an opportunity to examine their own practices. The OIG Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Medicare and Medicaid programs.

In developing these Special Fraud Alerts, the OIG has relied on a number of sources and has consulted directly with experts in the subject field, including those within the OIG, other agencies of the Department, other Federal and State agencies, and from those in the health care industry. To date, eight individual Special Fraud Alerts have been issued by the OIG and subsequently reprinted in the Federal Register on December 19, 1994 (59 FR 65372), August 10, 1995 (60 FR 40847) and June 17, 1996 (61 FR 30623).

##### **II. Section 205 of Public Law 104-191**

The Health Insurance Portability and Accountability Act of 1996, Public Law

104-191, effective August 21, 1996, now requires the Department to provide additional formal guidance regarding the application of the anti-kickback statute and the safe harbor provisions, as well as other OIG health care fraud and abuse sanctions. Among the provisions set forth in section 205 of Public Law 104-191 is the requirement that the Department develop and publish an annual notice in the Federal Register formally soliciting proposals for (1) modifying existing safe harbors, (2) developing new safe harbors and OIG Special Fraud Alerts, and (3) issuing requests for advisory opinions. After considering such proposals and recommendations, the Department, in consultation with the Department of Justice, will consider the issuance of new and modified safe harbor regulations, as appropriate. In addition, the OIG will consider the issuance of additional Special Fraud Alerts. Finally, in accordance with the statute, the OIG will formally begin accepting requests for advisory opinions on February 21, 1997. Regulations establishing the procedures and a process for accepting and issuing advisory opinions are being prepared for separate publication in the Federal Register and will be issued in the near future.

###### **Criteria for Modifying and Establishing Safe Harbor Provisions**

In accordance with the statute, we will consider a number of factors in considering proposals for new or modified safe harbor provisions, such as the extent to which the proposals would affect an increase or decrease in—

- Access to health care services;
- The quality of health care services;
- Patient freedom of choice among health care providers;
- Competition among health care providers;
- The cost to Federal health care programs;
- The potential overutilization of the health care services; and
- The ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

In addition, we will also take into consideration the existence (or nonexistence) of any potential financial benefit to a health care professional or provider that may vary based on their decisions of whether to (1) order a health care item or service, or (2) arrange for a referral of health care items or services to a particular practitioner or provider.

### *Criteria for Developing Special Fraud Alerts*

In determining whether to issue additional Special Fraud Alerts, we will also consider whether, and to what extent, those practices that would be identified in new Fraud Alerts may result in any of the consequences set forth above, and the volume and frequency of the conduct that would be identified in these Special Fraud Alerts.

### III. Solicitation of Public Comments

In order to address the requirements of section 205 of Public Law 104-191, we are requesting public comments from affected provider, practitioner, supplier and beneficiary representatives regarding the development of proposed or modified safe harbor regulations and new Special Fraud Alerts. A detailed explanation of justification or empirical data supporting the suggestion would prove helpful in our considering and drafting new or modified safe harbor regulations and Special Fraud Alerts.

Dated: December 20, 1996.

June Gibbs Brown,

*Inspector General, Department of Health and Human Services.*

Approved: December 20, 1996.

Donna E. Shalala,

*Secretary.*

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 25

[IB Docket No. 96-220; FCC 96-426]

### Non-Voice Non-Geostationary Mobile Satellite Service

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission has proposed rules and policies to govern the second processing round for the non-voice, non-geostationary mobile satellite service ("NVNG MSS") also referred to as the "Little LEO" service. The Commission's proposals include limiting the licensees in the second processing round to "new entrants;" adopting strict financial rules; adopting rules requiring licensees to time-share spectrum with existing commercial and government licensees; and seeking comment on conducting auctions if mutual exclusivity arises.

**DATES:** Comments must be submitted on or before January 6, 1997; reply

comments must be submitted on or before January 13, 1997.

**ADDRESSES:** Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554.

#### **FOR FURTHER INFORMATION CONTACT:**

Paula Ford, International Bureau, Satellite Policy Branch, (202) 418-0760; Brian Carter, International Bureau, Satellite Policy Branch, (202) 418-2119; Kathleen Campbell, International Bureau, Satellite Policy Branch (202) 418-0753.

#### Summary of Notice of Proposed Rulemaking

1. This Notice of Proposed Rulemaking ("NPRM") reflects the Commission's commitment to licensing applicants in the second processing round to provide Little LEO service and the Commission's continued efforts to promote competition in the U.S. satellite services market. With this NPRM, we propose service rules and policies for the licensing of three applicants in the second processing round.

2. In order to promote multiple entry and competition, the Commission proposes to limit the participation in the second processing round to pending applicants who are not Little LEO licensees or affiliated with a Little LEO licensee. We propose to identify an applicant as an affiliate if the applicant: (1) Directly or indirectly controls or influences a licensee; (2) is directly or indirectly controlled or influenced by a licensee; or (3) is directly or indirectly controlled or influenced by a third party or parties that also have the power to control or influence a licensee.

3. Given that future entry may not be possible in the Little LEO service and grant to an under-financed applicant will likely prevent a capitalized applicant from going forward, we propose to amend the current financial standard to require that each applicant demonstrate that it has finances necessary to construct, launch, and operate the entire system for a year. In cases where there are more applicants than the spectrum can accommodate, a grant to an under-financed space station applicant may preclude a capitalized applicant from implementing its system, and delay service to the public. In the past we have required a stringent financial showing in such cases.

4. We propose to license three Little LEO systems to operate in particular spectrum blocks: the first system in the 149.81 MHz/400.5050-400.5517 MHz bands; the second in the 148.905-149.81 MHz/137-138 MHz bands; the third system in the 149.95-150.05 MHz/

400.150-400.5050 MHz/400.645-401.0 MHz bands. The proposal requires all systems to time-share the spectrum and coordinate use of the spectrum with users of the bands. In the 137-138 MHz band, the Little LEO licensee would have to time-share spectrum with meteorological satellites of the National Oceanic and Atmospheric Administration. The Little LEO system operating in the 400.150-400.5050 MHz and 400.645-401 MHz bands would have to time-share the spectrum with meteorological satellites of the Department of Defense.

5. We also request comments on a number of other issues. If we have more qualified applicants than available spectrum in which they can operate, we asked for comment on how to resolve mutually exclusive applications and whether we should conduct an auction. We also ask for comment on effective methods of preventing transmissions into countries which have not authorized Little LEO service. Little LEO earth terminals have the physical capability to roam from one region or country to the next. Because of their inherent mobility, users may attempt to operate their earth terminals in a country in which the Little LEO licensee is not authorized to operate. In order to protect against this, we seek comment on methods to address this such as requiring each Little LEO user terminal to be equipped with position determination capabilities. In addition, we seek comment on whether we should adopt limitations on licensee's ability to enter into exclusive arrangements with other countries concerning communications to and from the United States. An exclusive arrangement may foreclose other Little LEO licensees from serving a foreign market and preventing that licensee from providing global service.

6. Finally, we also ask parties to submit amended applications on or before January 27, 1997 to operate in the spectrum blocks outlined in the NPRM. Amended applications must comply with the proposed rules. However, applicants are required to demonstrate finances sufficient to construct and operate only two satellites in their system for a year. Applicants will be allowed to further amend their applications once the Report and Order has been released only to the extent necessary because of the new obligations we have proposed that are different from the proposals in the Notice. If we adopt a strict financial standard we will allow applicants to amend their applications.