one-half the maximum contaminant level (MCL) as established under the Safe Drinking Water Act;

• The Army must upgrade the treatment system or pay any incremental costs caused by contamination from Schofield Barracks at wells that already have a treatment system in place;

• Conduct five year reviews with the State of Hawaii and EPA.

The following actions were taken to implement the remedy decision for OU2:

• The Army installed air-stripper treatment units on their four contaminated municipal water supply wells at Schofield and will continue to operate the treatment system as long as contaminants in the influent water are above maximum contaminant levels (MCLs) specified in the Safe Drinking Water Act.

• The Army has sampled drinking water wells, agricultural wells and monitoring wells semi-annually throughout the central plateau area of Oahu since 1993 and will continue to do so until such time as the Army, EPA and HDOH agree that contaminant levels throughout the plume are below action levels.

• The groundwater contaminant plume appears to be confined by a system of dike impoundments and natural attenuation. The EPA, HDOH and the Army believe that it will not impact any additional down-gradient wells. Therefore, the contingency remedy for additional wellhead treatment is not expected to be needed.

• Institutional controls have been implemented that will restrict the placement of new drinking water wells into the contaminant plume. The Honolulu Board of Water Supply controls the installation of drinking water wells via a permit process. They will require the installation of wellhead treatment, paid for by the Army, on any wells that are drilled into the plume area.

OU4

The ROD for OU4, the landfill, was signed by EPA on September 26, 1996. The selected remedy included the following actions:

• Access restrictions and site security to limit human exposure to the landfill contents, prevent trespassing, and protect the integrity of the cap;

• Semi-annual ground water monitoring to monitor the effectiveness of the landfill site cap and determine groundwater flow directions in the vicinity of the landfill;

• Regrade the existing landfill cover;

• Remove Guinea grass from the existing cover and revegetate to improve future cap maintenance;

• Perform long-term maintenance of the landfill cover;

• Maintain existing passive landfill gas venting; and

• Install additional gas monitoring points at the perimeter of the landfill.

The following actions were taken to implement the remedy decision for OU4:

• The Army installed chain-link fence around the perimeter of the accessible portions of the landfill as an access restriction and has installed signs warning of potential health risks. The Former Landfill is part of a military installation that has a guard stationed at the entrances to monitor access to the installation 24 hours per day.

• The Army completed regrading the cover, installing nine new multi-level gas probes, stabilizing the sideslopes, and replacing and improving the vegetative cover in June 1998.

• The Army has conducted semi-annual groundwater monitoring and quarterly gas probe monitoring since the completion of the remedial action in June 1998. The groundwater monitoring is conducted as part of the OU2 work and it shows that the groundwater plume around the landfill is stable and at low levels of TCE concentration. The gas probe monitoring typically detects methane in four out of the 27 gas probe sampling points. The highest detection during the February 2000 monitoring event was 0.2 percent, which is well below the acceptable limit of 5 percent.

On July 21, 1998, the Army, EPA and HDOH, conducted a final inspection and determined that the remedial action had been successfully executed for all OUs. EPA reclassified Schofield Barracks to construction complete status in September 1998.

Operation and Maintenance

The Army is responsible for conducting long-term maintenance and upkeep of the landfill cover and for monitoring landfill gas, groundwater, and drinking water wells, in accordance with the approved Long-Term Operation, Maintenance and Monitoring Plans for OUs 2 and 4.

Five Year Reviews

CERCLA requires a five-year review of all sites with hazardous substances remaining above the health-based levels for unrestricted use of the site. Since the cleanup of the site utilized containment of hazardous materials within the landfill and wellhead treatment for drinking water, the five-year review process will be used to ensure that human health and the environment remain protected in the future. The first five-year review is scheduled for the year 2002.

Community Involvement

The Army published its final Community Relations Plan on January 31, 1997, after interviews with local residents and officials. An information repository was established at the Wahiawa Public Library and all reports and fact sheets were sent to the repository as they were completed.

The Army conducted public meetings prior to completing each of the four Records of Decision, and the public had no negative comments about any of the actions at Schofield.

Applicable Deletion Criteria and State Concurrence

EPA has determined that all appropriate responses under CERCLA at Schofield Army Barracks have been completed, and that no further CERCLA response is appropriate to protect human health and the environment. The Hawaii Department of Health concurred with the proposed deletion of the site from the NPL in a letter dated March 13, 2000. Therefore, EPA proposes to delete the site from the NPL. Documents supporting this action are available from the docket at the Region 9 office and in the Army's docket on Oahu.

Dated: April 25, 2000.

Felicia Marcus,

Regional Administrator, Region IX.

[FR Doc. 00–12520 Filed 5–19–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991–AB05

Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Restocking Safe Harbor Under the Anti-Kickback Statute

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

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would set forth a new safe harbor, as authorized under section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, to protect certain arrangements involving hospitals that replenish drugs and medical supplies used by ambulance providers when

transporting emergency patients to the hospitals.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on July 21, 2000.

ADDRESSES: Please mail or deliver your written comments to the following address: Department of Health and Human Services, Office of Inspector General, 330 Independence Avenue, SW, Room 5246, Attention: OIG–62–P, Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file OIG–62–P.

FOR FURTHER INFORMATION CONTACT: Vicki L. Robinson, Senior Counsel, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce the referral of business reimbursable under the Federal 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 five years. Violations of the anti-kickback statute may also result in the imposition of a civil money penalty (CMP) under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)) or program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)).

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

Establishing the Original Safe Harbors

Since the statute on its face is so broad, concern had been expressed that some relatively innocuous commercial arrangements were technically covered by the statute and therefore were subject to criminal prosecution. As a response to the above concern, section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, 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 Federal and State health care programs, would not be treated as criminal offenses under the anti-kickback statute. Beginning in July 29, 1991, we have published in the **Federal Register** a series of final regulations establishing ''safe harbors'' in various areas.[1] These 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.

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, the CMP provision for anti-kickback violations or program exclusion authority related to kickbacks. In giving the Department the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be evolving rules that would be updated periodically to reflect changing business practices and technologies in the health care industry.

OIG Advisory Opinions on Restocking Ambulance Supplies

The OIG has issued four advisory opinions regarding arrangements between hospitals and other facilities providing emergency medical supplies, *i.e.,* ''receiving facilities'' and ambulance companies, under which the receiving facilities replenish ambulances with drugs and medical supplies used during the transport of *emergency* patients to the receiving facilities. In many of these arrangements, the drugs and supplies are replenished without charge to the ambulance company.

In OIG Advisory Opinion 97–6 (October 8, 1997), we responded to a request for an advisory opinion involving an ambulance replenishing arrangement that presented a specific set of facts clearly implicating the anti-kickback statute. The arrangement, as presented in the facts certified by the requesting party, contained no appropriate safeguards against fraud and abuse of the Federal health care programs and their beneficiaries. Accordingly, we concluded that the arrangement potentially violated the anti-kickback statute.

Subsequently, in 1998, we received several additional advisory opinion requests that involved ambulance replenishing arrangements, and issued three additional advisory opinions *approving* ambulance replenishing arrangements.[2] The facts of those three arrangements differed significantly from the facts that led to OIG Advisory Opinion 97–6. Specifically, the latter three opinions involved ambulance replenishing programs conducted in accordance with comprehensive, coordinated emergency medical delivery systems involving all of an area's ambulance providers and hospitals (as well as other components of the emergency medical system, such as physicians and local government officials). The OIG approved the three arrangements (with the limited exception of a portion of one of the three programs), persuaded that the arrangements posed little risk of Federal health care program fraud or abuse and that the arrangements promoted comprehensive and coordinated efforts to improve emergency medical care.

Since the release of OIG Advisory Opinion 98–14 in October 1998, the OIG has received no further advisory opinion requests on the topic of ambulance replenishing and few informal follow-up inquiries regarding these arrangements.

II. Provisions of the Proposed Rule

The OIG believes that, in general, the ambulance and hospital industries understand the distinction between the first unfavorable advisory opinion and the subsequent three favorable opinions and are generally able to assess and structure arrangements accordingly. However, the OIG is aware of anecdotal reports that some receiving facilities are curbing or eliminating ambulance replenishing programs in order to cut emergency room costs, while other receiving facilities feel pressured to participate in ambulance replenishment arrangements. Some receiving facilities would like to implement or continue operating replenishing programs, but are concerned about possible liability under the anti-kickback statute.

We continue to believe that properly structured replenishing arrangements serve a significant public interest by providing a means of ensuring that ambulances are fully stocked with current medications, sanitary linens and

[1] 56 FR 35952 (July 29, 1991); 61 FR 2122 (January 25, 1996); 64 FR 63518 (November 19, 1999); and 64 FR 63504 (November 19, 1999).

[2] OIG Advisory opinion 98–7 (June 11, 1998); OIG Advisory Opinion 98–13 (September 30, 1998); and OIG Advisory Opinion 98–14 (October 28, 1998).

appropriate supplies, and that those supplies are compatible with equipment used in local emergency rooms so as to expedite the transfer of critically ill or injured patients to emergency room systems. Such replenishing arrangements are consistent with Federal policy established over the past 25 years.[3]

In an effort to further assure those providers engaged in innocuous and beneficial replenishing arrangements, we are proposing a new safe harbor under § 1001.952 of our regulations to protect certain arrangements between receiving facilities (including hospitals) and ambulance companies under which the receiving facilities replenish ambulances with drugs and medical supplies used during the transport of *emergency* patients to the receiving facilities. Under this proposed rule, we would provide safe harbor protection for ambulance replenishing arrangements that satisfy all of the conditions in one of two categories established by the safe harbor. Both categories pertain only to *emergency* ambulance services; the safe harbor would not protect replenishing of ambulance supplies, linens or medications following routine ambulance transports.

Replenishing Arrangements Where Ambulance Provider Pays Receiving Facility Fair Market Value

The first new proposed safe harbor would protect replenishing arrangements where an ambulance provider pays the receiving facility fair market value, based on an arms-length transaction, for replenished drugs or supplies (including linens) used in connection with the transport of an emergency patient. Payment would not need to be made at the time of the replenishing, provided commercially reasonable and appropriate payment arrangements have been made in advance. For linens, an exchange of a comparable quantity of laundered linens for soiled linens would be considered fair market value, notwithstanding any economic value attributable to the laundering of linens by receiving facilities, which often have specialized laundering equipment needed for compliance with sanitation requirements. A non-profit receiving facility would be protected under this safe harbor if it sells replenished drugs or medical supplies to a non-profit ambulance provider at cost in order to comply with the Non-Profit Institutions Act.[4]

Remuneration in the Form of Contemporaneous Replenishing of Drugs or Medical Supplies

The second proposed safe harbor would protect remuneration in the form of contemporaneous replenishing of drugs or medical supplies (including linens) used during an emergency transport of a patient to the receiving facility, even if the replenishing is for free or at reduced prices. We are proposing that the following seven conditions be met in order to qualify for protection under this safe harbor:

(1) Receiving facilities must provide replenishing on an equal basis for all ambulance providers who bring emergency patients to the receiving facility. This condition is intended to prevent receiving facilities from inappropriately using replenishing to attract or reward high referring ambulance providers.

(2) The replenishing arrangement must be part of a comprehensive and coordinated effort to improve the EMS delivery system in the relevant service area and must be open to all emergency ambulance providers and receiving facilities operating in the service area. It must be implemented with the participation of, and monitored by, a regional EMS Council or functionally similar entity, organization or association (the Oversight Entity). The Oversight Entity must be a non-profit entity composed of representatives of a broad array of participants in a service area's emergency medical system, such as hospitals, ambulance providers, emergency room physicians and nurses, public safety organizations, paramedics, local educational institutions and community residents. The involvement of a wide range of representatives of the local EMS community provides substantial assurance that the replenishment arrangement is intended to benefit the local community, rather than a single provider or group of providers. Participation in the Oversight Entity should be open to all interested parties in the service area on equal terms and conditions, *i.e.*, the Oversight Entity cannot be composed solely of representatives of a single health system. Typically, Oversight Entities will engage in the following types of activities:

—Standardization of EMS practices and equipment;
—Education and training for pre-hospital care providers;
—Ongoing evaluation and improvement of EMS capabilities in the service area;
—Public information campaigns; and
—Other activities designed to promote EMS care for the service area.

We recognize that the size, composition, structure and scope of activities of Oversight Entities may necessarily vary depending on the size and resources of the particular service area. We would expect, for example, an Oversight Entity in a small rural area with one hospital, a few physicians and one ambulance provider to look and operate differently than one in a densely populated urban area with several hospitals, a number of transport providers and diverse physicians, teaching facilities, Government agencies and the like. Oversight Entities should be part of a comprehensive and coordinated regional EMS system appropriate to the size and resources of the service area. We are not specifying any particular structure or legal form for the Oversight Entity; it must simply be functionally similar to a regional EMS Counsel. The participants in the Oversight Entity should be representative of the service area's EMS system. We are specifically soliciting comments on our proposal that safe harbored replenishing arrangements must be a part of a comprehensive and consolidated regional EMS system.

(3) The replenishing arrangement must be memorialized in writing, whether through a contract signed under the auspices of the Oversight Entity by all participating ambulance providers and receiving facilities or by a generally applicable plan or protocol promulgated or approved by the Oversight Entity. The replenishing arrangement must in practice comport with the terms of the written documentation.

(4) The receiving facility must not bill any Federal health care program or Federal program beneficiary for the replenished drugs or supplies, or write off such drugs or supplies as bad debt. The purpose of this requirement is to

[3] See, *e.g.*, Emergency Medical Services Systems Act of 1973 (EMSSA), Public Law 93–154 (providing Federal funding for the development of regional Emergency Medical Services (EMS) systems at the State, regional, and local levels, and defining ''emergency medical services system'' as ''a system which provides for the arrangement of personnel, facilities and equipment for the effective and coordinated delivery in an appropriate geographical area of health care services under emergency conditions * * * and which is administered by a public or nonprofit private entity which has the authority and the resources to provide effective administration of the system.''); Highway Safety Act of 1966, Public Law 89–594 (establishing an EMS program in the Department of Transportation); Emergency Medical Services for Children Program, under the Public Health Act, Public Law 98–555 (providing funds for enhancing pediatric EMS); and Trauma Care Systems Planning and Development Act of 1990, Public Law 101–590.

[4] 15 U.S.C. 13(c) exception to the Robinson-Patman Act (15 U.S.C. 13(a)–(f)). Inquiries as to the applicability of, or compliance with, the Non-Profit Institutions Act or the Robinson-Patman Act should be directed to the Federal Trade Commission.

prevent double payments by Medicare, which pays hospitals under Part A (through fiscal intermediaries), but which typically pays ambulance providers for drugs and supplies used during emergency transports under Part B (through carriers).

(5) In order to prevent ''double dipping,'' ambulance providers may not bill any Federal health care program or Federal beneficiary *separately* for the replenished drugs or supplies.

(6) The receiving facility and the ambulance provider must maintain records of the replenished drugs or supplies and make those records available to the Secretary upon request.

(7) The receiving facility and ambulance provider must otherwise comply with all Federal, State and local laws regulating emergency medical care and the provision of drugs and medical supplies, including laws relating to the handling of controlled substances such as morphine.

Nothing in this preamble or the proposed regulations is intended to express any view as to the appropriate billing of the Federal health care programs for supplies used during emergency transport services. Parties seeking to comply with these proposed safe harbors would still need to comply with all relevant billing and claims filing rules. The fifth and sixth conditions described above for the second proposed safe harbor merely set forth criteria for determining whether a particular arrangement qualifies for safe harbor protection under the anti-kickback statute; the conditions do not purport to establish any reimbursement rule. Questions regarding reimbursement under the Medicare and Medicaid programs should be addressed to the Health Care Financing Administration or the party's relevant fiscal intermediary or carrier.

As with the existing safe harbor provisions currently codified in § 1001.952, compliance with these proposed safe harbors would be voluntary. Failure to fit into one of these safe harbors would not mean that an ambulance replenishment arrangement is *illegal.* Rather, it would simply mean that the arrangement would need to be evaluated on a case-by-case basis.

Meeting the Criteria for Establishing New Safe Harbors

Section 205 of the Health Insurance Portability and Accountability Act, Public Law 104–191, established certain criteria that the Secretary may consider when modifying or establishing safe harbors to the anti-kickback statute. We indicated our intent to consider these criteria in evaluating proposals for new safe harbors in our Notice of Intent to Develop Regulations (61 FR 69061; December 31, 1996). We have considered these criteria in developing this proposed rulemaking, and we believe, for the reasons described above, that the proposed safe harbor for certain ambulance replenishing arrangements is likely to: (l) Increase or have no effect on access for needy patients to health care services; (2) increase the quality of health care services for needy patients; (3) have little or no effect on the cost of Federal health care programs; (4) have little or no effect on competition; and (5) have little or no effect on the quantity of services provided in underserved areas. We further believe the proposed safe harbor contains safeguards that limit the potential for overutilization and assure that patients retain their freedom of choice of service providers.

III. Regulatory Impact Statement

Executive Order 12866, the Unfunded Mandates Reform Act, Executive Order 13132, and the Regulatory Flexibility Act

The Office of Management and Budget (OMB) has reviewed this proposed rule in accordance with the provisions of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and has determined that it does not meet the criteria for a significant regulatory action. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health, safety distributive and equity effects. Section 202 of the Unfunded Mandates Reform Act, Public Law 104–4, requires that agencies prepare an assessment of anticipated costs and benefits on any rulemaking that may result in an expenditure by State, local or tribal Government, or by the private sector of $100 million or more in any given year. Further, Executive Order 13132, Federalism, requires agencies to determine if a rule will have a significant affect on States, on their relationship with the Federal Government, and on the distribution of power and responsibility among the various levels of government.

In addition, under the Small Business Enforcement Act (SBEA) of 1996, if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the economic effect of a rule on small business entities and analyze regulatory options that could lessen the impact of the rule. In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the economic effect of a rule on small business entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity and available information. Regulations must meet certain standards, such as avoiding unnecessary burden. We believe that this proposed rule would have no significant economic impact. The proposed safe harbor provisions set forth in this rulemaking are designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. As indicated above, in doing so, these regulations impose no requirements on any party. 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 actions under the anti-kickback statute. We believe that any aggregate economic effect of these safe harbor regulations would be minimal and would impact only those limited few who engage in prohibited behavior in violation of the statute. As such, we believe that the aggregate economic impact of these proposed regulations is minimal and would have no effect on the economy or on Federal or State expenditures

Additionally, in accordance with the Unfunded Mandates Reform Act of 1995, we believe that there are no significant costs associated with these proposed safe harbor guidelines that would impose any mandates on State, local or tribal governments, or the private sector that will result in an expenditure of $100 million or more in any given year. Further, in reviewing this rule under the threshold criteria of Executive Order 13132, Federalism, we have determined that this rule would not significantly affect the rights, roles and responsibilities of States, and that a full analysis under these Acts are not necessary.

Further, in accordance with the Regulatory Flexibility Act (RFA) of 1980, and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, we are required to determine if this rule will have a significant economic effect on a substantial number of small entities and, if so, to identify regulatory options that could lessen the impact. While

these safe harbor provisions may have an impact on small entities, we believe that the aggregate economic impact of this rulemaking would be minimal, since it is the nature of the violation and not the size of the entity that will result in a violation of the anti-kickback statute. Since the vast majority of individuals and entities potentially affected by these regulations do not engage in prohibited arrangements, schemes or practices in violation of the law, we believe that these proposed regulations would not have a significant economic impact on a number of small business entities, and that a regulatory flexibility analysis is not required for this rulemaking.

Paperwork Reduction Act

In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995, we are required to solicit public comments, and receive final OMB approval, on any information collection requirements set forth in rulemaking. While compliance with the provisions in this safe harbor rule would be voluntary, proposed § 1001.952(v)(3) contains information collection requirements that would require approval by OMB. As such, we are required to solicit public comments under section 3506(c)(2)(A) of the PRA on these requirements. Specifically, in order to qualify for safe harbor protection for ambulance restocking arrangements under § 1001.952(v)(3), the regulations would require that replenishing agreements be set forth in writing in the form of (1) a contract signed under the auspices of the oversight entity by all participating ambulance providers and receiving facilities or (2) a generally applicable plan or protocol promulgated or approved by the oversight entity. There is no obligation to submit these agreements to the Secretary, however, in order to achieve initial compliance with the safe harbor. In addition, to qualify for safe harbor protection for ambulance restocking arrangements under § 1001.952(v)(3), the receiving facility and the ambulance provider must maintain records of the replenished drugs and medical supplies (including linens) and make those records available to the Secretary promptly upon request. However, as indicated above, the safe harbor does *not require* any submission of reports, data collection or other documents in order to be in compliance with the anti-kickback statute.

In accordance with the PRA requirements, we are inviting comments on (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on parties, including through the use of automated collection techniques or other forms of information technology. As part of the OMB approval for the collection of information contained in this rule, we are soliciting public comments on this requirement, thereby initiating the normal PRA clearance.

Title: Ambulance Restocking Safe Harbor Under the Anti-Kickback Statute.

Summary of the collection of information: Proposed § 1001.952(v) would set forth a new statutory exception to the anti-kickback statute that covers any gift or transfer of drugs or medical supplies (including linens) by a hospital or other receiving facility to an ambulance provider for the purpose of replenishing comparable drugs or medical supplies (including linens) used by the ambulance provider in connection with the transport of an emergency patient to the hospital or other receiving facility. Safe harbors do not create any affirmative obligation on any individuals or entities. Seeking protection under these safe harbor provisions is purely voluntary.

The aggregate information burden for the information collection requirements contained in this proposed rulemaking is set forth below.

Respondents: In accordance with proposed § 1001.952(v), the respondents for the collection of information described in these regulations are parties involved in written agreements between (1) a hospital or other receiving facility that replenishes drugs and medical supplies, and (2) ambulance providers who bring emergency patients to the receiving facility.

Estimated number of respondents: The safe harbor being proposed in § 1001.952(v) would protect those restocking arrangements between receiving facilities that replenish drugs and medical supplies on an equal basis to all ambulance providers who transport their emergency patients to the receiving facility. Virtually all such replenishing arrangements already are memorialized in written contracts as a matter of prudent business practice, irrespective of the existence of the proposed safe harbor. We believe that few, if any, parties will enter into written arrangements specifically for the purposes of safe harbor protection. Accordingly, we estimate that the number of parties entering into written agreements to qualify for safe harbor protection will be negligible.

Estimated number of responses per respondent: None.

Estimated total annual burden on respondents: We believe that the burden of preparing written agreements and the aggregate information burden for the information collection requirements contained in this proposed rulemaking would be minimal. As indicated above, in most, if not all, cases the parties already have written agreements as part of the parties' replenishing arrangements, independent of the safe harbor requirements. Accordingly, any burden imposed by these proposed regulations would impose no burden on such parties.

Comments on this information collection activity should be sent to: Allison Herron Eydt, OIG Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street. NW, Washington, DC 20053, FAX: (202) 395–6974.

Comments on these paperwork reduction requirements may be submitted to the above-cited individual within 60 days following the **Federal Register** publication of this proposed rule.

IV. Public Inspection of Comments and Response to Comments

Comments will be available for public inspection June 5, 2000 in Room 5518, Office of Counsel to the Inspector General, at 330 Independence Avenue, SW, Washington, DC on Monday through Friday of each week (Federal holidays excepted) between the hours of 9 a.m. and 4 p.m., (202) 619–0089.

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and will respond to the comments in the preamble of the final rule.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare.

Accordingly, 42 CFR part 1001 would be amended as set forth below:

PART 1001—[AMENDED]

1. The authority citation for part 1001 would continue to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(h), 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub.L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.952 would be amended by republishing the introductory text and by adding a new paragraph (v) to read as follows:

§ 1001.952 Exceptions

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

* * * * *

(v) *Ambulance restocking.* (1) As used in section 1128B of the Act, ''remuneration'' does not include any gift or transfer of drugs or medical supplies (including linens) by a hospital or other receiving facility to an ambulance provider for the purpose of replenishing comparable drugs or medical supplies (including linens) used by the ambulance provider in connection with the transport of an emergency patient to the hospital or other receiving facility if all of the applicable standards in either paragraph (v)(2) or (v)(3) of this section are satisfied.

(2)(i) Except as otherwise provided in paragraph (v)(2)(ii) of this section, the ambulance provider pays the receiving facility fair market value, based on an arms-length transaction, for the replenished drugs or medical supplies (including linens). A non-profit receiving facility will be deemed to meet this standard if it sells replenished drugs or medical supplies to a non-profit ambulance provider at cost in order to comply with the Non-Profit Institutions Act (15 U.S.C. 13(c)), exception to the Robinson-Patman Act (15 U.S.C. 3(a)–(f)).

(ii) If payment is not made contemporaneously with the replenishing of the drugs or medical supplies (including linens), the receiving facility and the ambulance provider make commercially reasonable payment arrangements in advance.

(3)(i) The receiving facility replenishes drugs and medical supplies (including linens) on an equal basis for all ambulance providers who bring emergency patients to the receiving facility.

(ii) The replenishing arrangement must be implemented with the participation of, and monitored by, an oversight entity (as defined in paragraph (v)(4)(ii) of this section) as part of a comprehensive and coordinated regional emergency medical system appropriate to the size and resources of the service area and must be open and available to all emergency ambulance providers and receiving facilities in the service area.

(iii) The replenishing arrangement must be memorialized in writing. The writing may be in the form of—

(A) A contract signed under the auspices of the oversight entity by all participating ambulance providers and receiving facilities or

(B) A generally applicable plan or protocol promulgated or approved by the oversight entity.

(iv) The receiving facility refrains from billing any Federal health care program or Federal health care program beneficiary for the replenished drugs or medical supplies (including linens) and does not write off the cost of such drugs or medical supplies (including linens) as bad debt.

(v) The ambulance provider refrains from billing any Federal health care program or Federal health care program beneficiary *separately* for the replenished drugs or medical supplies (including linens).

(vi) The receiving facility and the ambulance provider maintain records of the replenished drugs and medical supplies (including linens) and make those records available to the Secretary promptly upon request.

(vii) The receiving facility and the ambulance provider otherwise comply with all Federal, State and local laws regulating emergency medical care and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances.

(4) For purposes of paragraph (v)(3) of this section—

(i) A ''receiving facility'' is a hospital or other facility that provides emergency medical services; and

(ii) An ''oversight entity'' is a regional emergency medical services council or functionally similar entity, association or organization that—

(A) Is described in section 501(c)(3) or 501(c)(4) of the Internal Revenue Code and exempt from taxation under section 501(a) of that Code;

(B) Includes, or is composed of, representatives of a broad array of participants in a service area's emergency medical system (*e.g.,* hospitals, ambulance providers, emergency room physicians, paramedics, public safety organizations, local educational institutions and community residents);

(C) Is open to all interested parties in the service area on equal terms and conditions; and

(D) Has as its mission the improvement of the emergency medical services delivery system in the relevant service area.

Dated: November 2, 1999.

June Gibbs Brown,

Inspector General.

Approved: November 18, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 00–12697 Filed 5–19–00; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF DEFENSE

48 CFR Parts 209 and 223

[DFARS Case 2000–D004]

Defense Federal Acquisition Regulation Supplement; Pollution Control and Clean Air and Water

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: The Acting Director of Defense Procurement is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to revise and relocate policy on the level of approval required to except a contract from certain restrictions of the Clean Air Act or the Clean Water Act. The policy is moved from the Pollution Control and Clean Air and Water subpart to the Debarment, Suspension, and Ineligibility subpart of the DFARS, because the Federal Acquisition Regulation (FAR) subpart on Pollution Control and Clean Air and Water has been removed.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before July 21, 2000, to be considered in the formation of the final rule.

ADDRESSES: Interested parties should submit written comments on the proposed rule to: Defense Acquisition Regulations Council, Attn: Ms. Sandra G. Haberlin, PDUSD (AT&L) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telefax (703) 602–0350.

E-mail comments submitted via the Internet should be addressed to: dfars@acq.osd.mil

Please cite DFARS Case 2000–D004 in all correspondence related to this proposed rule. E-mail correspondence should cite DFARS Case 2000–D004 in the subject line.