(B) Organics	Maximum allowable leachate conc. (mg/l)	Maximum allowable total conc. (mg/kg)
Trichloropropane, 1,2,3-	7.69e-04	1.54e-02
Trinitrobenzene, sym-	6.49e+00	1.30e+02
Vinyl chloride	2.34e-03	4.68e-02
Xylenes (total)	3.20e+02	6.40e+03

(4) *Changes in Operating Conditions:* If GROWS significantly changes the treatment process or the chemicals used in the treatment process, GROWS may not manage the treatment sludge filter cake generated from the new process under this exclusion until it has met the following conditions: (a) GROWS must demonstrate that the waste meets the delisting levels set forth in Paragraph 3; (b) it must demonstrate that no new hazardous constituents listed in Appendix VIII of Part 261 have been introduced into the manufacturing or treatment process: and (c) it must obtain prior written approval from EPA and the Pennsylvania Department of Environmental Protection to manage the waste under this exclusion.

(5) *Reopener:*

(a) If GROWS discovers that a condition at the facility or an assumption related to the disposal of the excluded waste that was modeled or predicted in the petition does not occur as modeled or predicted, then GROWS must report any information relevant to that condition, in writing, to the Regional Administrator or his delegate and to the Pennsylvania Department of Environmental Protection within 10 days of discovering that condition.

(b) Upon receiving information described in paragraph (a) of this section, regardless of its source, the Regional Administrator or his delegate and the Pennsylvania Department of Environmental Protection will determine whether the reported condition requires further action. Further action may include repealing the exclusion, modifying the exclusion, or other appropriate response necessary to protect human health and the environment.

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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 Replenishing Safe Harbor Under the Anti-Kickback Statute

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

ACTION: Final rule.

SUMMARY: This final rule sets forth a 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 or other receiving facilities that replenish drugs and medical supplies used by ambulance providers (or first responders) when transporting patients to the hospitals or receiving facilities.

EFFECTIVE DATE: These regulations are effective on January 3, 2002.

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

SUPPLEMENTARY INFORMATION:

Overview—Establishing a New Safe Harbor for Ambulance Restocking Arrangements

This final regulation establishes safe harbor protection for ambulance restocking arrangements.[1] Ambulance restocking is the practice, commonplace in many parts of the country, of hospitals or other receiving facilities restocking ambulance providers[2] with drugs or supplies used during the transport of a patient to the hospital or receiving facility. (For simplicity, we sometimes use the shorthand ''hospital'' or ''receiving hospital'' in this preamble; such terminology is intended to include other types of receiving facilities, such as urgent care or community health care clinics that provide emergency care services). Restocking enables the ambulance to depart the hospital ready for the next emergency call, fully stocked with current medications, sanitary linens, and a full complement of appropriate medications and supplies, and helps ensure that supplies, such as intravenous tubing and catheters, 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. *Bona fide* restocking arrangements serve a significant public interest and are consistent with Federal policy established over the past 25 years.[3]

Set forth below is a brief background discussion addressing the anti-kickback statute and the proposed safe harbor for ambulance restocking; a summary of the provisions being adopted into the final regulations; and a review of the public

[1] Because these arrangements are commonly known as ''restocking,'' we use that term in this preamble. As further discussed below, the regulations use the word ''replenish'' to make clear that the safe harbor only applies to the gifting or transfer of drugs and supplies that replace comparable drugs and supplies administered by the ambulance provider (or first responder) to a patient before the patient is delivered to the receiving facility. The rule is not applicable to any arrangements for the general stocking of the inventories of ambulance providers. Depending on the circumstances, such arrangements may fit into other safe harbors, such as the group purchasing organization safe harbor at § 1001.952(j) or the discount safe harbor at § 1001.952(h) of this part.

[2] In this preamble and regulations text, unless otherwise specified, the term ''ambulance provider'' compasses both independent ambulance suppliers and hospital-based providers, including ''under arrangements'' providers.

[3] *See,* e.g., Emergency Medical Services Systems Act of 1973, 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.

comments received and our responses to those concerns.

I. Background

A. Ambulance Restocking and the Anti-Kickback Statute

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 (i.e., anything of value, in cash or in kind) in order to induce the referral of business reimbursable by a Federal health care program. Violations of the statute may also result in civil money penalties under section 1128A(a)(7) of the Act or program exclusion under section 1128(a)(7) of the Act. The statute has been in existence since 1977 and applies broadly to all kinds of health care providers and suppliers. Payments tied to referrals corrupt the health care system, increasing the risks of overutilization of items and services, increased costs to the Federal health care programs, inappropriate steering of patients, and unfair competition. Ambulance restocking arrangements technically implicate the anti-kickback statute because the receiving hospital gives something of value (e.g., drugs or medical supplies) to a potential source of Federal health care program business, i.e., ambulance providers who deliver patients.

Notwithstanding the *potential* for a violation, the OIG believes that the vast majority of ambulance restocking arrangements are lawful under the anti-kickback statute. We fully recognize the importance of ambulances being restocked and ready for emergency use at all times. Properly structured restocking arrangements contribute to this laudable goal without significant risk of fraud or abuse.

B. OIG Advisory Opinions

The OIG was first asked to address an ambulance restocking arrangement in 1997 when two hospitals submitted a request for an advisory opinion under section 1128D of the Act. As required by the statute, the OIG responded to the request, even though the subject matter was not of significant concern to the OIG. As with all determinations under the anti-kickback statute, our review turned on the specific facts and circumstances of the arrangement as presented by the requesting hospitals. The request presented an unusual set of facts under which an unscrupulous party *could* potentially use an ambulance restocking arrangement for an unlawful purpose, namely the steering of patients to a particular hospital in exchange for remuneration. The OIG opined that the facts of the particular arrangement—as presented by the hospitals—would be likely to involve prohibited remuneration.[4] By law, the opinion applied only to the hospitals that requested it.

Subsequently, the OIG issued several favorable advisory opinions approving restocking arrangements that it believed to be much more representative of typical restocking arrangements.[5] Most recently, in December 2000, the OIG issued a favorable advisory opinion approving a hospital's proposal to restock only volunteer ambulance companies that do not charge anyone for their services.

C. The Proposed Safe Harbor

On May 22, 2000, we published a notice of proposed rulemaking to promulgate safe harbor regulations for ambulance restocking arrangements (65 FR 32060). In the notice of proposed rulemaking, we proposed protecting two categories of ambulance restocking arrangements: (1) Arrangements under which the ambulance provider pays a receiving facility fair market value for restocked drugs or supplies; and (2) arrangements under which the ambulance service provider receives contemporaneous restocking of drugs or medical supplies used during emergency transport of a patient to the receiving facility, even if the restocking is without charge or at reduced prices. The proposed rule was designed to protect restocking for emergency transports only.

Proposed § 1001.952(v)(2), the fair market value category, was designed to protect restocking arrangements where an ambulance provider pays the receiving facility fair market value, based on an arms-length transaction, for restocked drugs or supplies (including linens) used in connection with the transport of an emergency patient. Under the proposal, payment need not be made at the same time as the restocking, provided commercially reasonable and appropriate payment arrangements are made in advance.

Proposed § 1001.952(v)(3) was designed to protect remuneration in the form of restocking of drugs or medical supplies (including linens) used during an emergency transport of a patient to the receiving facility, even if the restocking is for free or reduced prices. Under the proposed rule, the restocking arrangements would have to be implemented on a community-wide basis with some involvement of an oversight entity. The proposed safe harbor would not protect unilateral referral arrangements that were not open to all hospitals and ambulance companies in the service area.

Most commenters supported a new safe harbor, but many objected to certain aspects of the proposed rule. Some found the rule too narrow or burdensome, while others found the provisions of the proposed regulations ambiguous or impracticable. Of particular concern to many commenters were the proposed safe harbor conditions relating to monitoring by an oversight entity, written memorialization of the arrangement, and billing for restocked drugs and supplies. We have eliminated or substantially revised these conditions, as described in greater detail in section II. below.

II. Summary of the Final Rule

As with the proposed rule, the goal of this final rule is safe harbor protection for the vast majority of ambulance restocking arrangements that further the important mission of insuring that pre-hospital emergency medical services (EMS) are timely, effective and efficient.

A. Major Changes

We have modified the proposed rule in a number of areas in response to public comments. Among the substantial changes and clarifications being made in the final regulations are:

- Eliminating the oversight entity condition in favor of a public operation and disclosure condition;
- Clarifying that no complicated written contracts or agreements are required and providing a short sample disclosure notice;
- Conforming the billing conditions to existing Federal health care program payment and coverage rules and regulations;
- Expanding the safe harbor to include restocking for non-emergency runs so long as the ambulance is also used for emergency runs;
- Allowing hospitals to limit the scope of protected restocking to all non-profit ambulance providers or all ambulance providers that do not charge for their services;
- Simplifying the documentation conditions so that only one party to the restocking arrangement is required to document the restocking;
- Adding specific safe harbor protection for Government-mandated ambulance restocking; and

[4] OIG Advisory Opinion 97–6 (October 8, 1997).

[5] OIG Advisory Opinion 98–7 (June 11, 1998); OIG Advisory Opinion 98–13 (September 30, 1998); OIG Advisory Opinion 98–14 (October 28, 1998); and OIG Advisory Opinion 00–09 (December 8, 2000).

• Including restocking of drugs or supplies initially administered to the patient by a first responder at the scene of the illness or injury.

B. Final Safe Harbor Conditions

The final safe harbor regulations establish broad protection for most existing ambulance restocking arrangements, while precluding protection for any abusive arrangements that use targeted or selective restocking for the purpose of inducing or rewarding referrals. The final regulations address three categories of restocking: (1) General restocking (whether for free or for a charge), (2) fair market value restocking, and (3) Government-mandated restocking. Parties need only satisfy the conditions applicable to any *one* of these categories. Parties who are unsure whether their restocking is at fair market value or is mandated by a Government authority may look to the general restocking category.

The final regulations provide that ''remuneration'' under the anti-kickback statute 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 (or a first responder) in connection with the transport of a patient by ambulance to the hospital or receiving facility if all applicable safe harbor conditions are satisfied.

The regulations are divided into two parts. First, there are four conditions, codified at § 1001.952(v)(2), that apply to all three of the restocking categories being protected by the safe harbor. Second, there are specific conditions codified at § 1001.952(v)(3) for each of the three categories being set forth (general restocking, fair market value restocking, and Government mandated restocking). To qualify for safe harbor protection, a restocking arrangement must meet all of the conditions in the first part and all of the conditions relevant to *one* category in the second part.

1. Conditions Applicable to All Safe Harbor Restocking Arrangements

The four conditions applicable to all safe harbor restocking arrangements are:

(a) *Appropriate billing of Federal health care programs.* The final rule conditions safe harbor protection on Federal health care program billing for restocked drugs and medical supplies that is consistent with all applicable program payment and coverage rules and regulations. The ambulance provider and the hospital may not both bill for the same restocked drug or supply. For purposes of this safe harbor, billing includes submitting claims for bad debt. Compliance with the requirement that billing be appropriate will be determined separately for receiving facilities and ambulance providers. For example, if a hospital improperly bills for restocked supplies, the ambulance provider who received the supplies may still be protected, so long as the provider has not done anything to impede the hospital's compliance with the billing rules.

(b) *Documentation requirements.* We have simplified the documentation requirements. Under the final rule, either the hospital or the ambulance provider may generate the necessary documentation, so long as the other party receives and maintains a copy of it for 5 years. This 5-year period is consistent with the recordkeeping requirements of the Centers for Medicare and Medicaid Services' (CMS) [6] hospital conditions of participation. The pre-hospital care report typically prepared by the ambulance service provider (sometimes called the trip sheet, patient care report or patient encounter report) will be sufficient to satisfy this requirement if (i) the report identifies the drugs and supplies used on the patient and subsequently restocked and (ii) a copy of the report is filed with the receiving facility within a reasonable amount of time. For arrangements that include restocking of linens, an exchange of linens will be presumed to occur with each run, absent documentation to the contrary. The pre-hospital care report or other documentation may be prepared and filed with the other party in hard copy or electronically.

(c) *No ties to referrals.* In the light of the easing of the billing conditions, we are adding a safeguard similar to one found in other safe harbors that prohibits any restocking arrangement that is conditioned on, or otherwise takes into account, the volume or value of any referrals or other business generated between the parties for which payment may be made in whole or in part by a Federal health care program (other than the delivery to the receiving facility of the particular patient for whom the drugs and medical supplies are restocked).

(d) *Compliance with all other applicable laws.* We have retained the proposed condition that the receiving facility and the ambulance provider must comply with all Federal, State and local laws regulating ambulance services, including, but not limited to, emergency services, and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances.

2. Safe Harbor Conditions Applicable to the Specific Categories of Safe Harbor Protection

The safe harbor conditions applicable to the three specific categories of safe harbor protection are summarized as follows:

(a) *General restocking.* This safe harbor for general restocking is available for free restocking arrangements, as well as arrangements under which the ambulance provider pays some amount for the restocked drugs and supplies (whether or not the amount is fair market value). (Any payment for drugs must comply with applicable Federal, State and local laws.) Two specific conditions apply to the general restocking category. First, the receiving facility must restock medical supplies or drugs on an equal basis for ambulance providers in one or more of three categories: (i) All ambulance providers; (ii) all non-profit and governmental providers; or (iii) all non-charging providers (typically volunteers and municipal providers). A receiving facility can offer restocking to more than one category, and can offer a different restocking program to each category that it restocks, so long as the restocking is uniform within each category. The final regulations make clear that safe harbor protection does not require each hospital and receiving facility in the service area to offer restocking, nor all ambulance providers to accept it.

Second, the restocking must be conducted publicly. As detailed in the regulations text, a restocking arrangement will be considered to be conducted publicly if: (i) The arrangement is memorialized in a conspicuously posted writing that outlines the terms of the restocking program and copies are available publicly (a sample disclosure form is included in the regulations); *or* (ii) The restocking program operates in accordance with a plan or protocol of general application promulgated by an EMS council or comparable organization. For purposes of safe harbor compliance, the writing need not disclose confidential proprietary or financial information.

(b) *Fair market value restocking.* This category protects restocking arrangements where an ambulance provider pays the receiving facility fair

[6] Until June 2001, CMS was known as the Health Care Financing Administration.

market value, based on an arms-length transaction, for restocked medical supplies (including linens). For consistency with the Prescription Drug Marketing Act,[7] and some State laws, the final regulations do not include the resale of drugs in this category. (Restocking of drugs may be covered under other safe harbor categories.) This safe harbor category has two conditions: (i) The restocking must be at fair market value, and (ii) payment arrangements must be commercially reasonable and made in advance. For reasons discussed in greater detail in the responses to comments in section III. of this preamble, we are not including any special accommodation related to the Non-Profit Institutions Act, 15 U.S.C. 13(c), exception to the Robinson-Patman Act.[8]

(c) *Government-mandated restocking.* This final safe harbor protects restocking of drugs and supplies undertaken in accordance with a State or local statute, ordinance, regulations or binding protocol that requires hospitals or receiving facilities in the area subject to such requirement to restock ambulances that deliver patients to the hospital with drugs or medical supplies that are used during the transport of that patient.

C. Safe Harbor Compliance Is Voluntary

As with all safe harbors, compliance with these new safe harbors is *voluntary*. While the vast majority of ambulance restocking arrangements should fit in this new safe harbor, failure to fit does not mean that an arrangement is illegal under the anti-kickback statute. Rather, it simply means that the legality of the arrangement must be evaluated on a case-by-case basis. If no purpose of the arrangement is to induce or reward the generation of Federal health care program business, there would be no violation of the statute. The obligation of parties to comply with the anti-kickback statute pre-dates this safe harbor rulemaking, and arrangements that were lawful before the rulemaking will continue to be lawful, whether or not they meet the safe harbor requirements. The safe harbor does not require the restructuring of any arrangements, although parties may choose to restructure to take advantage of the safe harbor protection. Parties who are unsure whether their existing or proposed arrangements fit in a safe harbor or would be subject to OIG sanctions may apply for an advisory opinion under section 1128D of the Act. The procedures for applying for an advisory opinion are set forth at 42 CFR part 1008 and on the OIG Web site at *http://www.dhhs.gov/progorg/oig/advopn/index.htm*.

III. Public Comments and Responses

In response to our proposed rulemaking, the OIG received a total of 46 timely-filed comments from a cross-section of ambulance providers, hospitals, local and regional emergency medical boards, professional associations and other interested parties. Set forth below is a summary of the issues raised by the commenters and our responses to those specific concerns.

A. General Comments

The vast majority of the public comments supported promulgation of a safe harbor for ambulance restocking, although many commenters took issue with one or more specific aspects of the proposal.

Comment: Several commenters believed that the OIG advisory opinions on ambulance restocking under the anti-kickback statute, especially the first one issued in 1997, have had a chilling effect on ambulance restocking arrangements.

Response: While this comment reflects a common perception in the industry, we have learned that a major source of the reluctance of many hospitals to enter into, or continue, restocking programs is financial. In other words, their willingness to participate in restocking arrangements is directly related to their ability to be reimbursed by Medicare or other insurers for costly supplies and drugs provided without charge to local ambulance services. Many of these drugs and supplies are increasingly becoming the standard of care for pre-hospital services. In many cases, financially strapped hospitals are unwilling to continue to subsidize the emergency medical system in the absence of definitive assurance that they will be adequately reimbursed for drugs and supplies used during ambulance transports. Some hospitals have used the unfavorable 1997 advisory opinion as a pretext for justifying decisions to terminate, or decline to participate in, restocking arrangements in order to blunt negative publicity and adverse local community reaction.

Comment: A number of commenters misread the proposed regulations as an effort by the OIG to dictate Medicare payment policy.

Response: The OIG does not set Medicare payment and coverage policy. As stated in the proposed rule, we express no view in these regulations as to the appropriate Federal health care program payment or coverage policy for drugs and supplies used during ambulance transports. Those determinations are properly made by the relevant Federal program. In crafting safeguards to include in safe harbor regulations, we considered the ways in which a particular payment policy or practice may affect the risk of patient or program abuse.

Comment: An ambulance provider with a limited budget, and in an area with a low call volume, explained that it could not maintain an Advanced Life Support level of service, because it was unable to restock drugs from a local hospital. According to the commenter, their costs of purchasing expensive drugs in small quantities makes such drugs prohibitively expensive. In addition, the commenter observed that many small providers do not have the facilities to maintain proper environmental conditions for larger supplies of these types of drugs.

Response: Nothing in these regulations prohibits hospitals from restocking ambulances with drugs or prohibits ambulance providers from taking advantage of (i) volume discounts obtained by hospitals (to the extent otherwise permitted under Federal, State and local law) or (ii) any hospital facility for storing such drugs.

Comment: Several commenters indicated that in some parts of the country, local and State governments have imposed mandatory requirements relating to the restocking of ambulances that deliver patients to hospitals. These commenters requested an additional category of safe harbor protection to address arrangements controlled by State or local government requirements.

Response: Nothing in the safe harbor regulations precludes State and local governments from regulating ambulance restocking. If the State or local law or regulation is duly promulgated, and the restocking arrangement is conducted in accordance with its mandate, the OIG sees little risk under the anti-kickback statute, which requires a showing of unlawful intent. Accordingly, we are including an additional safe harbor category for Government-mandated restocking, and have adapted language suggested by a major trade association. We note that nothing in State or local government laws or regulations mandating ambulance restocking affects the reimbursement rules under Medicare or other Federal health care programs.

Comment: Some commenters questioned whether ambulance

[7] Public Law 100–293, April 22, 1998, 102 Stat. 95.

[8] 15 U.S.C. 13(a)–(f).

restocking arrangements raise kickback concerns at all. Specifically, with respect to patient steering risks, one commenter explained that conscious patients select their own destination, and unconscious or unstable patients are taken to the nearest facility. Other commenters expressed the view that instances of fraud in ambulance restocking arrangements would be isolated.

Response: We agree that fraud and abuse are likely to be uncommon in *bona fide* ambulance restocking arrangements. Nonetheless, in crafting safe harbors, we must be mindful not only of the benefits of the practices we seek to protect, but also the potential abuses. With ambulance restocking, the risks are low but not absent.

Comment: Several commenters requested clarification of the term ''emergency patient'' as used in the proposed safe harbor. These commenters inquired whether this term referred to the patient's actual condition or to the manner by which the ambulance is summoned. One commenter suggested that an emergency patient be defined as a patient delivered to a *bona fide* emergency department for medical or traumatic care.

Response: Because we are expanding the safe harbor to cover non-emergency transports, we do not believe any regulatory definition of the term ''emergency patient '' is required. However, we are adding a definition of ''emergency ambulance service'' for purposes of identifying those ambulances and ambulance providers that provide emergency transports and are thus eligible for safe harbor-protected restocking. For purposes of these final regulations, we are defining an ''emergency ambulance service'' as one that results from a call through 9–1–1 or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient and available at the receiving facility.

Comment: Paragraph (v)(1) of the proposed regulations indicated that remuneration ''* * * does not include any gift or transfer of drugs or medical supplies (including linens) * * *'' A commenter found the use of the word ''gift'' in this phrase confusing, since the safe harbor protects what is essentially an equal or equivalent exchange (i.e., what was used is restocked) and not the gifting of additional goods.

Response: The commenter is correct that the safe harbor is not designed to protect remuneration in the form of additional goods or services beyond the restocking of drugs or medical supplies (including linens) used on particular patients transported to the receiving facility. It does, however, protect restocking in the form of a gift, i.e., restocking bestowed voluntarily and without compensation.

Comment: A large self-insured manufacturing company that maintains its own private ambulance service to transport ill or injured employees to its preferred provider hospitals expressed concern about the impact of the proposed rule on its restocking arrangement. According to the commenter, the company negotiates preferred provider plans with hospitals in accordance with which the hospitals restock the ambulances at the hospitals' expense. No employees transported by the company's ambulance service are covered by Medicare or Medicaid, but the company is concerned that the safe harbor would affect restocking practices at the hospital.

Response: Because the company's ambulance service transports only private pay patients, nothing in this rule will directly affect the commenter's restocking arrangements. Short of making clear in this preamble discussion that the arrangement described in the comment need not be modified to comply with these rules, we know of no way of preventing the collateral impact anticipated by the company in particular cases.

B. General Restocking

1. Non-Emergency Transports

Comment: A number of commenters urged the OIG to expand the proposed safe harbor to cover the restocking of drugs and medical supplies for non-emergency transports. Given that ambulances that provide non-emergency transports are frequently on call for emergencies, commenters noted that it would be contrary to the public health and safety goals of restocking to bar restocking of an ambulance that arrives at a hospital with a non-emergency patient. One commenter recommended that we expand the safe harbor to apply to all patients brought to the hospital or, in the alternative, to all patients brought to the emergency room.

Response: In general, the scope of replenishing needed after a non-emergency transport is likely to be minimal, since relatively few drugs or supplies are typically administered to non-emergency patients during a transport. Nevertheless, to further the goal of protecting restocking arrangements that ensure that ambulances are stocked and ready to respond to emergencies at all times, we are expanding the safe harbor to cover the restocking of drugs and supplies used on both emergency and non-emergency transports, provided that the ambulance that is restocked is used with some degree of regularity to respond to emergency calls (i.e., calls from 9–1–1 or another emergency access number). We do not intend to protect restocking of ambulances that are not used with some degree of regularity for emergencies. The fact that such restocking is outside the scope of this rulemaking does not mean that such restocking is illegal. Whether arrangements for restocking of non-emergency ambulances violate the anti-kickback statute must be determined on a case-by-case basis. Parties to such arrangements may request an OIG advisory opinion.

In order to create a bright line rule that is simple to apply, this expansion requires a measure for determining when an ambulance is used for emergency calls with sufficient regularity to qualify for replenishing under the safe harbor. The new regulations provide that an ambulance will satisfy this standard if the ambulance is used to respond to emergencies an *average* of three times per week measured over *any* reasonable time period. This test does *not* mean that the ambulance must actually make three emergency runs every week. Rather, over a reasonable period of time, the ambulance must be used an *average* of three times per week. Thus, for example, if an ambulance is used 12 times during a month, the test will be met. Similarly, the test will be met if the ambulance is used for emergency runs 156 times in a year, even if there are some weeks in which the ambulance receives no emergency calls. In essence, the three runs test is designed to differentiate between ambulances that are reasonably likely to be called out for an emergency transport, and thus have a compelling need to be restocked by a receiving facility after a non-emergency run, and those that are not.

Restocking arrangements for ambulances or ambulance providers that only provide routine, non-emergency services, or that do not meet the three runs test described above, must be evaluated under the anti-kickback statute on a case-by-case basis. Finally, nothing in these regulations will require restocking of non-emergency transports or the expansion of existing restocking programs to cover non-emergency transports.

2. Uniform Restocking

Comment: The proposed rule conditioned safe harbor protection on a receiving hospital's provision of restocked drugs and supplies on an

equal basis to all ambulance providers that deliver patients to the hospital. This condition was intended to insure that the safe harbor did not protect selective or targeted arrangements that are not *bona fide* restocking for the purpose of enhancing the delivery of EMS. Commenters argued that the safe harbor should protect receiving facilities that opt to restock only certain categories of ambulance providers. For example, some wanted to restock only volunteer ambulance providers or only ambulance providers that do not charge patients or insurers. Tax-exempt hospitals commented that requiring them to restock for-profit ambulance providers could jeopardize their tax-exempt status. Other commenters wanted to offer different restocking programs to different types of ambulance providers, such as offering full restocking to non-charging volunteer companies and more limited restocking to companies that charge for services.

Response: Having reviewed the comments, we have concluded that an appropriate safe harbor can be structured that would afford hospitals greater flexibility in crafting restocking programs, while preserving the principle that protected restocking programs should not be unilateral arrangements for the benefit of selected providers. (Of course, unilateral arrangements in remote service areas where there is only one receiving facility or one ambulance service provider are protected if they meet all the safe harbor conditions.) The final regulations protect restocking of: (i) All ambulance providers; (ii) all non-profit and governmental ambulance providers; or (iii) all ambulance providers that do not charge patients or insurers (typically volunteers and municipal providers). A hospital can offer restocking to more than one category and can offer a different restocking program to each category that it restocks, so long as the restocking is uniform within each category (i.e., non-charging providers may be offered a larger scope of restocked items than charging providers). Limiting the scope of free restocking to providers within these categories represents a reasonable distinction that will ensure that arrangements qualifying for safe harbor protection will not be related to the volume or value of referrals or other business generated for the hospitals. This modification accommodates hospitals' legitimate interests in containing the cost of their restocking programs. (The issue of the effect, if any, of a restocking arrangement on a hospital's tax exempt status would be a matter for the Internal Revenue Service.)

Comment: A commenter expressed concern that the ''all ambulances'' condition in the proposed rule would not permit facilities to restock only small, low volume volunteer companies without charge or at below cost. The commenter explained that, in their region, hospitals could not afford to restock large, high volume commercial ambulance companies for free.

Response: We have revised the safe harbor to permit hospitals to restock volunteer companies only. To qualify for safe harbor protection, the hospital must restock all volunteer companies uniformly. The safe harbor does not protect differential restocking based on the volume of transports, although offering free or discounted restocking only to low volume companies would not necessarily violate the anti-kickback statute.

Comment: Several commenters requested clarification as to whether all ambulance providers and receiving facilities in a service area would be required to participate in a restocking arrangement in order for the arrangement to qualify for safe harbor protection.

Response: All ambulance providers in a service area are *not* required to participate in order for an arrangement to fit in the safe harbor. Under the proposed rule, we did not intend to require all ambulance providers and receiving facilities in a service area actually to participate in a restocking arrangement in order for the arrangement to qualify for safe harbor protection. We did intend to require that a protected restocking arrangement be open to the voluntary participation of all ambulance providers and receiving facilities in a service area. The final regulations—including the new public operation and disclosure condition—generally reflect this intent. We have made exceptions for arrangements that limit the scope of restocking to the particular subcategories of ambulance providers described in the preceding response or that limit the scope to emergency transports. These limitations are a reasonable means of constraining the costs of restocking and are not related to the actual or potential volume or value of referrals or other business generated between the parties that is payable by a Federal health care program.

3. Billing

Comment: Some commenters objected to the proposed billing conditions. While designed to limit safe harbor protection to those arrangements that posed no risk of double payments or ''double dipping,'' the conditions were misconstrued by many commenters as prohibiting legitimate billing practices under Medicare payment rules, or as barring all billing by both the hospitals and the ambulance providers for the restocked drugs and supplies. Some commenters wondered why a safe harbor under the anti-kickback statute would need to take into account the question of billing at all. Commenters recommended that the conditions on billing in the proposed safe harbor be removed or altered to provide only that any billing for restocked items must be consistent with applicable Federal reimbursement provisions.

A commenter explained that ambulance providers in its State are not allowed to purchase or bill for drugs. The drugs used in the field are purchased and owned by the hospitals and restocked locally through a system of State-approved protocols. The commenter believed the following language would better accomplish the safe harbor objectives, while still allowing one party to bill for drugs: ''Under no circumstances may the ambulance provider and the receiving facility both bill for the actual drug or supply. Restocked drugs or supplies may only be billed to any Federal health care program by either the ambulance provider or the receiving facility.'' Several other commenters suggested similar language.

Response: We agree with the commenters that a safe harbor regulation is not a tool for setting program payment and coverage policy and doing so was not our intent. The billing conditions we proposed were designed to ensure that the safe harbor would not protect arrangements that could result in Medicare paying twice for the same drugs and supplies (i.e., situations in which both the ambulance company and the hospital bill for the same drug or supply), or in the ambulance services provider receiving a double benefit by billing Medicare for drugs and supplies for which it obtained free replacements (double-dipping). In both circumstances, ambulance restocking arrangements have the potential to increase costs to Medicare and other Federal health care programs. In the interest of simplification, we are adopting the commenters' suggestion and modifying the billing conditions to require that any billing of the Federal health care programs comport with applicable payment and coverage rules and regulations. Under applicable Medicare rules, a particular drug or supply administered to a patient in a pre-hospital setting will be covered

under either the ambulance or the outpatient hospital benefit, depending on the circumstances (e.g., whether the ambulance transport is provided ''under arrangements'' with the hospital); thus, the ambulance provider and the hospital may not both bill for the same drug or supply.[9]

Comment: Commenters raised a number of issues related to reimbursement for restocked drugs or supplies in particular circumstances. For example, a commenter explained that several volunteer rescue squads in its region do not bill any Federal health care programs. The commenter believes the proposed rule, as written, did not consider how a hospital would be reimbursed for drugs and supplies used by a volunteer service when an emergency patient is not admitted to the hospital. Some commenters questioned how ambulance providers would be reimbursed for new lifesaving drugs that could not have been included in the base rate payable to ambulance providers because the drugs did not exist, or were not used in a pre-hospital setting, when the base rates were set. Several commenters asked that we create a separate safe harbor to cover restocking arrangements that deal with specific drugs or devices that are administered at the order of a physician at the receiving hospital or centralized medical control. A commenter observed that unless private ambulance companies recover costs for expensive new medications, they will likely cease providing emergency services, thus shifting the entire responsibility onto the local governments to provide emergency medical care.

Response: The question of reimbursement in the circumstances described by the commenters is outside the scope of the OIG's regulatory authority and should be directed to CMS or the relevant fiscal intermediary or carrier. We included a condition in the proposed safe harbor that would have denied safe harbor protection for arrangements under which ambulance providers billed separately (i.e., in addition to the base rate payment) for restocked drugs and supplies. The condition would not have barred the restocking of any particular drugs or supplies. However, we have removed the former billing condition and replaced it in the final regulations with one that requires appropriate billing of the Federal health care programs, as determined by CMS or other relevant payment agency. Restocking of lifesaving drugs will be protected so long as the safe harbor conditions are met. None of the safe harbor conditions strikes us as imposing any particular burden on restocking of lifesaving drugs. Given this, we see no need for the additional safe harbor suggested by the commenters.

Comment: Several commenters observed that hospitals are unwilling to absorb the cost of emergency medications and supplies provided for free or below fair market values.

Response: Nothing in these regulations requires hospitals to provide ambulances with free or below cost medications or supplies for emergency services. Our interest in developing the safe harbor provisions is in insuring that the anti-kickback statute does not chill *bona fide* hospital restocking arrangements by hospitals that wish to provide them. To the extent that reimbursement policies may adversely impact the delivery of EMS, those concerns should be addressed to CMS.

Comment: A commenter asked about the intended impact of these safe harbor regulations on current and future arrangements involving hospitals that have negotiated prospective payment arrangements that may incorporate medication charges or EMS providers that have negotiated fee structures that bundle such charges in one overall set of base-rate and mileage charges. The commenter pointed out that CMS's negotiated rulemaking process for EMS rate setting may alter these arrangements as new rates, including bundled charges, are phased in.

Response: These rules should have no impact on the arrangements described by the commenter. Nothing in these rules alters or changes any billing practice or arrangement.

4. Documentation

Comment: Several commenters raised concerns about the documentation requirement in the proposed safe harbor. Commenters believed that requiring both the hospital and the ambulance provider to document the restocking was unnecessary and duplicative. The commenters generally suggested that existing patient care reports (sometimes known as trip sheets or patient encounter reports) already maintained for other purposes, such as ensuring continuity of care and billing, should be sufficient. Commenters explained that in a busy emergency room, it would be difficult to maintain multiple logs for multiple ambulance providers for both supplies and medications. Several commenters noted that maintaining a record of every restocked item in a large urban EMS system with a large volume of patients would create large amounts of paperwork, consume limited resources, and slow down the response time of ambulances. Alternatively, some commenters suggested that parties could agree that either the hospital or the ambulance provider, but not both, should bear the responsibility for record keeping.

Response: We have modified the documentation requirement to permit either party to maintain records of the restocked drugs and medical supplies, so long as the other party receives and maintains a copy of the records. (In the alternative, both the hospital and the ambulance provider can maintain separate records of the restocking, in which case they need not file copies of their respective documentation with the other party.) Patient care reports, trip sheets, patient encounter reports, and the like (collectively being referred to as pre-hospital care reports in the final regulations) are sufficient to meet this requirement if they document the restocked drugs and medical supplies and are filed with the receiving facility within a reasonable time, in hard copy or electronically. It is our understanding that the preparation of a pre-hospital care report is the standard of care for transferring a patient to a receiving facility and is required by law in many States. However, parties may decide individually or between themselves to document the restocking using other kinds of paper or electronic records. In the case of first responder restocking, we are requiring that the restocked drugs and medical supplies be documented in the pre-hospital care report prepared by the transporting ambulance provider *or* in records maintained by the hospital and shared with the transporting provider.

Comment: One commenter favored the proposed documentation requirement in most situations, but suggested that this requirement might be rethought for linen exchanges and other routinely used items. In the commenter's view, the requirement that hospitals and ambulance providers keep records pertaining to routine items, like linens, is unduly burdensome. The commenter argued that there is little risk to the programs from a one-for-one exchange of soiled linen for clean linen, and that these exchanges are so prevalent throughout the industry that record keeping would be required on

[9] Nothing in this preamble or these safe harbor regulations should be construed as approving or establishing any particular billing or payment practice. Questions regarding Medicare billing should be addressed to CMS or the appropriate fiscal intermediary or carrier. Questions regarding Medicaid billing should be addressed to the State Medicaid agency. Questions regarding billing in other Federal health care programs should be addressed to the relevant agency.

virtually every transport for many ambulance providers.

Response: We agree that providers need not document the exchange of linens. If they are part of a restocking arrangement, linens will be presumed to have been exchanged on a one-for-one basis. The commenter did not identify, and it would not be feasible to enumerate in these regulations, other supplies that may be so routinely used as to warrant a comparable presumption. We think parties will be able to devise simple means of documenting such routine restocking.

Comment: One commenter requested guidance on the length of time providers need to maintain records of restocked drugs and supplies.

Response: As indicated above, we have simplified the documentation requirements. Under the final regulations, either the hospital or the ambulance provider may generate the necessary documentation, so long as the other party receives and maintains a copy of it for 5 years, a period consistent with the CMS's hospital conditions of participation recordkeeping requirements.

5. Writing Requirement

Comment: Some commenters objected to the proposed condition requiring the restocking arrangement to be memorialized in writing. The proposed rule required that the ambulance restocking arrangement be memorialized in writing, *either* (i) in a plan or protocol of general application *or* (ii) in a written contract between the parties. Some commenters misread this condition as requiring providers to enter into written contracts or agreements. In addition, we have heard, anecdotally, that some industry consultants and counselors have been advising ambulance providers and hospitals that the proposed rule required the creation of lengthy and detailed contracts.

Response: As is typical of most safe harbor regulations, the proposed rule required that the protected ambulance restocking arrangement be memorialized in writing. Under the proposal, the writing could be *either* a plan or protocol of general application *or* a written contract or agreement between the parties. Under the final rule, no particular form of writing is mandated. Indeed, the writing can take the form of a simple disclosure statement. A sample disclosure statement is being included as an appendix to part 1001, subpart C of the regulations. This sample is intended for guidance purposes only. Parties are free to use other formats or to substitute written contracts or protocols. No public disclosure of confidential proprietary or financial information is required.

We believe that virtually all existing restocking arrangements are already being conducted in accordance with some form of written description of the arrangement. So long as the written description is conspicuously posted and publicly available and describes (i) The category, or categories, of ambulance provider that qualifies for restocking; (ii) the drugs or medical supplies included in the restocking program for each category; and (iii) the procedures for documenting the restocking, no new paperwork is required to qualify for safe harbor protection.

6. Publicly-Conducted restocking

Comment: Many commenters objected to the ''oversight entity'' condition included in the proposed rule. Among other things, commenters argued that mandating a regional oversight body would unduly burden local communities by requiring the creation of a significant infrastructure and layers of bureaucracy. Some commenters expressed concern that the proposed rule was unclear as to the scope of the oversight entities' responsibilities and that such a requirement could lead to logistical problems for entities that would have to develop, review and monitor contracts for all regional providers. In some places, this would entail oversight of more than 80 receiving facilities. A hospital association expressed concern that the term ''oversight'' could imply a regulatory, rather than strictly an oversight, role. Some commenters thought the proposed rule tasked oversight entities with responsibility for monitoring contractual arrangements over which they might have little control. Some commenters noted that coordinated EMS councils do not exist in all parts of the country, and, where they do operate, it would often not be realistic to expect them to oversee the restocking programs of many different hospitals and ambulance providers. Other commenters found the language regarding the composition of the oversight entity confusing and questioned whether particular parties, such as labor unions, could be participants in the oversight entities.

Response: We originally proposed protecting ambulance restocking arrangements that were part of a comprehensive and coordinated EMS delivery system to ensure that the safe harbor would protect *bona fide* restocking arrangements and not selective arrangements used to attract or reward referrals. To effectuate this requirement, we proposed that restocking arrangements be implemented with the participation of, and monitored by, a regional EMS council or comparable entity.

While we had intended the oversight entity condition to be broad and flexible in accordance with local conditions, encompassing a broad array of entities of various composition that were representative of their service areas, the comments made clear that many in the industry found the requirement burdensome. Accordingly, we have eliminated the oversight entity condition, and in its place we have substituted three flexible safe harbor conditions that we believe will provide sufficiently comparable protection from a safe harbor perspective. These include conditions that: (i) Require a publicly conducted restocking arrangement, (ii) require uniformity in the restocking arrangement, and (iii) prohibit restocking that takes into account the volume or value of referrals (other than the referral of the particular patient to whom the restocked drugs and medical supplies were furnished). These new requirements should effectively exclude improperly selective or preferential arrangements from safe harbor protection, while protecting those arrangements that are truly intended to promote the safe, efficient and effective delivery of pre-hospital EMS.

Comment: One commenter noted that requiring restocking arrangements to be part of a comprehensive regional EMS delivery plan was an important way to guarantee compliance on the part of providers.

Response: Participation in a comprehensive regional EMS delivery system is an effective means of ensuring that ambulance restocking arrangements further the public interest in timely, effective and efficient EMS and are not improperly targeted at high referrers. Under the final rule, restocking arrangements that are conducted in accordance with a protocol or plan established by an EMS council or comparable body will satisfy the public operation and disclosure requirements of the safe harbor and will likely satisfy the other safe harbor requirements as well.

Comment: One commenter suggested that, as an alternative to the oversight entity condition, the OIG require hospitals (i) to have written policies, approved by the governing board, stating that their restocking program is open to all emergency ambulance providers; and (ii) to develop an internal system to confirm and verify this arrangement.

Response: We have essentially adopted this commenter's views in the

final rule, although hospitals may limit the scope of their restocking programs to certain subcategories of ambulance providers. We are not requiring governing board approval or the development of internal compliance systems as part of this safe harbor regulation, but note that such practices may be prudent as part of the hospital's overall anti-fraud and abuse compliance program and necessary to ensure proper billing of the Federal health care programs.

Comment: One commenter urged that the proposed safe harbor conditions, especially the oversight entity condition, be eased for restocking arrangements in rural or isolated areas since ambulance providers in these areas have, in effect, no choice of where to deliver a patient.

Response: We believe the final rule, as modified, accommodates the special circumstances of rural and isolated areas. As stated above, we are no longer requiring establishment of an oversight entity. We believe the remaining safe harbor conditions are reasonable and impose few, if any, additional burdens on providers.

7. First responders

Comment: A commenter requested safe harbor protection for restocking for first responders. The commenter described the following situation:

> A search and rescue company delivers a patient to an ambulance that transports the patient to the hospital. The search and rescue company is restocked for supplies used on the patient by the ambulance transport provider, which, in turn, is restocked by the hospital. The hospital charges the patient for the restocked supplies.

Response: The final regulations protect hospital restocking of first responders as described by the commenter, provided the safe harbor conditions are satisfied. Specifically, the safe harbor accommodates those arrangements in which a 9–1–1 (or comparable emergency access number) first responder—including, but not limited to, a fire department, paramedic service or search and rescue squad—administers drugs or supplies to the patient, but does not transport the patient to the receiving facility. In these circumstances, the transporting ambulance provider may restock the first responder and then, in turn, be restocked by the hospital. Any billing by the hospital, the ambulance provider, or the first responder would be subject to the applicable Federal health care program payment and coverage rules and regulations. This safe harbor only addresses restocking by hospitals. Restocking of first responders by ambulance transport providers (independent of any hospital restocking) was outside the scope of the proposed rulemaking and is not addressed in these final regulations. Such arrangements must be analyzed on a case-by-case basis for compliance with the anti-kickback statute. Parties may seek an OIG advisory opinion about such arrangements.[10]

C. Fair Market Value Restocking

Comment: Several commenters raised concerns about the fair market value safe harbor's application to the transfer of drugs. As these commenters explained, many hospitals participating in EMS systems historically have ''owned'' the medication and supplies used by the ambulances on emergency transports without passing title to the ambulance provider. In many cases, the drugs are controlled substances under State laws and cannot be the property of a fire department or ambulance company. The commenters asserted that if title does not pass to the ambulance provider, then the hospital does not provide anything of value when it replaces the drugs on the ambulance. In addition, several commenters questioned how prescription drugs could be *sold* to ambulance providers by hospitals. One commenter stated that the Prescription Drug Marketing Act of 1987 (21 U.S.C. 353(c)) specifically forbids hospitals from re-selling prescription drugs, except under narrow circumstances.

Response: We agree that the fair market value safe harbor category should be restricted to the resale of supplies and non-prescription drugs (which are included as ''supplies'' under Medicare's ambulance payment system). Nothing in these regulations should be construed as permitting any action in contravention of applicable Federal, State, or local laws governing the purchase and administration of controlled substances and prescription medications. Whether the transfer of drugs that cannot be owned by an ambulance provider, and that remain the property of the hospital when placed on an ambulance in accordance with State or local law, is remuneration to the ambulance provider that administers the drugs in the field turns, in the first instance, on whether the drugs are covered under Medicare's ambulance benefit or under the outpatient hospital benefit in the particular circumstances. As noted above, questions regarding appropriate coverage and payment under Medicare should be directed to CMS.

Comment: A commenter expressed concern that the fair market value safe harbor would make it impossible for a hospital to provide the goods on a *pro bono* basis to a small volunteer ambulance service. The commenter believed the proposed safe harbor required facilities either to charge volunteer companies the same rates they charge commercial or municipal services or to charge no one.

Response: The commenter misread the proposed safe harbor. Nothing in these regulations precludes *bona fide* charitable contributions by hospitals to volunteer ambulance services. The fair market value safe harbor at § 1001.952(v)(3)(ii) does not require that a receiving facility charge all ambulance providers the same prices. Rather, the safe harbor protects those arrangements that are at fair market value. Arrangements that are not at fair market value, such as free or deeply discounted restocking to volunteer companies or others, may be protected instead under the general restocking safe harbor at § 1001.952(v)(3)(i).

Comment: One commenter was concerned that market power disparity among receiving facilities could affect the fair market value prices ambulance companies pay, in turn creating an incentive for ambulance providers to take patients to larger hospital systems in a position to negotiate volume discounts for their drugs and supplies and pass those discounts on to ambulance companies. The commenter suggested that the OIG add provisions to guard against this risk.

Response: In applying the fair market value condition, fair market value should be measured in terms of prices the ambulance provider would pay for like supplies if it purchased them in an arms-length transaction from a seller (other than a receiving facility) for whom the ambulance provider is not a potential referral source. In many situations, fair market value will be a range of prices, not a single price. (Restocking at prices that are below fair market value is not protected by this safe harbor category, although the restocking may be protected by one of the other restocking safe harbor categories.) We recognize that there may be a potential inducement when the fair market value charged is at the low end of the range of fair market value prices. However, nothing in the anti-kickback statute prohibits legitimate price competition.

Comment: Some commenters questioned the reference in the

[10] The procedures for applying for an advisory opinion are set forth at 42 CFR part 1008 and on the OIG Web site at *http://www.dhhs.gov/progorg/oig/advopn/index.htm.*

proposed fair market value safe harbor to the Non-Profit Institutions Act (NPIA), 15 U.S.C. 13(c). The proposed safe harbor would have protected certain sales of supplies at cost by non-profit hospitals to non-profit ambulance providers if the sales were designed to take advantage of the NPIA exception to the Robinson-Patman Act.[11] One commenter indicated that the proposed language did not appear to address the situation of a non-profit hospital reselling supplies to a ''for profit'' ambulance provider. Another commenter asserted that absent definitive guidance from the Federal Trade Commission (FTC) that reselling supplies to an ambulance provider would fit within 15 U.S.C. 13(c), hospitals would be wary about complying with the safe harbor condition.

Response: We have reconsidered the need for the language referencing the NPIA in the fair market value safe harbor. Given the substantial easing of the conditions applicable to the general restocking safe harbor category, we believe that the final regulations provide adequate and easily achievable protection for all legitimate restocking, whether at fair market value prices, below fair market value prices or without charge. To the extent it may be unclear whether a particular resale of supplies is at fair market value, we do not believe it will pose any undue burden on non-profit hospitals to seek shelter under the general restocking safe harbor category, which offers protection to restocking without regard to what price, if any, the hospital charges for the restocked drugs or supplies. The question whether particular restocking arrangements undertaken by non-profit hospitals run afoul of the Robinson-Patman Act or qualify for the NPIA exception is an FTC concern outside the scope of our regulatory authority.

IV. 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 have considered the criteria establishing in our notice of intent to develop regulations (61 FR 69061; December 31, 1996) in developing this final rule, and we believe, for the reasons described above, that these final safe harbor regulations for certain ambulance restocking arrangements is likely to: (1) 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) increase, or have no effect on, the quantity of services provided in underserved areas. We further believe that this safe harbor contains safeguards that limit the potential for overutilization and assure that patients retain their freedom of choice of service providers.

V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866, the Unfunded Mandates Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96–354). 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 effects, distributive impacts and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any given year). Since this regulation will not have a significant effect on program expenditures and as there is no additional substantive costs to implement the resulting provision, we do not consider this to be a major rule. The provisions in this rule are designed to permit individuals and entities to engage freely in competitive business practices and arrangements; health care providers and others may voluntarily seek to comply with these safe harbor provisions so that they have the assurance that their that business practices are not subject to any enforcement actions under the anti-kickback statute.

Additionally, in accordance with the Unfunded Mandates Reform Act of 1995, we believe that there are no significant costs associated with these 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 $110 million or more, adjusted for inflation, in any given year. Further, in reviewing this rule under the threshold criteria of Executive Order 13132, Federalism, we have determined that this rule will 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 SBREFA 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. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and Government agencies. Most hospitals (and most other providers) are small entities, either by nonprofit status or by having revenues of $5 million to $25 million or less annually. For purposes of the RFA, most ambulance companies are considered to be small entities. Individuals and States are not included in the definition of a small entity. In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural providers. This analysis must conform to the provisions of section 603 of the RFA.

While these safe harbor provisions may have an impact on small entities and rural providers, we believe that the aggregate economic impact of this rulemaking will be minimal, since it is the nature of the conduct 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 are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule does not have a significant impact on a substantial number of small entities, or a significant impact on the operations of a substantial number of small rural providers.

The Office of Management and Budget has reviewed this rule in accordance with Executive Order 12866.

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, §§ 1001.952(v)(2) and (v)(3) include information collection activities 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 information collection activities.

[11] 15 U.S.C. 13(a)–(f).

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

Summary of the collection of information: While complying with safe harbor provisions under the anti-kickback statute is voluntary, to qualify an ambulance restocking arrangement for safe harbor protection, parties must satisfy the following recordkeeping and disclosure requirements set forth in the regulations:

• The ambulance provider or the receiving facility must maintain for five years records documenting the replenished drugs and medical supplies, provide copies of such records to the other party within a reasonable period of time (unless the other party is separately maintaining records), and make the records available to the Secretary promptly upon request. These records may be in the form of pre-hospital patient care reports already in use for other purposes. *See* § 1001.952(v)(2)(ii)(A).

• Except for government-mandated or fair market value restocking, protected restocking arrangements must be conducted in an open and public manner. This condition may be achieved by posting a written disclosure notice at the receiving facility (with copies available to the public upon request) or by operating in accordance with a plan or protocol of general application promulgated by an EMS Council or comparable entity (with copies available to the public upon request). *See* § 1001.952(v)(3)(i)(B).

We have attempted to reduce any paperwork burden associated with compliance with these safe harbor regulations by permitting parties to utilize documentation produced or developed for other business purposes wherever possible, and we believe that most, if not all, of these recordkeeping requirements will be satisfied using such documentation. With respect to keeping and maintaining documentation of the restocking, most pre-hospital care reports (sometimes known as trip sheets or patient encounter reports) already maintained for other purposes, such as ensuring continuity of care and billing, will suffice. It is our understanding that the preparation of a pre-hospital care reports is the standard of care for transferring a patient to a receiving facility and is required by law in many States. However, parties may decide individually or between themselves to document restocking using other kinds of paper or electronic records. The five year record retention period is consistent with CMS's hospital conditions of participation.

With respect to the disclosure requirement, a written disclosure notice can take any reasonable form, and we anticipate that most parties engaged in ambulance restocking arrangements will have pre-existing materials that can be used for this purpose. For those who need or choose to produce a written disclosure notice, we have provided a short, sample disclosure form in these regulations. EMS Council plans and protocols are likely to be existing documents used to promote comprehensive and coordinated emergency medical services in local communities. These regulations do not require any drafting of new plans or protocols. Nothing in these regulations requires parties to draft or enter into contracts or written agreements. We expect that these regulations will result in few public requests for copies of disclosure notices or plans or protocols.

Brief description of the need for, and proposed use of, the information. The documentation and disclosure requirements set forth in these safe harbor regulations are necessary (i) to ensure that protected ambulance restocking arrangements pose a minimal risk of fraud or abuse and (ii) to enable parties to demonstrate—and the Government to verify where necessary—whether all safe harbor conditions are met.

Description of likely respondents and proposed frequency of response to the information collection request. The respondents for the collection of information described in these regulations are hospitals, other receiving facilities, and ambulance providers that participate in ambulance restocking arrangements and that want safe harbor protection under the anti-kickback statute. We believe that a significant number of hospitals, receiving facilities, and ambulance providers are engaged in, or desire to engage in, ambulance restocking arrangements and that many will want safe harbor protection. We do not anticipate any response that exceeds routine business practice.

Estimated burden that shall result from the collection of information. We are assigning only one burden hour to this collection, because we believe that compliance can be achieved with existing documents produced in the course of routine business practice.

In accordance with the PRA requirements, we are inviting comments on (1) whether the 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 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, thereby initiating the normal PRA clearance.

Comments on these information collection activities should be sent to the following address within 60 days following the **Federal Register** publication of this final rule:

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.

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 is amended as set forth below:

PART 1001—[AMENDED]

1. The authority citation for part 1001 continues 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 is amended by republishing the 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 replenishing.* (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 (or a first responder) in connection with the transport of a patient by ambulance to the hospital or other receiving facility if all of the standards in paragraph (v)(2) of this section are satisfied *and* all of the applicable standards in *either* paragraph (v)(3)(i), (v)(3)(ii) or (v)(3)(iii) of this section are satisfied. However, to qualify

under paragraph (v), the ambulance that is replenished must be used to provide emergency ambulance services an average of three times per week, as measured over a reasonable period of time. Drugs and medical supplies (including linens) initially used by a first responder and replenished at the scene of the illness or injury by the ambulance provider that transports the patient to the hospital or other receiving facility will be deemed to have been used by the ambulance provider.

(2) To qualify under paragraph (v) of this section, the ambulance replenishing arrangement must satisfy *all* of the following four conditions—

(i)(A) Under no circumstances may the ambulance provider (or first responder) and the receiving facility both bill for the same replenished drug or supply. Replenished drugs or supplies may only be billed (including claiming bad debt) to a Federal health care program by either the ambulance provider (or first responder) or the receiving facility.

(B) All billing or claims submission by the receiving facility, ambulance provider or first responder for replenished drugs and medical supplies used in connection with the transport of a Federal health care program beneficiary must comply with all applicable Federal health care program payment and coverage rules and regulations.

(C) Compliance with paragraph (v)(2)(i)(B) of this section will be determined separately for the receiving facility and the ambulance provider (and first responder, if any), so long as the receiving facility, ambulance provider (or first responder) refrains from doing anything that would impede the other party or parties from meeting their obligations under paragraph (v)(2)(i)(B).

(ii) (A) The receiving facility or ambulance provider, or both, must

(*1*) Maintain records of the replenished drugs and medical supplies and the patient transport to which the replenished drugs and medical supplies related;

(*2*) Provide a copy of such records to the other party within a reasonable time (unless the other party is separately maintaining records of the replenished drugs and medical supplies); and

(*3*) Make those records available to the Secretary promptly upon request.

(B) A pre-hospital care report (including, but not limited to, a trip sheet, patient care report or patient encounter report) prepared by the ambulance provider and filed with the receiving facility will meet the requirements of paragraph (v)(2)(ii)(A) of this section, provided that it documents the specific type and amount of medical supplies and drugs used on the patient and subsequently replenished.

(C) For purposes of paragraph (v)(2)(ii) of this section, documentation may be maintained and, if required, filed with the other party in hard copy or electronically. If a replenishing arrangement includes linens, documentation need not be maintained for their exchange. If documentation is not maintained for the exchange of linens, the receiving facility will be presumed to have provided an exchange of comparable clean linens for soiled linens for each ambulance transport of a patient to the receiving facility. Records required under paragraph (v)(2)(ii)(A) of this section must be maintained for 5 years.

(iii) The replenishing arrangement must not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program (other than the referral of the particular patient to whom the replenished drugs and medical supplies were furnished).

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

(3) To qualify under paragraph (v) of this section, the arrangement must satisfy *all* of the standards in *one* of the following three categories:

(i) *General replenishing.* (A) The receiving facility must replenish medical supplies or drugs on an equal basis for all ambulance providers that bring patients to the receiving facility in any one of the categories described in paragraph (v)(3)(i)(A)(*1*), (*2*), or (*3*) of this section. A receiving facility may offer replenishing to one or more of the categories and may offer different replenishing arrangements to different categories, so long as the replenishing is conducted uniformly within each category. For example, a receiving facility may offer to replenish a broader array of drugs or supplies for ambulance providers that do no not charge for their services than for ambulance providers that charge for their services. Within each category, the receiving facility may limit its replenishing arrangements to the replenishing of emergency ambulance transports only. A receiving facility may offer replenishing to one or more of the categories—

(*1*) All ambulance providers that do not bill any patient or insurer (including Federal health care programs) for ambulance services, regardless of the payor or the patient's ability to pay (i.e., ambulance providers, such as volunteer companies, that provide ambulance services without charge to any person or entity);

(*2*) All not-for-profit and State or local government ambulance service providers (including, but not limited to, municipal and volunteer ambulance services providers); or

(*3*) All ambulance service providers.

(B)(*1*) The replenishing arrangement must be conducted in an open and public manner. A replenishing arrangement will be considered to be conducted in an open and public manner if one of the following two conditions are satisfied:

(*i*) A written disclosure of the replenishing program is posted conspicuously in the receiving facility's emergency room or other location where the ambulance providers deliver patients and copies are made available upon request to ambulance providers, Government representatives, and members of the public (subject to reasonable photocopying charges). The written disclosure can take any reasonable form and should include the category of ambulance service providers that qualifies for replenishment; the drugs or medical supplies included in the replenishment program; and the procedures for documenting the replenishment. A sample disclosure form is included in Appendix A to subpart C of this part for illustrative purposes only. No written contracts between the parties are required for purposes of paragraph (v)(3)(i)(B)(*1*)(*i*) of this section; or

(*ii*) The replenishment arrangement operates in accordance with a plan or protocol of general application promulgated by an Emergency Medical Services (EMS) Council or comparable entity, agency or organization, provided a copy of the plan or protocol is available upon request to ambulance providers, Government representatives and members of the public (subject to reasonable photocopying charges). While parties are encouraged to participate in collaborative, comprehensive, community-wide EMS systems to improve the delivery of EMS in their local communities, nothing in this paragraph shall be construed as requiring the involvement of such organizations or the development or implementation of ambulance

replenishment plans or protocols by such organizations.

(*2*) Nothing in this paragraph (v)(3)(i) shall be construed as requiring disclosure of confidential proprietary or financial information related to the replenishing arrangement (including, but not limited to, information about cost, pricing or the volume of replenished drugs or supplies) to ambulance providers or members of the general public.

(ii) *Fair market value replenishing.* (A) Except as otherwise provided in paragraph (v)(3)(ii)(B) of this section, the ambulance provider must pay the receiving facility fair market value, based on an arms-length transaction, for replenished medical supplies; and

(B) If payment is not made at the same time as the replenishing of the medical supplies, the receiving facility and the ambulance provider must make commercially reasonable payment arrangements in advance.

(iii) *Government mandated replenishing.* The replenishing arrangement is undertaken in accordance with a State or local statute, ordinance, regulation or binding protocol that requires hospitals or receiving facilities in the area subject to such requirement to replenish ambulances that deliver patients to the hospital with drugs or medical supplies (including linens) that are used during the transport of that patient.

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

(i) A *receiving facility* is a hospital or other facility that provides emergency medical services.

(ii) An *ambulance provider* is a provider or supplier of ambulance transport services that provides emergency ambulance services. The term does not include a provider of ambulance transport services that provides only non-emergency transport services.

(iii) A *first responder* includes, but is not limited to, a fire department, paramedic service or search and rescue squad that responds to an emergency call (through 9–1–1 or other emergency access number) and treats the patient, but does not transport the patient to the hospital or other receiving facility. 47

(iv) An *emergency ambulance service* is a transport by ambulance initiated as a result of a call through 9–1–1 or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient and available at the receiving facility.

(v) *Medical supplies* includes linens, unless otherwise provided.

3. A new appendix A is added to subpart C to read as follows:

Appendix A to Subpart C of Part 1001

The following is a sample written disclosure for purposes of satisfying the requirements of § 1001.952(v)(3)(i)(B)(*1*)(*i*) of this part. This form is for illustrative purposes only; parties may, but are not required to, adapt this sample written disclosure form.

Notice of Ambulance Restocking Program

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers (other than ambulance providers that do not provide emergency services) that bring patients to Hospital X [or to a subpart of Hospital X, such as the emergency room] in the following category or categories: [insert description of category of ambulances to be restocked, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and Government ambulance providers]. [Optional: We only offer restocking of emergency transports.]

2. The restocking will include the following drugs and medical supplies, and linens, used for patient prior to delivery of the patient to Hospital X: [insert description of drugs and medical supplies, and linens to be restocked].

3. The ambulance providers [will/will not] be required to pay for the restocked drugs and medical supplies, and linens.

4. The restocked drugs and medical supplies, and linens, must be documented as follows: [insert description consistent with the documentation requirements described in § 1001.952(v). By way of example only, documentation may be by a patient care report filed with the receiving facility within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.]

5. This restocking program does not apply to the restocking of ambulances that only provide non-emergency services or to the general stocking of an ambulance provider's inventory.

6. To ensure that Hospital X does not bill any Federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any Federal health care program. Participating ambulance providers must agree to work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.

7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.

8. For further information about our restocking program or to obtain a copy of this notice, please contact [name] at [telephone number].

Dated: _____

/s/ _____

Appropriate officer or official

Dated: July 12, 2001.

Michael F. Mangano,

Acting Inspector General.

Approved:

Tommy G. Thompson,

Secretary.

[FR Doc. 01–29875 Filed 12–3–01; 8:45 am]

BILLING CODE 4150–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 76

[FCC 01–345]

Implementation of Interim Filing Procedures for Certain Commission Filings

AGENCY: Federal Communications Commission.

ACTION: Temporary procedural requirements.

SUMMARY: In this document, the Commission amends its procedures on an emergency, interim basis to require the filing or refiling of certain documents electronically (*i.e.*, by facsimile or e-mail), by overnight delivery, or by hand delivery to the Commission's Capitol Heights, Maryland location. Due to recent events in Washington, DC, resulting in the unforeseeable and understandable disruption of regular mail delivery and of the processing of other deliveries, the Commission is unable to confirm receipt of certain Commission filings that may affect processing of applications and other urgent agency business. The intended effect of this action is to continue the timely processing of applications and other urgent agency business.

EFFECTIVE DATE: December 4, 2001.

FOR FURTHER INFORMATION CONTACT: Magalie Roman Salas at 202–418–0303.

SUPPLEMENTARY INFORMATION: This *Order,* adopted November 21, 2001, and released November 29, 2001, will be available for public inspection during regular business hours at the FCC Reference Information Center, Room CY–A257, at the Federal Communications Commission, 445 12th St., SW., Washington, DC 20554. The complete text is available through the Commission's duplicating contractor: Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail at qualexint@aol.com.