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Anthony M. Wylie,

Acting Area Director, Alaska Flight Services Operations.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305, and 1307

[Docket No. DEA-108F]

RIN 1117-AA19

Definition and Registration of Reverse Distributors

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is finalizing, without change, the interim rule with Request for Comment published in the **Federal Register** July 11, 2003 at 68 FR 41222. The interim final rule amended Title 21, Code of Federal Regulations, parts 1300, 1301, 1304, 1305 and 1307 to define the term "reverse distributor" and establish a new category of registration for persons handling controlled substances. The amendments established the regulatory standards under which reverse distributors may handle unwanted, unusable, or outdated controlled substances acquired from another DEA registrant. These standards ensure the proper documentation and recordkeeping necessary to prevent diversion of such controlled substances to illegal purposes. This final rule makes these changes permanent.

DATES: *Effective Date:* May 2, 2005.

FOR FURTHER INFORMATION CONTACT:

Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:

Overview of and Benefits of the Interim Final Rule

On July 11, 2003 (68 FR 41222), the Drug Enforcement Administration (DEA) published an interim final rule to define the term "reverse distributor" and to establish a new category of registration for persons handling controlled substances. The interim final rule mostly codified existing practices that reverse distributors follow under memoranda of understanding (MOUs) with DEA. This approach is consistent

with the comments received on the Notice of Proposed Rulemaking (NPRM) (60 FR 43732, August 23, 1995) that stated that reverse distributors would be significantly and adversely impacted if, as was proposed, they were classified as manufacturers. In recognizing this activity as a separate registration category of distributors, DEA believes the entire controlled substances industry will benefit. Reverse distributors previously operating under MOUs are becoming fully recognized registrants under DEA rules. Thousands of other registrants who need to dispose of unneeded or outdated inventories are now able to turn to a fully registered group of distributors. Furthermore, by essentially codifying existing practices these benefits are being achieved with minimal need for change or for disruption to the affected industry.

Because of the length of time since the NPRM was published and the evolving nature of this industry, DEA used an interim final rule to give an additional opportunity for comment. DEA has considered the comments received on the appropriateness and the practical application of these rules to current industry practice. The comments are discussed below.

Background

The overall goal of the Controlled Substances Act (CSA) and of DEA's regulations in Title 21, Code of Federal Regulations (CFR), Parts 1300-1316 is to provide a closed distribution system so that a controlled substance is at all times under the legal control of a person registered, or specifically exempted from registration, by the Drug Enforcement Administration until it reaches the ultimate user or is destroyed. DEA achieves this goal by registering manufacturers, distributors, importers, exporters, and dispensers of controlled substances as well as analytical laboratories and researchers. Thus, any movement of controlled substances between these registered persons is covered by DEA regulations, which ensure that all controlled substances are accounted for from their creation until their dispensing or destruction.

When a controlled substance has become outdated or otherwise unusable, the registrant who possesses the substance must dispose of it. However, over the past decade, environmental concerns and regulatory changes have caused drug manufacturers and government agencies (including DEA and State authorities) to become increasingly reluctant to be involved in the disposal process. Thus, some disposal options are no longer available.

Nonetheless, disposal of controlled substances can occur in several ways:

1. The distributor or dispenser can return the controlled substance to the pharmaceutical manufacturer who, as a service to its customers, accepts returns of outdated/damaged controlled substances. Distributors, dispensers, and manufacturers are all registered with DEA.

2. The distributor, dispenser, or manufacturer can itself dispose of the controlled substances under the procedures outlined in 21 CFR 1307.21.

Under 21 CFR 1307.21, any person may request permission to dispose of controlled substances without the benefit of a DEA or State witness. In many cases, blanket permission for disposal of controlled substances is granted to registrants who have an ongoing need to dispose of unwanted controlled substances. DEA must authorize the disposal in writing and may require that a set schedule be established. Other registrants are granted disposal authority on a case-by-case basis. DEA normally requires that the registrant provide two designated responsible individuals to accompany the drugs to the disposal site and witness the destruction. This achieves DEA's goal of ensuring the controlled substances are rendered nonrecoverable. Disposal under the authority of 21 CFR 1307.21 maintains the closed distribution system because the controlled substances remain under the legal control of a registrant at all times.

3. The distributor, dispenser, or manufacturer can distribute the controlled substances to a reverse distributor to take control of the controlled substances for the purpose of returning them to the manufacturer or, if necessary, disposing of them.

For many years, DEA opposed granting DEA registrations to firms solely or primarily engaged in the disposal (whether the transportation portion, actual disposal, or both) of controlled substances because they were not considered an essential link in the closed distribution system that the Controlled Substances Act established to control the flow of drugs from the manufacturer to the ultimate user. In recent years, however, increasingly stringent requirements imposed by the U.S. Environmental Protection Agency (EPA) resulted in fewer and fewer approved disposal facilities. As a result, a new type of business developed that collects controlled substances from registrants and either returns them to the manufacturer or arranges for their disposal. The businesses performing this middleman service refer to

themselves as “reverse distributors” or “returns processors.”

The interim final rule dealt only with the distribution of controlled substances to reverse distributors. The first two categories—direct returns of controlled substances by distributors or dispensers to manufacturers, and disposals by the distributor, manufacturer or dispenser—are already covered by the existing rules. Only the third category, *i.e.*, persons who distribute controlled substances to reverse distributors, was not expressly covered by the regulations, although DEA regulated reverse distributors for many years under the terms of Memoranda of Understanding (MOUs), through which they were granted DEA registrations as distributors. The interim final rule eliminated the need for MOUs. However, since the interim final rule essentially codified existing DEA policies and practices, it did not impose any significant additional burden on reverse distributors.

On August 23, 1995, DEA issued a Notice of Proposed Rulemaking (NPRM) (60 FR 43732) that proposed regulatory standards governing disposers of controlled substances. DEA proposed to accomplish this by amending its regulations to define the term “Disposer” to account for this middleman function in the regulations and establish a new category of manufacturer registration under which persons performing this function would be registered. DEA also proposed amending the regulations to exempt disposers from the quota requirements; to identify the records and reports required of disposers; and to establish order form procedures for disposers. Finally, DEA proposed amendments to a number of gender-specific sections to make them gender neutral.

DEA originally based its decision to define the persons performing the reverse distribution function as disposers on the definition of “manufacturer.” In 21 CFR 1300.01(b)(27), DEA defines manufacture in part as “the producing, preparation, propagation, compounding, or processing of a drug or other substance * * *.” The section further defines a manufacturer as “a person who manufactures a drug or other substance * * *.” In the proposed rule, DEA stated that by its nature, a disposer processes a drug or other substance. Therefore, DEA proposed to place disposers within the definition of manufacturer, under a new disposer subcategory. Commenters to the proposed rule objected to being categorized as disposers and manufacturers for the reasons explained

in the Interim Final Rule preamble. Therefore, in the interim final rule, DEA established a definition for “reverse distributor” and established a new category of registration as reverse distributors.

Even before the interim final rule was published, DEA issued certificates of registration as distributors to persons performing the reverse distribution function. Since reverse distributors were not specifically identified in the regulations, DEA entered into a Memorandum of Understanding (MOU) with the person performing the reverse distribution function. DEA did not experience any difficulties in treating reverse distributors as distributors for purposes of registration and other requirements. Any reverse distributor that was registered under the terms of a MOU must be reregistered as a reverse distributor under the terms of the interim final rule in the next renewal cycle and will be specifically identified in DEA’s records as a reverse distributor. Persons currently conducting reverse distribution operations must notify DEA by no later than the time of renewal of their registration so that they may be properly identified as reverse distributors in DEA’s records.

The requirements for a reverse distributor in the interim final rule are similar to those imposed on all registrants at the distributor level. They include, but are not necessarily limited to:

- **Security:** All applicants must install, at the registered premises, physical security controls that meet the existing standards of 21 CFR 1301.71 and 1301.72.

- **Recordkeeping:** In accordance with 21 CFR part 1304, periodic inventories and records of all controlled substances received, destroyed, or returned to the original, registered manufacturers must be maintained for two years. The registrant must adequately describe the receipt and accountability methods and records to be employed to ensure the establishment of effective controls against diversion.

- **Order Forms** must be completed for all Schedule I and II items prior to their transfer to the reverse distributor. Only after the order form has been received by the reverse distributor may the controlled substances be transferred.

- **Reports** are required under the Automation of Reports and Consolidated Orders System (ARCOS), as specified in 21 CFR 1304.33.

In addition to DEA requirements, reverse distribution applicants must obtain the appropriate State and Federal

approvals for controlled substances and disposal activities.

Public Comments on the Interim Final Rule

Five comments were received regarding the interim final rule. Commenters included reverse distributors, waste management companies, and a distributor’s association. The following discussion summarizes the issues raised by commenters and DEA’s response to these issues.

Reverse Distributor Receipt of Controlled Substances From Non-Registrants.

Three commenters addressed the issue of whether reverse distributors should be allowed to receive controlled substances from non-registrants.

One commenter believed that DEA should create uniform regulations for the management and destruction of controlled substances that a reverse distributor receives from a non-registrant. The commenter asserted that the procedure recommended in the preamble to the interim final rule could lead to inconsistencies because procedures for such transactions would be developed with various DEA offices.

Alternatively, the commenter suggested that a non-registrant and a reverse distributor be allowed to: “(1) create a destruction plan for a waste controlled substance and (2) communicate that plan in writing to the local DEA office, the non-registrant and the reverse distributor can implement that destruction plan if no objection is received from the DEA office within ten business days of the submittal.” The commenter also suggested a procedure to be followed if the DEA office did object.

A second commenter stated that the procedure for dealing with this issue described in the interim final rule “is fundamentally flawed in the protection of both the public and our environment.” The commenter stated that its studies have shown that a majority of long term care facilities and nursing homes are improperly accounting for and disposing of their controlled substances, indicating that sewage is a primary means of disposal and that EPA has concluded that improper disposal results in contamination. The commenter proposed an amendment to the interim final rule that would allow exceptions for reverse distributors. It stated that its proposal “allows for Reverse Distributors to account and dispose of controlled substances from non-registrants so long as the Return

Distributor obtains written approval from the DEA if certain conditions are met." The commenter recommended that the conditions "would consist of an internal system of accountability, Standard Operational Procedures, and archiving of records for two (2) years."

While specifically addressing the definition of "reverse distributor," the third commenter discussed the issue of a reverse distributor receiving controlled substances from a non-registrant. The commenter stated that the definition "will have significant, negative environmental concerns and increase the opportunity for controlled substances to be diverted."

The overall thrust of the commenter's comments and of its recommended changes related to the problem of a reverse distributor receiving controlled substances from a non-registrant. The commenter requested that the reverse distributor definition be modified to allow reverse distributors to receive controlled substances not only from another DEA registrant, but also from any person lawfully in possession of a controlled substance. The commenter also requested that § 1307.12 be modified to allow this. According to the commenter:

The requested change will allow a reverse distributor to provide proper disposal and documentation of controlled substances for patient medications from legal entities such as dispensers and Long Term Care Facilities which is currently the accepted practice by and in many States as a standard option of destruction with the approval of the DEA (see attached California Department of Health Services March 5, 1999, letter to California Long Term Care Facilities {and related patient-care entities} Item #3).

DEA Response: DEA addressed the issue of whether reverse distributors can receive controlled substances from non-registrants in the preamble to the interim final rule (68 FR 41226) and on several other occasions. The issue arises because most long term care facilities are not DEA registrants. In a notice document published in 2001 (66 FR 20833, April 25, 2001) and in a follow up notice of proposed rulemaking published in 2003 (68 FR 62255, November 3, 2003), DEA proposed to address the issue under the title, "Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities" (LTCFs).

DEA's position is that because LTCFs are not registrants they may not transfer controlled substances to either the pharmacy from which they came or to a reverse distributor, or any other registrant for disposal. The LTCF must dispose of the excess controlled substances directly. DEA's position is

based on the fact that controlled substances in the possession of a LTCF are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability. As stated in the interim final rule preamble, "In cases where long term care facilities must dispose of controlled substances, they should follow the guidelines within their State for disposing of the drugs and maintain appropriate documentation of the disposal."

DEA's position has not changed although, as noted, DEA has issued an NPRM that would attempt to address the problem by allowing registered pharmacies to operate automated dispensing systems at LTCFs; these systems allow single dosage dispensing, reducing the amount of drugs that become waste.

Definitions

One commenter supported the new definition as written.

A second commenter suggested adding a new definition of "employee" to make clear which persons are allowed to witness a destruction event under new language in 21 CFR 1304.11(e). The commenter believed that a definition is necessary because of what it described as past liberal interpretation within the industry that has led to the use of "destruction plant personnel and other people that are not gainfully employed by the reverse distributor registrant."

DEA Response: DEA does not agree that a definition of "employee" is needed. DEA is using the word as defined in a typical dictionary which means that persons who are not actually employed by the registrant reverse distributor would not be eligible to perform the witness function during the destruction.

Registration Process

While supporting the reverse distributor registration process as a whole, one commenter expressed some concern about companies doing business as both types of distributors without fully disclosing the extent of their return or disposal business when partnering with another dispensing distributor. The commenter stated that if its interpretation is correct, namely that a company involved in both distributing and reverse distributing will need to register independently as a distributor and reverse distributor, that DEA should add clarifying language to the rule.

A second commenter stated that public notice should exist, just as it does for the importers, exporters, and manufacturers.

DEA Response: Under current regulations, any registrant is allowed to distribute (i.e., return) a controlled substance to the distributor or manufacturer from which the registrant originally obtained that controlled substance without needing a separate registration as a distributor. This type of transaction is considered to be a normal business transaction. However, any registrant that obtains returns from someone they did not distribute to for the purpose of returning the controlled substances to the manufacturer or for disposal must obtain a separate registration as a reverse distributor.

DEA intends to use the same registration process for reverse distributors as it does for distributors because of the similarities between distribution and reverse distribution, rather than the process used for manufacturers, importers, and exporters. Therefore, DEA does not agree that a public notice requirement is appropriate for reverse distributors.

Reporting and Recordkeeping; ARCOS Reporting

One commenter recommended that the reverse distributor reporting requirement be limited to Schedules I and II and that reverse distributors not be required to report any controlled substance received for destruction that is outside the DEA closed system of distribution.

A second commenter recommended adding "an ARCOS transaction code that would accurately document Destruction in lieu of a Sale." The commenter also noted that "a DEA Form requires that in order for the substance to be replaced, the manufacturer must now ask for Additional, quota (sic) instead of Replacement Quota." The commenter further suggested that recordkeeping should be augmented to require National Drug Code (NDC) numbers, as NDC numbers are required for ARCOS and other recordkeeping.

The commenter also expressed concern that using a reverse distributor could have impact on a manufacturer's ability to obtain more quota. The commenter requested that DEA clarify that there will be no impediments in obtaining replacement or additional quotas when using the services of a Reverse Distributor and when actual evidence of proper destruction is provided.

DEA Response: DEA agrees that distribution by a manufacturer to a reverse distributor for destruction could be recorded as a disposal and not a sale. However, DEA also needs complete ARCOS records of all transactions by reverse distributors so no change is

being made in the reporting requirements.

Regarding replacement quotas needed by manufacturers of controlled substances, DEA will evaluate such needs based on the registrant's authorized procurement quota and information submitted to DEA regarding destruction of a manufacturer's controlled substances by a reverse distributor. To evaluate and process requests for replacement quotas, DEA requires the following documentation regarding destruction of controlled substances from the registered manufacturer requesting the replacement quota:

(1) A completed copy of the DEA Form 222 "U.S. Official Order Form for Schedule I and II Controlled Substances" showing the transfer of controlled substances from the registered manufacturer to a reverse distributor.

(2) A copy of the completed DEA Form 41 "Registrant's Inventory of Drugs Surrendered" with the corresponding destroyed by and witness by signatures. The reverse distributor provides the DEA Form 41 to the registered manufacturer documenting the surrender and disposal of the controlled substances.

Replacement quota does not count against a registrant's procurement quota; however these materials must be acquired in the same calendar year the replacement quota is granted.

Disposal and Destruction of Controlled Substances

One commenter stated that DEA should require registrants to use a Reverse Distributor to destroy controlled substances because registrants who dispose of their own controlled substances have the ability to influence their destruction records and because there is not an arm's length relationship. The commenter asserted that "Validation exists at every other step in the closed-loop system DEA has established, except for this very step."

The commenter also believed that listed chemicals should require the same recordkeeping and destruction requirements as controlled substances since DEA has indicated that listed chemicals have become an increased source of diversion into illicit markets.

Another commenter stated that DEA's use of the terms "dispose, disposal, disposer" and "destruction" appears to be interchangeable throughout the preamble and that this could inadvertently lead to mishandling of controlled substances. The commenter urged DEA to clarify that "only those disposal methods that permanently

destroy the controlled substance are allowable forms of destruction." The commenter stated that all technologies other than incineration should require approval of DEA's Drug and Chemical Evaluation Section.

The commenter also believed that DEA should make it clear that at no point during the loading, unloading, or destruction process should the controlled substances be left unattended by either of the two Registrant employees.

DEA Response: In general, the intent of the final rule is to codify the concept of a reverse distributor with minimal change from standard business practices of other distributors and with minimal change from practices under the MOUs that have worked well for many years. DEA does not have any justification for mandating delivery of controlled substances to reverse distributors whether for return to a manufacturer or for destruction.

Listed chemicals are subject to a totally different set of requirements and any changes to those requirements would be outside of the scope of this rulemaking.

With respect to the "permanent destruction" of controlled substances, DEA believes that destruction under the terms of current 21 CFR 1307.21 is consistent with the goals stated by the commenters. While DEA does not require incineration, other methods designed to render a controlled substance unusable, while acceptable, may trigger a more intense review by DEA or subject the disposer to the requirements of other agencies, such as EPA.

Summary

In summary, the registration and other requirements for reverse distributors under the interim final rule are the same as those currently imposed on distributors and the same as previously imposed on reverse distributors under MOUs, *i.e.*, registration requirements under existing 21 CFR 1301.13; security requirements under existing 21 CFR 1301.71 and 1301.72; recordkeeping requirements under existing 21 CFR 1304.22; reporting requirements under existing 21 CFR 1304.33 (ARCOS reports); and order form requirements under existing 21 CFR 1305.08 (Persons entitled to fill order forms). In some cases these rules have been modified to apply specifically to reverse distributors, including inventory requirements under existing 21 CFR 1304.11. In addition, DEA amended 21 CFR 1307.11 and 1307.12 to clarify that registrants can transfer ("distribute") controlled substances to a reverse

distributor, even if the registrant is not registered as a distributor.

The closed system of distribution established under the CSA for controlled substances relies on certain fundamental principles, including registration, security, and accountability (*i.e.*, inventories, recordkeeping, and reporting), to achieve a system of controls that allows for legitimate commerce while minimizing the potential for diversion. The fact that reverse distributors engage in a unique activity within the controlled substances chain and are faced with certain challenges that other registrants do not normally encounter does not override the fundamental principles of DEA's controls. Reverse distributors must register, provide security, and maintain accurate records for all controlled substances in their possession. However, the regulatory structure does provide some flexibility and, where possible, DEA has made adjustments to address some of the problems the industry has encountered, including use of a separate category of registration and application of the inventory requirements for dispensers and researchers.

Regulatory Certifications

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including making this rule effective upon the date of publication. DEA finds good cause to make this rule effective upon publication, as this Final Rule merely confirms existing regulatory requirements implemented as part of the Interim Rule published July 11, 2003 at 68 FR 41222.

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. Therefore, no regulatory flexibility analysis is required. This rule finalizes, without change, an Interim Final Rule which mostly codified existing practices that reverse distributors followed under memoranda of understanding (MOUs) with DEA. DEA drafted the interim rule partly in response to concerns by reverse distributors that they would be significantly and adversely impacted if they were classified as manufacturers. In recognizing reverse distributors as a separate registration category of

distributors, DEA believes the entire controlled substances industry will benefit. Reverse distributors previously operating under MOUs are becoming fully recognized registrants under DEA rules. Thousands of other registrants who need to dispose of unneeded or outdated inventories are now able to turn to a fully registered group of distributors. Furthermore, by essentially codifying existing practices these benefits are being achieved with minimal need for change or for disruption to the affected industry.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). DEA has determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget.

Executive Order 12988

The Deputy Assistant Administrator further certifies that this regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$115,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the

ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

The Interim Final Rule amending Parts 1300, 1301, 1304, 1305, and 1307 of Title 21, Code of Federal Regulations, which was published in the **Federal Register** on July 11, 2003 at 68 FR 41222, is hereby adopted as a Final Rule without change.

Dated: April 26, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 05-8692 Filed 4-29-05; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AM11

Elimination of Copayment for Smoking Cessation Counseling

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: This interim final rule amends the Department of Veterans Affairs (VA) medical regulations concerning copayments for inpatient hospital care and outpatient medical care. This rule designates smoking cessation counseling (individual and group sessions) as a service that is not subject to copayment requirements. The intended effect of this interim final rule is to increase participation in smoking cessation counseling by removing the copayment barrier.

DATES: Effective Date: May 2, 2005.

Comments must be received on or before July 1, 2005.

ADDRESSES: Written comments may be submitted by: Mail or hand-delivery to Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; fax to (202) 273-9026; e-mail to VAregulations@mail.va.gov; or, through <http://www.Regulations.gov>. Comments should indicate that they are submitted in response to "RIN 2900-AM11." All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 273-9515 for an appointment.

FOR FURTHER INFORMATION CONTACT: Eileen P. Downey, Program Analyst, Policy Development, Chief Business

Office (16), (202) 254-0347 or Dr. Kim Hamlet-Berry, Director, Public Health National Prevention Program, Veterans Health Administration, 810 Vermont Avenue NW., Washington, DC 20420, (202) 273-8929. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: Smoking is the leading preventable cause of morbidity and mortality in the United States, with a 43 percent higher prevalence of smoking among veterans than in the comparable general population, based on age- and gender-comparisons. Many veterans, particularly WWII and Korean War era veterans began smoking in the military as cigarettes were routinely provided as part of K-rations. Veterans who receive their health care in the VA represent the subgroups that have the highest prevalence of smoking, notably individuals from lower socioeconomic levels, substance abuse populations, and individuals with psychiatric disorders. The prevalence of smoking has continued to be very high among these groups despite substantial decreases in smoking in the general population.

The prevalence of smoking among VA's population is costly. In 2003, the Veterans Health Administration (VHA) conducted an analysis of the costs and benefits of the current copayment for smoking cessation. The analysis revealed that smoking-related illnesses account for up to 23.81 percent of total health care costs in VA. Treatment of smoking and prevention of smoking-related illnesses is likely to continue to be a public health priority for VA in the future. The 2003 Department of Defense Survey of health-related behaviors among active military personnel noted the first increase in rates of smoking since 1980, with rates at or approaching the prevalence of smoking in VA populations.

Smoking cessation is effective and has been cited in medical literature as the gold standard for cost-effectiveness among medical/preventive interventions, second only to routine immunizations of children. Significant medical literature suggests the copayments can serve as a barrier to accessing counseling for smoking cessation. Both the 2000 U.S. Public Health Service Guidelines on Smoking Cessation and the Centers for Disease Control and Prevention Task Force on Community Preventive Services strongly recommend reduction or elimination of out-of-pocket expenses for smoking cessation services.

Given the clinical challenges facing the VA population, the cost of smoking-related illness, the effectiveness of