

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From Peminic Inc. dba The Peminic-Greeley PSO

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Delisting.

SUMMARY: AHRQ has accepted a notification of voluntary relinquishment from Peminic Inc. dba The Peminic-Greeley PSO of its status as a Patient Safety Organization (PSO). The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), Public Law 109-41, 42 U.S.C. 299b-21—b-26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule), 42 CFR part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, including when a PSO chooses to voluntarily relinquish its status as a PSO for any reason.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight E.T. (2400) on September 13, 2011.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.AHRQ.gov/index.html>.

FOR FURTHER INFORMATION CONTACT: Susan Grinder, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety Rule to implement the Patient Safety

Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule (PDF file, 450 KB. PDF Help) relating to the listing and operation of PSOs. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs. AHRQ has accepted a notification from Peminic, Inc. dba The Peminic Greeley PSO, PSO number P0006, to voluntarily relinquish its status as a PSO as a result of its merger with Verge Solutions, LLC. Accordingly, the Peminic, Inc. dba The Peminic Greeley PSO was delisted effective at 12:00 Midnight ET (2400) on September 13, 2011. A component of Verge Solutions, LLC sought and received a new listing as Verge Patient Safety Organization, P0118, which became effective on September 14, 2011.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Dated: October 28, 2011.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-240]

Public Meeting and Request for Information: Carcinogen and Recommended Exposure Limit (REL) Policy Assessment

AGENCY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting and request for public comments.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) announces a public meeting to review its approach to classifying carcinogens and establishing recommended exposure limits (RELs) for occupational exposures to hazards associated with cancer. NIOSH requested initial input on these issues (including answers to five questions listed below under **SUPPLEMENTARY**

INFORMATION), to be submitted to NIOSH Docket number 240. Written comments to this Docket will be accepted until December 30, 2011. Written comments submitted to the docket will be used to inform NIOSH with the review and revision of the carcinogen policy and the REL policy. NIOSH has also created a new NIOSH Cancer and REL Policy Web Topic Page [see <http://www.cdc.gov/niosh/topics/cancer/policy.html>] to provide additional details about this effort and progress updates.

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DATES: *Date and Time:* December 12, 2011, 9 a.m.—4 p.m., Eastern Time. Please note that public comments may end before the time indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend the meeting at the start time listed.

Place: Hubert H. Humphrey Building, Room 800, U.S. Department of Health and Human Services (HHS), 200 Independence Avenue SW., Washington, DC 20201.

Status: The meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 135 people. In addition, there will be an audio conference for those who cannot attend in person. There is no registration fee to attend this public meeting. However, those wishing to attend are encouraged to sign up by November 28, 2011 with the contact person in this notice.

Security Considerations: Due to mandatory security clearance procedures at the Hubert H. Humphrey Federal Building, in-person attendees must present valid government-issued picture identification to security personnel upon entering the building and go through an airport-type security check.

Non-U.S. citizens are encouraged to participate in the audio conferencing due to the extra clearance involved with in-person attendance. To attend in person, a non-U.S. citizen will have to call or send an email before November 28, 2011, to the contact person in this

notice, and provide passport information. If clearance is received, you will be notified; otherwise, you will not be able to attend the meeting in person.

Attendee and Speaker Registration: Attendees are encouraged to sign up by November 28, 2011 with the contact person in this notice. Individuals wishing to speak during the meeting may sign up when registering with the contact person. Those who have not signed up to present in advance may be allowed to present at the meeting if time allows.

Agenda: The meeting will begin with a brief introduction by Federal officials, followed by discussions focused on each of five questions related to the NIOSH Cancer and RELs policies (See **SUPPLEMENTARY INFORMATION, II. Matters to Be Discussed**). The intent of the meeting is to engage stakeholders and members of the public in discussions of the relevant issues pertaining to review and assessment of NIOSH Cancer (Carcinogens) and RELs policies. Following these discussions, time has been set aside for presentations from attendees who register to speak. Each speaker will be limited to five minutes in order to maximize the number of presentations during the meeting. If all registered presentations are made before the end time, there will be an open session to receive comments from anyone who has not signed up on the speaker registration list who may wish to speak. Open session comments will also be limited to five minutes per person. After the last speaker or at 3:50 p.m., whichever occurs first, there will be brief closing comments by Federal officials and the meeting will be adjourned.

For Registration Information Contact: Karen Dragon or Sherri Diana (513) 533-8611, NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, facsimile (513) 533-8285, E-mail nioshdocket@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

NIOSH and stakeholders have expressed concerns recently about limitations in the NIOSH Carcinogen Policy, prompting NIOSH to initiate a review of the carcinogen policy in 2010. A major limitation in the policy is the use of the term "Potential Occupational Carcinogen" which dates to the 1980 OSHA hazard classification for carcinogens outlined in 29 CFR 1990.103 and is defined as "* * * any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant

neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals." A major limitation of this definition is that the policy allows for only one cancer category, which is "potential occupational carcinogen." The adjective "potential" conveys uncertainty that is not warranted with many carcinogens such as asbestos, benzene, and others. This policy does not allow for classification on the basis of the magnitude and sufficiency of the scientific evidence. In contrast, other organizations, such as the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) allow for a more differential classification. The revision of the NIOSH Carcinogen Policy also coincides with the international realization that there is a need for more efficient and quicker means of classifying chemicals. Qualitative and semi-quantitative approaches such as hazard banding are increasingly being investigated as a means of addressing the vast numbers of unregulated chemicals. NIOSH has been in collaboration with various organizations to consider utilizing hazard banding approaches to control chemicals. This will also be reflected in the review of the carcinogen and RELs policies.

It is anticipated that NIOSH will develop a report on the revised NIOSH Carcinogen and REL Policies to be made available in 2012. Additional information regarding NIOSH plans to assess and revise the Carcinogen and REL Policy can be found in the April 2011 NIOSH e-news at <http://www.cdc.gov/niosh/enews/enewsV8N12.html> and on the NIOSH Cancer and REL Policy Web Topic Page [see <http://www.cdc.gov/niosh/topics/cancer/policy.html>].

II. Matters To Be Discussed

Input from the public is sought on each of the five questions listed below pertaining to the NIOSH Cancer (Carcinogens) and RELs policies.

(1) Should there explicitly be a carcinogen policy as opposed to a broader policy on toxicant identification and classification (e.g., carcinogens, reproductive hazards, neurotoxic agents)?

(2) What evidence should form the basis for determining that substances are carcinogens? How should these criteria correspond to nomenclature and categorizations (e.g., known, reasonably anticipated, etc.)?

(3) Should 1 in 1,000 working lifetime risk (for persons occupationally exposed) be the target level for a recommended exposure limit (REL) for carcinogens or should lower targets be considered?

(4) In establishing NIOSH RELs, how should the phrase "to the extent feasible" (defined in the 1995 NIOSH Recommended Exposure Limit Policy) be interpreted and applied?

(5) In the absence of data, what uncertainties or assumptions are appropriate for use in the development of RELs? What is the utility of a standard "action level" (i.e., an exposure limit set below the REL typically used to trigger risk management actions) and how should it be set? How should NIOSH address worker exposure to complex mixtures?

III. Transcript

A transcript will be prepared and posted to NIOSH Docket number 240 within 30 days after the meeting. Each person making a comment will be asked to give his or her name and affiliation, and all comments (including their name and affiliation) are considered to be in the public domain, and the transcript will be archived in the NIOSH Docket and posted on a public Web site.

You may submit comments, identified by docket number NIOSH-240 by any of the following methods:

- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

- **Facsimile:** (513) 533-8285.

- **Email:** nioshdocket@cdc.gov.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available within 30 days of the closing date on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: T.J. Lentz, telephone (513) 533-8260, or Faye Rice, telephone (513) 533-8335, NIOSH, MS-C32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Dated: November 9, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2011-29700 Filed 11-16-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0802]

Role of Naloxone in Opioid Overdose Fatality Prevention; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in collaboration with the Office of the Assistant Secretary for Health, National Institutes of Drug Abuse, and the Centers for Disease Control and Prevention, is announcing a scientific workshop to initiate a public discussion about the potential value of making naloxone more widely available outside of conventional medical settings to reduce the incidence of opioid overdose fatalities. Academia, government, industry experts, and patient advocates will be assembled to discuss which populations are at risk for opioid overdose and how public health groups are working together to curb the abuse of opioids. We will also seek to identify potential health concerns, social concerns, legal concerns, regulatory issues, and future research needs related to making naloxone more widely available.

Date and Time: The public workshop will be held on April 12, 2012, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm 1503), Silver Spring, MD 20993-0002.

Contact Person: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, (301) 796-3519, Mary.Gross@fda.hhs.gov; or Matthew Petcovic, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, (301) 796-5242, Matthew.Petcovic@fda.hhs.gov.

Registration: If you wish to attend the public workshop or provide testimony

during the open public hearing, please email your registration to CDER_Naloxone_Workshop@fda.hhs.gov by March 28, 2012. Those without email access may register by contacting one of the persons listed in the *Contact Person* section of this document. Please provide complete contact information for each attendee; including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the public workshop will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm277119.htm>.

An open public hearing will be held between 2:45 p.m. and 3:45 p.m. on April 12, 2012, during which speaker testimony will be accepted. We will try to accommodate all persons who wish to testify; however, the duration of each speaker's testimony during this open public hearing may be limited by time constraints. Those wishing to participate in the open public hearing should limit their remarks to a discussion of the advantages and/or disadvantages to making naloxone more easily accessible to patients outside of conventional medical settings.

Comments: Submit either electronic or written comments by June 12, 2012. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is necessary to send only one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

If you need special accommodations due to a disability, contact Mary Gross or Matt Petcovic (see *Contact Person*) at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

I. Introduction

The number of prescriptions filled for opioid pain relievers has increased dramatically in recent years. Nearly 257 million prescriptions for opioid drugs were written in the United States in 2009 alone and the increased availability to prescription opioid drugs appear to be contributing significantly to abuse and the potential for overdose

in the United States. In the United States, mortality rates closely correlate with opioid sales. In 2007, approximately 36,034 people died from unintentional overdoses. At least 14,459 of these deaths involved prescription opioid analgesics. Moreover, according to the Substance Abuse and Mental Health Services Administration, the number of Americans in 2009 aged 12 and older currently abusing pain relievers has increased by 20 percent since 2002. Naloxone, a mu-opioid antagonist, is an injectable medicine that can rapidly reverse the overdose of either prescription (e.g., OxyContin) or illicit (e.g., heroin) opioids. It is currently the standard treatment for those who overdose on opioid drugs, but is most commonly used only by trained medical personnel in emergency departments and on ambulances. The purpose of this public workshop is to discuss the issues around making naloxone more widely available. This includes work to expand its use through the development of novel formulations as well as work to potentially support its use by individuals other than the trained medical personnel currently authorized to use it.

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm277119.htm>.

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be made available. It will be accessible at <http://www.regulations.gov>, and may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville MD 20857.

Dated: November 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.
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