

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Food and Drug Administration

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[Docket No. 2007N-0179]

Implementation of Risk Minimization Action Plans (RiskMAPs) to Support Quality Use of Pharmaceuticals: Opportunities and Challenges; Public Workshop

AGENCIES: Agency for Healthcare Research and Quality; Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) and the Food and Drug Administration (FDA) are announcing a 2-day joint public workshop entitled "Implementation of Risk Minimization Action Plans (RiskMAPs) to Support Quality Use of Pharmaceuticals: Opportunities and Challenges." This public workshop is intended to seek constructive input from a wide range of stakeholders, including clinicians, pharmacists, patients, third party payers of care, the pharmaceutical and biotechnology industries, researchers, and innovators in health information technology (HIT), to help in the development and implementation of mechanisms to minimize the risks of pharmaceuticals with unusual safety and patient monitoring concerns. This meeting is an initial step that is part of FDA's commitment to monitor the performance of RiskMAPs consistent with the goal articulated in the proposed PDUFA IV agreement to undertake regular follow up of these plans.

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DATES: The public workshop will be held on June 25 and 26, 2007, from 8:30 a.m. to 5 p.m. See section III of this document for information on deadline and on how to register to attend or present at the meeting.

We are opening a docket to receive your written or electronic comments. Written or electronic comments must be submitted to the docket by July 31, 2007.

ADDRESSES: The public workshop will be held at the Agency for Healthcare Research and Quality (AHRQ), 540 Gaither Rd., John M. Eisenberg Bldg., Rockville, MD 20850. Submit electronic comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm*. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5392, FAX: 301-827-4312, e-mail: *Coralee.Lemley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Risk minimization action plans (RiskMAPs) are safety programs designed to minimize significant risks of a product by using one or more risk minimization tools. A variety of risk minimization tools have been used; these tools are broadly categorized as follows: (1) Education and outreach tools intended to inform patients and healthcare practitioners (HCPs) about a product's risks and measures that should be taken to prevent or mitigate the

risks; (2) Reminder systems intended to prompt or guide HCPs and/or patients in prescribing, dispensing, or using a product in ways that minimize risk; and (3) performance-linked access (PLA) systems that link product access to required laboratory testing or other documentation. The latter two categories have exhibited some success in minimizing risk, but may lead to disruptions in medical and pharmacy practice and unintended consequences, such as obstructing patient access to a product's benefits. It is the latter two tool categories (Reminder and PLA systems) that are the primary focus of this workshop. The following are a few of the products with Reminder or PLA systems: Isotretinoin (iPLEDGE), Thalidomide (STEPS), and Tysabri (TOUCH).

The workshop objectives are as follows: (1) Initiate constructive dialogue and information-sharing among regulators, researchers, and organizations and individuals affected by RiskMAP programs, particularly those using Reminder and PLA systems; (2) share key lessons learned about how to design and implement effective risk management systems to accommodate and promote quality healthcare and pharmacy practices; and (3) explore how tools being actively developed (such as electronic prescribing and integrated electronic health and medical records) and used to support high-quality, evidence-based practice may improve the development of RiskMAPs where Reminder and PLA systems are used or being considered for use.

Panel discussions as well as stakeholder presentations and testimony will focus on implementation strategies using Reminder and PLA systems to promote appropriate behavior changes to optimize patient outcomes, autonomy, access, cost, and logistics while reducing drug risks. We invite presentations that suggest ways to mitigate drug safety risks by improving healthcare system processes or emerging health information technologies.

Examples might include linkages of electronic prescribing to laboratory or to patient electronic health records designed to improve the effectiveness of risk minimization efforts.

AHRQ and FDA are working together to refine the conference agenda and invite speakers. The agenda will be made available at <http://www.fda.gov/cder/meeting/riskMAPs.htm> not later than June 15, 2007. We are seeking broad participation by physicians, pharmacists, patients, health care quality and safety researchers, health systems officials, and payers of care. We anticipate issuing a summary of the conference findings, including a discussion of implications and next steps for further research or regulatory guidance development.

II. Comments

The agency is interested in hearing comments at the public workshop or receiving written comments (see **ADDRESSES**) on the following issues:

(1) Based on the diversity of experiences of different groups in implementing existing Reminder and PLA system RiskMAPs, what lessons have been learned that can be applied to future programs in the following areas:

- Minimizing risks;
- Maintaining provider and patient access to therapeutic choices;
- Minimizing burdens on the healthcare system;
- Being compatible with diverse technologies and settings of care;
- Avoiding adverse unintended consequences.

(2) How can healthcare information technology be used to assist quality prescribing, dispensing, and patient use to improve the effectiveness of RiskMAPs for drugs with risks where Reminder and PLA systems are used or

likely to be used? How might HIT solutions be pursued and applied in light of the underdeveloped use of this technology in healthcare?

(3) How might professional organizations, third party payers of care, and others support the appropriate use of medications with processes or requirements such as those used with Reminder and PLA system RiskMAPs?

(4) Who are the relevant stakeholders in healthcare to involve in the design and choice of risk minimization tools? How can these stakeholders be best engaged in meaningful and productive partnerships and collaborations?

(5) Which activities and research should be pursued to develop a strong evidence base of healthcare system approaches, processes, and tools that support appropriate use of medications with safety problems where Reminder and PLA RiskMAPs are being used or considered for use?

(6) What partnerships will support evaluations of effectiveness of RiskMAPs or pilot interventions to minimize risk and promote appropriate medication prescribing, dispensing, and use?

(7) What future actions should AHRQ and FDA take to promote continued collaborations and contributions to the high-quality, appropriate use of medications with RiskMAPs?

III. Registration

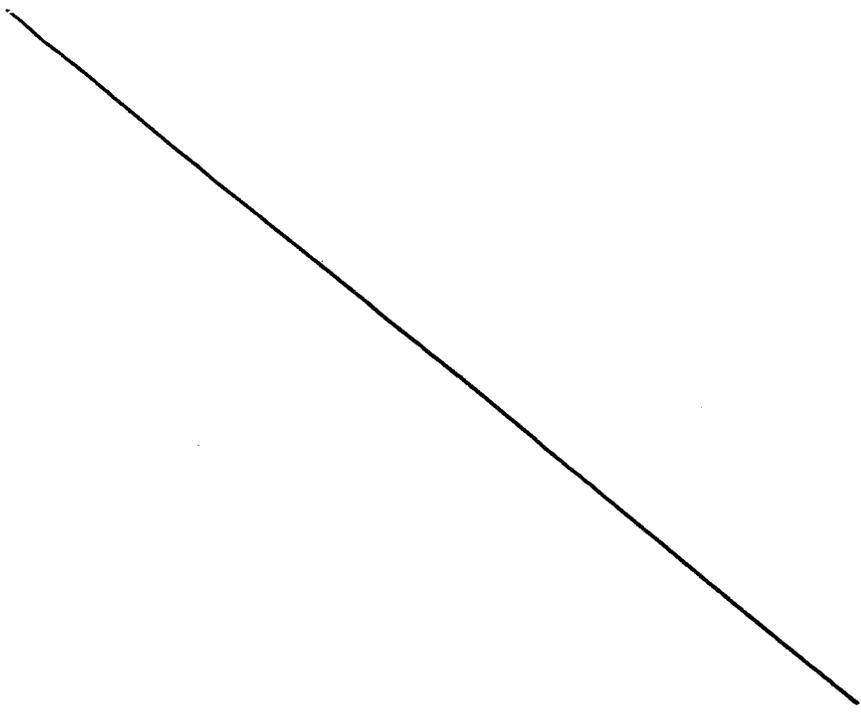
The AHRQ Conference Center is a Federal facility with limited seating and security procedures for entrance. For these reasons, pre-registration is necessary for all attendees. Registration is available on a first-come basis. Individuals who wish to speak during the open public hearing must register on or before June 8, 2007; all other attendees must register on or before June 15, 2007. To register, contact register@consolidatedsafety.com or call 703-877-3345.

Ample time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage written comments to the docket.

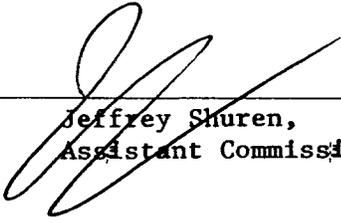
If you need special accommodations because of disability, please contact Lee Lemley (see **CONTACT FOR FURTHER INFORMATION**) at least 7 days before the workshop.

IV. Workshop Transcripts

The workshop will be transcribed. The transcript will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 30 days after the workshop.



Dated: 5/10/07
May 10, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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Dated: _____

Carolyn Clancy

SR
5-18-07

Carolyn Clancy,
Director,
Agency for Healthcare Research and Quality,
Department of Health and Human Services.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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[Signature]