

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[CMS-1307-CN]

RIN 0938-ZA74

**Medicare Program; Criteria and Standards for Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2006; Correction Notice****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Correction notice.

**SUMMARY:** This document corrects technical errors that appeared in the general notice with comment period published in the **Federal Register** on September 23, 2005 entitled "Medicare Program; Criteria and Standards for Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2006."

**EFFECTIVE DATE:** This correction is effective October 1, 2005.

**FOR FURTHER INFORMATION CONTACT:** Richard Johnson, (410) 786-5633.

**SUPPLEMENTARY INFORMATION:****I. Background**

In FR Doc. 05-18923 of September 23, 2005 (70 FR 55887), there were technical errors that are identified and corrected in the Correction of Errors section below.

**II. Correction of Errors**

In FR Doc. 05-18923 of September 23, 2005 (70 FR 55887), make the following corrections:

1. On page 55887, in the third column, second paragraph, lines 2 and 3, the date "October 24, 2005" is corrected to read "October 1, 2005."

2. On page 55888, in the first column, first paragraph, lines 2 through 4, the phrase "beginning on the first day of the first month following publication of this notice in the **Federal Register**" is corrected to read, "October 31, 2005'.

3. On page 55888, in the first column, fourth paragraph, lines 5 and 6, the Web site address "or to <http://www.regulations.gov>" is deleted.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 26, 2005.

**Jacquelyn Y. White,***Director, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 2005D-0385]

**Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Guidance for Industry: Using Electronic Means to Distribute Certain Product Information," dated September 2005. The draft guidance explains that persons can distribute certain product information, such as for recalls and drug safety, by electronic means. We encourage the use of electronic communications for conveying all such important product safety information. We are making clear in this draft guidance that manufacturers may disseminate communications by e-mail or other electronic methods.

**DATES:** Submit written or electronic comments on the draft guidance by November 29, 2005, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Policy (HF-11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 301-827-3360. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jarilyn Dupont, Office of Policy (HF-

11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

**SUPPLEMENTARY INFORMATION:****I. Background**

The timely dissemination of communications about recalls of FDA regulated products, important drug safety information, and other important product safety information is essential for the protection of the public health. We have encouraged manufacturers to provide such information in a timely manner to distributors, doctors, and others. Over the years, we have worked with manufacturers to promote the use of electronic methods of communication and encourage the use of innovative technologies to disseminate safety information, particularly those that provide a public health benefit. We are making clear in the draft guidance that manufacturers may disseminate the communications discussed in §§ 7.49 and 200.5 (21 CFR 7.49 and 200.5) by e-mail or other electronic methods. The draft guidance also applies to those instances, not addressed in any regulation, where we recommend that manufacturers and distributors voluntarily convey certain safety information about their products to members of the public.

The use of e-mail and other electronic communications has dramatically changed how we and the public convey information. Electronic communications have a number of advantages over paper-based communications. They can significantly shorten the time between an event and the public's knowledge of the event. When the event involves product safety, it is even more important that accurate safety information be transmitted rapidly. E-mail and other electronic communications are generally considered more efficient and more timely than regular or traditional mail. These communications involve considerably less cost to the sender than older, more traditional delivery services. Verification of receipt or delivery is less expensive and can be automatically accomplished. Any necessary followup (such as when receipt of the e-mail is not acknowledged) also can be accomplished electronically. If receipt is never acknowledged, the sender can resort to more traditional methods of notification.

We interpret the provisions of §§ 7.49 and 200.5 to allow the use of e-mail and other electronic communication methods, such as fax or text messaging, to accomplish any recall notification or distribution of important safety information. Section 7.49(b) provides