



INLAND EMPIRE HEALTH PLAN

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

October 4, 2010

Reminder: Criteria for Compounded Prescriptions

Dear IEHP Healthcare Provider,

This letter is being sent to you as a reminder of Inland Empire Health Plan's (IEHP) criteria for all compounded prescriptions. IEHP requires that all requests for compounded prescriptions be submitted to IEHP Pharmaceutical Services including **BOTH** a completed Pharmacy Exception Request (PER) form enclosed and a copy of the prescription. All requests will be reviewed according to the guidelines listed below:

1. The product contains at least one prescription or one formulary over-the-counter (OTC) ingredient; AND
2. The compounded product is **NOT** a copy of commercially available FDA-approved drug product; AND
3. The compounded product does **NOT** have a commercially available alternative for the prescribed indication; AND
4. The safety and effectiveness of use for the prescribed indication is supported by FDA-approval or adequate medical and scientific evidence in the medical literature.

As a reminder, the FDA considers virtually all compounded drugs as unapproved new drugs for which safety and efficacy have not been demonstrated with the type of data the FDA requires to approve a new drug. However, the FDA also considers "traditional compounding" to be a valuable service and does not take enforcement action against these practices. The FDA defines traditional compounding as any customization of a drug; for example, compounding a liquid dosage form specifically for a younger patient. Providers should discuss with their patients in detail whether the use of compounded medications in lieu of FDA-approved and clinically tested products is indeed the best option for their specific medical needs.

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A Public Entity



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Patients or practitioners who encounter problems (e.g. adverse drug events, etc.) with compounded products are asked to file a MedWatch report with the FDA at:

Telephone 800-332-1088, or

Fax 800-FDA-0178, or

Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or

Via the Internet: www.fda.gov/medwatch

In order to expedite the process, Healthcare Providers (i.e. Physicians, Nurses, Physician Assistants) may submit PERs for compounded prescriptions directly by fax to IEHP Pharmaceutical Services at (909) 890-2058. If the request is approved, IEHP will facilitate with locating a qualified IEHP Pharmacy Provider capable of compounding the prescription.

If you have any questions or comments, please feel free to contact us at (909) 890-2067.

Sincerely,

IEHP Pharmaceutical Services

Enclosure: