**Section 2085.35 Research Order Blanks for Dispensing Delta-9-THC Capsules**

a) The hospital pharmacy may dispense delta-9-THC upon presentation of a "Research Order for Delta-9-Tetrahydrocannabinol Medication" signed by a physician who:

1) Has a current DEA registration and Illinois Controlled Substances number;

2) Has registered with the pharmacy by filing a Form FDA-1573 and has been approved by the participating pharmacy, the Department, the Illinois Department of Law Enforcement, and NCI;

3) Affirms that the patient consent form has been signed by the patient;

4) Limits the use of the drug to the indications outlined in the Guidelines;

5) Will report adverse drug reactions on Form FD 1639-a to the Investigational Drug Branch of the NCI and the Department; and

6) Has met all other requirements imposed by the NCI as set forth in the Mechanism.

b) Procedure for Filling a Research Order for Medication:

1) delta-9-THC medication may be dispensed only pursuant to a "Research Order for Delta-9-THC Medication" issued by the Department. All Research Order Forms for delta-9-THC medication shall be written in duplicate. The following items of information are on a valid research order:

A) The name, address and zip code of the hospital pharmacy.

B) The pharmacy DEA registration number.

C) The patient's full name, address and zip code.

D) The date of issuance.

E) The period of time covered by the research order:

AGENCY NOTE: The Research Order expiration date represents the period of time for which the THC has been dispensed to the participating patient. The Research Order expiration and the lot expiration date need not always be the same. The lot expiration date represents the period of time for which NCI states the THC to be effective.

F) The name, strength, quantity and lot number of the drug.

G) The directions for use.

H) The name of the person (other than the patient) to whom the drug may have given on behalf of the patient, if anyone.

I) Confirmation of informed patient consent.

J) The signature of the prescribing physician.

K) The DEA registration number and the Illinois Controlled Substances registration number of the prescribing physician.

L) Confirmation that the physician is registered with the hospital to prescribe delta-9-THC.

AGENCY NOTE: A samples research order form is attached as Exhibit C.

2) For outpatient treatment, if any of the above items are missing, the Research Order is to be considered invalid and is not to be filled. For inpatient treatment, the pharmacist shall, upon receipt of a completed physician order (the written order of a physician as required for controlled substances by law and current hospital procedures pursuant to Section 313 of the Illinois Controlled Substances Act (Ill. Rev. Stat. 1981, ch. 56½, par. 1313)) complete the Research Order and fill it. When filled by the pharmacy for inpatient treatment, the physician and patient signatures are not required on the Research Order Form. The informed consent form must be completed by both inpatients and outpatients.

3) The hospital pharmacy, at the time of presentment of a Research Order and prior to filling shall include on the Research Order, the date of filling, confirmation of the prescribing physician's affiliation with the hospital, the signature of person to whom the medication is delivered, the method used to verify the identification of the recipient and the signature of the dispensing pharmacist.

4) Partial filling of a quantity ordered pursuant to the Research Order shall constitute a completed order for recordkeeping purposes.