



UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

1880 Regal Row
Dallas, Texas 75239
October 23, 1979

Mr. Don Jones, Vice President
The Owen Company
8181 Commerce Park Drive, Suite 786
Houston, Texas 77036

Dear Mr. Jones:

On August 15, 1979, a meeting was held at the office of the Texas State Board of Pharmacy with representatives from the Texas State Board of Pharmacy, Texas Department of Public Safety, the Drug Enforcement Administration, and independent pharmaceutical management firms, to discuss the handling of controlled substances by the independent pharmaceutical firms in a hospital situation.

During the meeting it was determined that the hospital would have overall responsibility as it relates to controlled substances. A sample Overall Hospital Responsibility Agreement form was given to each representative to use as a guide. Each was asked to take the form back to their offices for review and then to let the Drug Enforcement Administration's Dallas office know their feeling as it pertains to the proposed agreement.

As of October 16, 1979, we have received several responses from independent management firms. The majority of the responses favored the agreement and stated that they would utilize it.

* { At that meeting you were advised by Program Manager James D. Flewellen that in the month of September 1979 he would be attending a Program Managers Conference to be held at El Paso, Texas. Mr. Flewellen did meet with the other program managers from the other four DEA regions and did discuss the Overall Hospital Responsibility Agreement. The agreement was accepted by the other program managers as well as by officials from the DEA Headquarters Washington office.

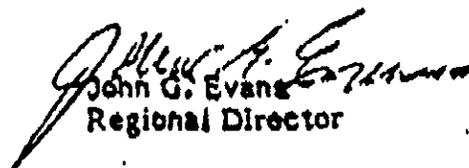
Therefore, as discussed at the Austin, Texas, meeting the Overall Hospital Responsibility Agreement will be utilized by independent pharmaceutical management firms in the states (within the South Central Region) where permitted by state law.

The states that are located within the South Central Region are as follows:

Texas, Oklahoma, Arizona, New Mexico, Colorado, Utah, Wyoming.

If you have any questions please contact Mr. Flewellen, Regional Compliance Program Manager, at telephone number 214/767-7121.

Sincerely,


John G. Evans
Regional Director



HOSPITAL OVERALL RESPONSIBILITY

1. Owen Healthcare, Inc. under the terms of the current Pharmacy Services Agreement, is responsible for furnishing complete pharmacy services required by the HOSPITAL. HOSPITAL, with Owen Healthcare's assistance and cooperation, is responsible for obtaining all necessary Local, State and Federal licenses and permits required for the operation of the hospital and/or pharmacy. Power of Attorney will be issued to Owen Healthcare by HOSPITAL for purposes of ordering and purchasing controlled substances on behalf of HOSPITAL. However, HOSPITAL agrees to assume overall responsibility for the hospital premises, including hospital pharmacy.

2. In assuming overall responsibility for the record keeping and security of controlled substances, HOSPITAL shall delegate to Owen Healthcare through its pharmacist in charge, the responsibility for maintaining proper record keeping and security requirements for controlled substances as required by applicable State, Local and Federal laws. Owen Healthcare agrees to undertake every reasonable effort to ensure compliance with such record keeping and security requirements. If such compliance is impossible for reasons beyond its control, Owen Healthcare shall immediately notify HOSPITAL of the fact and the reasons thereof.

3. The HOSPITAL shall be responsible for ensuring that Owen Healthcare is maintaining proper record keeping and security of controlled substances within the hospital premises and the hospital pharmacy. Periodically, the HOSPITAL shall review and evaluate the record keeping and security of controlled substances and make appropriate recommendations to HOSPITAL'S administration.

Hospital

Authorized Hospital Signature

Date

For Owen Healthcare



U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

OCT 29 2009

John A. Gilbert, Jr.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Dear Mr. Gilbert:

This is in response to your letter dated September 30, 2009, re: DEA Registration for Hospitals Outsourcing Inpatient Pharmacy Operations, in which you inquired about the applicable Drug Enforcement Administration ("DEA") registration requirements for hospitals that outsource management of their inpatient pharmacy services. In your letter you stated that Cardinal Health Pharmacy Services ("CHPS"), a subsidiary of Cardinal Health, Inc., provides hospital pharmacy management services under a contractual arrangement with client hospitals for over 200 hospital pharmacies in 42 states.

You stated that based on your experience, DEA has traditionally considered the party having control and physical possession of controlled substances to be the entity that holds the DEA registration and, therefore, responsible for compliance with DEA laws and regulations. You further stated that in dealing with outsourced hospital pharmacy management situations, DEA's prior guidance to the industry has indicated that if the contractual agreement between the management company and the hospital clearly delineates that the hospital maintains overall responsibility for controlled substances, the hospital would retain the DEA registration.

You stated that one of CHPS models for managing hospital pharmacies includes a financial arrangement whereby CHPS takes title to the drugs even though the drugs remain within and under the control of the hospital. The hospital would order the drugs under its DEA registration number for delivery to the hospital pharmacy and CHPS would obtain title to the drugs as a financial arrangement between CHPS and the hospital only, which would alleviate the hospital's burden of inventory carrying costs. You further state that the maintenance, possession and control of the controlled substances in the hospital would remain the responsibility of the hospital and the hospital would have control over the hospital pharmacy and also the personnel within it.

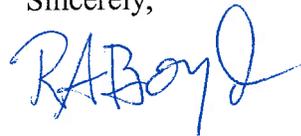
Given the information you have provided and the fact that the hospital will be ultimately responsible for the possession, maintenance, oversight, and overall control of the controlled substances and responsible for compliance with applicable federal laws and regulations, then DEA is in agreement with your position. A separate controlled substance registration would not be required for CHPS while under contract with a DEA registered hospital, provided a contractual agreement between the hospital and the management company for the hospital pharmacy exists, clearly defining

the hospital as the overall responsible party for controlled substances for the facility.

Furthermore, DEA will hold ultimate liability for such controlled substances to be the responsibility of the registered hospital.

If you require any further assistance with this matter, please contact me at (202) 307-4925.

Sincerely,

A handwritten signature in blue ink that reads "RABoyd". The signature is written in a cursive, slightly slanted style.

Richard A. Boyd, Chief
Registration and Program Support
Office of Diversion Control

Rule §291.74

(a) Licensing requirements.

(1) A Class C pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(2) If the institutional pharmacy is owned or operated by a hospital management or consulting firm, the following conditions apply.

(A) The pharmacy license application shall list the hospital management or consulting firm as the owner or operator.

(B) The hospital management or consulting firm shall obtain DEA and DPS controlled substance registrations that are issued in their name, unless the following occurs:

(i) the hospital management or consulting firm and the facility cosign a contractual pharmacy service agreement which assigns overall responsibility for controlled substances to the facility; and

(ii) such hospital pharmacy management or consulting firm maintains dual responsibility for the controlled substances.