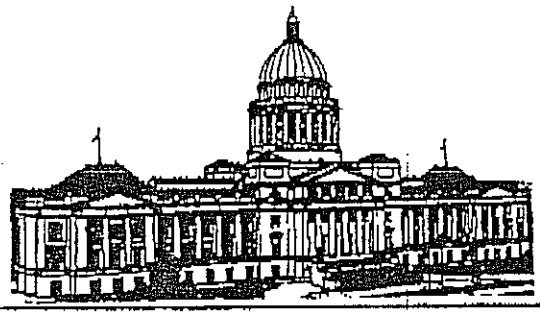
ARKANSAS REGISTER

Transmittal Sheet



Sharon Priest
Secretary of State
State Capitol Room 017
Little Rock, AR 72201-1094

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Name of Agency ARKANSAS STATE BOARD OF PHARMACY

Department

Contact Person John T. Douglas, P.D.

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REGULATION 33 & 34

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CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted In Compliance with Act 434 of 1967 As Amended.

John T Douglas P.D.
Signature

EXECUTIVE DIRECTOR
Title

July 17, 1997
Date

FILED
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SHARON PRIEST
SECRETARY OF STATE
STATE OF ARKANSAS
BY

33. REGULATING THE USE OF ELECTRONIC DATA PROCESSING IN LIEU OF PRESENT RECORD KEEPING SYSTEMS IN PHARMACIES HOLDING PHARMACY PERMITS

A. These regulations shall be construed, if possible, so as not to be violative of or in conflict with any federal regulation or requirement and if any part hereof is held invalid because of such conflict such invalidity shall not affect other provisions or applications of these regulations which can be given effect without the invalid provisions and to this end, the provisions of these regulations are declared severable. In any event D.E.A. permission to use Electronic Data Processing record keeping systems must be obtained.

B. The Arkansas State Board of Pharmacy must approve system prior to implementation.

C. Input of drug information into system may be performed only by a pharmacist or pharmacy technician under the supervision of a pharmacist. The final verification of prescription information, into the computer, shall be made by the supervising pharmacist who is then totally responsible for all aspects of the data and data entry. Any judgmental decision concerning patient utilization of drugs must be performed by a pharmacist.

D. The original prescription order must be numbered, dated, initialed or signed by dispensing pharmacist at the time of the first filling of the prescription order and filed according to regulation.

E. Any electronic data processing system must be capable of the following:

1. Must provide on-line retrieval (CRT or hard copy) of original prescription order information. This shall include, but not be limited to, the following:
   a. Original prescription order number, date filled; full name and address of patient; name, address and DEA number (if applicable) of practitioner.
   b. Trade name (or generic name and manufacturer's name), strength, dosage form and quantity of drug dispensed.
   c. Number of authorized refills or, if not refillable, it must be so indicated.
2. Must provide on-line retrieval (CRT or hard copy) of refill history of each prescription order to include in addition to information in parts a and b, subsection 1 above, but not limited to the following:
   a. Initials or code designation of dispensing pharmacist for each refill.
   b. Date refilled.
   c. Number of authorized refills remaining.

3. A. Must provide daily hard copy printout of each day's prescription order activity to include but not limited to the following:

a. Date of record.

b. Prescription order number, patient's name, name of drug, quantity dispensed and dosage form of drug, practitioner's name and DEA number (if applicable), and dispensing pharmacist's designation or initials on each prescription.

c. Above record shall be verified and signed by each pharmacist each day who has filled or refilled one or more prescriptions.

The signature should appear at the end of the printout and it signifies that the pharmacist has reviewed the printout and accepts the responsibility for any prescription with his or her designation or initials on it.

d. Daily log may be replaced by monthly log containing same information. This information must be maintained at pharmacy for a period of two years.

e. Any pharmacy employing a computerized system must have above printout in its possession in 48 hours.

f. Any electronic data processing system must also assure strict confidentiality of patient records.

g. All required information must be entered on the records of all prescription orders filled at the pharmacy including nonrefillable prescriptions.

h. Must be capable of producing a patient profile (CRT or hard copy) indicating all drugs being taken and dates of refills for the patient.

i. A pharmacy shall make arrangements with supplier of data processing services or materials to assure continuing adequate and complete prescription orders and dispensing records. If for any reason the relationship with said supplier terminates, the pharmacy shall assure the continuity of records.

j. Registrants holding a Hospital Pharmaceutical Services Permit shall comply with Regulation No. 34 "Regulating the use of electronic data processing in lieu of present record keeping systems in Hospital Pharmacies holding Hospital Pharmacy Permits."

B. In lieu of signing a daily hard copy printout, the pharmacist in charge of the pharmacy may maintain a bound log book in which an individual pharmacist involved in such dispensing may sign a statement each day, attesting to the fact that the

prescription information entered into the computer that day has been reviewed by him and is correct as shown. The log should identify the time of day at which the pharmacist started filling prescriptions and the time of day at which the pharmacist stopped filling prescriptions. Said log book shall be maintained, by the pharmacist in charge or his successor, in the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized prescription. The pharmacy must still provide a daily hard copy printout of each day's prescription order activity as described in 33. E. 3. (A) above.

4. Must be capable of providing a refill-by-refill audit trail for any specific strength and dosage form of any drug in the system to contain but not limited to the following:
   a. Practitioner's name.
   b. Name and address of patient.
   c. Name of drug (must include manufacturer's name if generic name used).
   d. Quantity dispensed on original and each refill.
   e. Prescription order number.
   f. Initials or code designation of dispensing pharmacist on original and each refill.
   g. Date of original and each refill.
   h. Above printout must be made available within 48 hours after authorized request.
5. If the pharmacy closes, the pharmacist in charge, at the date of closing, shall store said records and within 14 days of closing shall notify the Board of Pharmacy where said records are located. A hard copy printout of any daily log(s) shall be produced and made available to the Board on its request and to any other person authorized by law to examine or receive copies of prescription records.
6. In event of computer breakdown (down time), the pharmacy must have an approved auxiliary record keeping system. This system must contain all necessary information to insure prompt data entry into system as soon as computer is available. 10/09/80

34. REGULATING THE USE OF ELECTRONIC DATA PROCESSING IN LIEU OF PRESENT RECORD KEEPING SYSTEMS IN HOSPITAL PHARMACIES HOLDING HOSPITAL PHARMACY PERMITS.

In accordance with the Drug Enforcement Administration's final ruling June 30, 1977, which allows a pharmacy to use a data processing system as an additional manner of storing and retrieving prescription refill information for Schedule III and IV controlled substances, the following proposed regulation is submitted to regulate the use of Electric Data Processing (EDP) systems for holders of Hospital Pharmaceutical Services Permits in the State of Arkansas.

A. These regulations shall be construed, if possible, so as not to be violative of or in conflict with any federal regulation or requirement. If any part hereof is held invalid because of such conflict, such invalidity shall not affect other provisions or applications of these regulations which can be given effect without the invalid provisions of these regulations are declared severable.

B. The Arkansas State Board of Pharmacy must approve system prior to implementation.

C. Input of drug information into system may be performed by a pharmacist or supportive personnel (pharmacy technician). The final verification of prescription information, into the computer shall be made by the supervising pharmacist who is then totally responsible for all aspects of the data and data entry. Any judgemental decision concerning patient utilization of drugs must be performed by a pharmacist.

D. Any Electronic Data Processing System must be capable of furnishing the following information:

1. Patient Medication Profile (accessible electronically on line or by hard copy.) INTERPRETATION: The Patient Medication Profile is the basic document used by the Hospital Pharmacist to monitor a patient's medication regimen, drug compliance, drug interactions, allergies and drug usage.

a. The Patient Medication Profile must contain as a minimum the following: Patient name, patient identification number, practitioner's name, drug name, drug strength and dosage form, number of doses issued, initials, name or identification number of pharmacist approving original order into the system, and date original order was entered into the system.

b. The Final Patient Medication Profile must be maintained by the pharmacy for a period of two years in hard copy or on electronic media.

E. 1. Patient Daily Medication Printout (hard copy printed daily is required). INTERPRETATION: The Patient Daily Medication

Printout is a supporting document to the Patient Medication Profile. It is printed on a daily basis and may be used to fill patient medication orders for transport to the patient care area and may serve as a daily log of all medication issued on any given day.

a. The Patient Daily Medication Printout (daily hard copy) must contain as a minimum the following: date of record, patient name, patient identification number, drug name, drug strength and dosage form and number of doses issued on that day.

b. The following additional information must appear on the Patient Daily Medication Printout if it is not shown on the Patient Medication Profile described in D.1 above; initials of the Pharmacist who checked and verified the doses issued on the Patient Daily Medication Printout.
INTERPRETATION: Since the Patient Medication Printout is a supporting document to the Patient Medication Profile, some information such as practitioner's name, initials, name or identification number of pharmacist entering the original order into the system and the date of the original order may or may not be duplicated because the information is readily retrievable from the base document.

c. The Patient Daily Medication Printout or daily log must be signed by all pharmacists filling orders, and may be replaced by a monthly log containing same information. This information must be maintained at the Pharmacy for a period of two years. INTERPRETATION: The Patient Daily Medication Printout provides a daily refill-by-refill audit trail on all drugs issued and supplements the base document, the Patient Medication Profile.

In lieu of signing this daily hard copy printout, the pharmacist in charge of the hospital pharmacy may maintain a bound log book in which an individual pharmacist involved in such dispensing may sign a statement each day, attesting to the fact that the prescription information entered into the computer that day has been reviewed by him and is correct as shown. The log should identify the time of day at which the pharmacist started filling prescriptions and the time of day at which the pharmacist stopped filling prescriptions. Said log book shall be maintained, by the pharmacist in charge or his successor, in the hospital pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized prescription.

2. Assure strict confidentiality of all patient records.

3. Must be capable of receiving a hard copy printout of all the above mentioned reports within 48 hours.

4. If the hospital pharmacy closes, the pharmacist in charge, at the date of closing, shall store said records and within 14 days of closing shall

notify the Board of Pharmacy where said records are located. A hard copy printout of any daily log(s) shall be produced and made available to the Board on its request and to any other person authorized by law to examine or receive copies of prescription records.

F. Hospital pharmacies who make arrangements with outside suppliers of data processing services or materials must assure themselves of continuing adequate and complete drug information data and issuing records. If for any reason the relationship with said supplier terminates, the pharmacy shall assure the continuity of records.

G. In the event of computer breakdown (down time), the pharmacy must have an auxiliary record keeping system. The backup system must contain all necessary information to insure prompt data entry into the system as soon as computer is again available.

H. Registrants holding a Hospital Pharmaceutical Service Unit Permit who fill outpatient prescriptions and who wish to utilize Electric Data Processing Equipment as a record keeping system must then comply with all the requirements of the Arkansas State Board of Pharmacy Regulation Number 33.

I. The electronic data processing systems described in this regulation are acceptable as the disposition records for all drugs, except that the actual signed disposition (proof of use) records for Schedule II Controlled Substances must be retained separate from other records for a period of two years. 10/09/80 (Revised 6/15/95)

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