NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and filing and the agency decides to prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Register citation and date of the original Notice of Proposed Rulemaking:

7 A.A.R. 3204, August 3, 2001

2.

Sections Affected	Rulemaking Action
R4-23-110	Amend
R4-23-404	Amend
R4-23-405	Amend
R4-23-406	Amend
R4-23-407	Amend
R4-23-409	Amend

3. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 32-1904(A)(1), and 32-1904(B)(3) and (5)

Implementing statutes: A.R.S. §§ 32-1926(B), 32-1927(B)(3), 32-1963.01(K), 32-1964 and 32-1968(C)

4. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@qwest.net

5. An explanation of the rule, including the agencys reasons for initiating the rule:

The Boards Five-year Rule Review in September 1997 identified Sections R4-23-404, R4-23-405, R4-23-406, R4-23-407, and R4-23-409 for amending. Sections R4-23-404, R4-23-405, R4-23-406, R3-23-407, and R4-23-409 are amended to increase the clarity, conciseness, and understandability of the sections. The definition for "immediate notice" in Section 405 is moved to Section R4-23-110 with the Boards other rule definitions. R4-23-406(A) and (B) are repealed, and R4-23-406(C) and (D) are renumbered. R4-23-406(A) is a repeat of statutory language and is not necessary. R4-23-406(B) is not necessary because the drugs listed is subsection (B)(1) are now available as FDA-approved generic equivalent drug products. The dosage forms listed in subsection (B)(2) are not substitutable by statutory definition in A.R.S. § 32-1963.01(L)(3). The amendments to Section R4-23-407 make changes that clarify prescription order requirements, prescription refill documentation requirements, and expand and improve the prescription transfer process and recordkeeping, by, among other things, making requirements for electronic transfer of a prescription between pharmacies owned by the same company and using a common database. The amended rule will include format, style, and grammar changes necessary to comply with the current Administrative Procedure Act and Secretary of State rules.

The Board believes that making these rules will benefit the public health and safety by establishing standards for professional practices and benefit pharmacists and pharmacies by recognizing the use of improved technology as part of the established standards.

6. An explanation of the substantial change which resulted in this supplemental notice:

A written comment received by the Board on the proposed rulemaking prompted the Board to make the substantive change that required this notice. The written comment pointed out that subsection R4-23-407(D)(2) as proposed is more restrictive than federal law. The subsection deals with the number of times a controlled substance prescription may be transferred. The written comment asked the Board to use the federal requirements. After some discussion, the Board decided that using the less restrictive federal requirements in subsection R4-23-407(D)(2) will continue the Boards goal of protecting public health and maintaining uniform controlled substance regulation between state and federal agencies. Subsection R4-23-407(D)(2) is changed by reformatting the subsection into (a) and (b) subsections and incorporating by reference 21 CFR 1306.25 in subsection (a).

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The preliminary summary of the economic, small business, and consumer impact:

The cost to the Board of Pharmacy and the Secretary of State for writing and publishing the rules will be minimal. The proposed rules will have little economic impact on pharmacies. The rules clarify and update existing language that relates to unethical practices, change of pharmacist-in-charge, substitution of prescription drugs, prescription requirements, and returning drugs and devices. The proposed rules add subsection R4-23-407(D)(5) to establish standards for the electronic transfer of original prescription order information between pharmacies owned by the same company. This new subsection may provide a nonquantifiable cost savings to pharmacies related to more efficient use of pharmacy personnel and electronic prescription transfers. The existing rule requires that a prescription transfer is made between two pharmacists. The proposed rule will allow the use of pharmacy interns and pharmacy technicians for many transfers. The use of nonpharmacist personnel for some prescription transfers may also provide a nonquantifiable cost savings to pharmacies through more efficient use of pharmacy personnel. The proposed rule will have no economic impact on the public. The majority of the changes in the proposed rules are updates in format, style, and grammar to provide a clear, concise, and understandable document. The Board, pharmacies, and the public benefit from rules that establish standards for unethical practices, change of pharmacist-in-charge, substitution of prescription drugs, prescription requirements, and returning drugs and devices in Arizona.

10. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@qwest.net

11. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, November 26, 2001. An oral proceeding is scheduled for:

Date:	November 26, 2001
Time:	10:00 a.m.
Location:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person in item #10.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

21 CFR 1306.25, published April 1, 2001, and no future amendments or editions, located at A.A.C. R4-23-407(D)(2)(a)

14. The full text of the changes follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-404. Unethical Practices
R4-23-405. Change of Responsibility
R4-23-406. Substitution for Prescription Drugs
R4-23-407. Prescription Requirements
R4-23-409. Returning Drugs and Devices

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products.
"Immediate notice" means a notice sent by mail, facsimile, or electronic mail to the Board Office within 24 hours of an event, such as the termination of a pharmacist-in-charge, or knowledge of a pending event.
"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-404. Unethical Practices

A. Rebates prohibited~~:~~. ~~The offer, delivery, receipt or acceptance, by any~~ A pharmacist or ~~non-pharmacist~~ pharmacy permittee~~, of~~ shall not offer, deliver, receive, or accept any unearned rebate, refund, commission, preference, patronage dividend, discount, or other unearned consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest of co-ownership in or with any person to whom such patients, clients or customers are referred~~, is prohibited;~~ except for those rebates or premiums that are paid completely and directly to ~~the~~ a patient. ~~Among other things, this~~ A prohibited rebate shall also include the following:

1. ~~Payment to medical practitioner:~~ Payment to a medical practitioner in money or other consideration for prescription orders prescribed by the medical practitioner~~.~~; and
2. ~~Payment to nursing home:~~ Payment to a ~~nursing home~~ long-term care or assisted living facility or other health care institution in money, discount, rental, or other consideration for:
   a. Prescription medication or devices dispensed or sold for the patients or inhabitants of such facility or institution above the prevailing rate ~~which might be considered a rebate~~; or
   b. Drug selection and drug utilization review services, collaborative drug therapy management services, or other pharmacy consultation services provided for the patients or inhabitants of such facility or institution above the prevailing rate.

B. Prescription order blanks advertising prohibited~~:~~. ~~No~~ A pharmacist or pharmacy permittee shall not:

1. Directly or indirectly furnish~~, or cause to be furnished to, any medical practitioner~~ to a medical practitioner a prescription order ~~blanks referring~~ blank that refers to ~~any~~ a specific pharmacist or pharmacy in any manner ~~whatsoever.~~; and
2. ~~No pharmacist or pharmacy shall~~ Actively or passively participate in any arrangement or agreement ~~whereby~~ where a prescription ~~orders are~~ order is prepared, written, or issued in a manner ~~which~~ that refers to a specific pharmacist or pharmacy.

C. Claiming professional superiority~~.~~ ~~No~~ A pharmacist or pharmacy permittee shall not advertise professional superiority in a manner ~~to reflect~~ that reflects adversely on the qualifications of ~~others~~ another pharmacist or pharmacy.

D. Fraudulent claim for service~~.~~ ~~No~~ A pharmacist or pharmacy permittee shall not claim the performance of a service ~~which he~~ that the pharmacist or pharmacy permittee knows or should have known ~~had~~ was not ~~been~~ performed~~;~~, such as, claiming to have dispensed a prescription medication that was not dispensed.

E. Fraudulent claim for a fee~~.~~ ~~No~~ A pharmacist or pharmacy permittee shall not claim a fee for a service that was not performed or ~~was not~~ earned. It is not fraudulent to divide a prescription order into two or more portions of prescription medication at the request of ~~the~~ a patient, or for some other ethical reason, and charge a dispensing fee for such additional service. It is fraudulent to divide such a prescription order merely to obtain an additional fee.

~~**F.** Acceptance of prescription order and distribution of prescription medication: No pharmacist shall participate in any arrangement or agreement whereby prescription orders or prescription medication may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy; provided, however, that nothing in this regulation shall prohibit a pharmacist or pharmacy by means of its employee or by use of a common carrier, from picking up prescription orders or delivering prescription medications at the office or home of the medical practitioner, at the residence of the patient, or at the hospital or medical care facility in which the patient is confined.~~

~~**G.**~~**F.** Prohibiting ~~prescribed drugs~~ a prescription-only drug from being dispensed over the counter~~.~~ ~~No~~ A drug or device shall not be dispensed from the information on a prescription order unless the prescription medication or device is properly dispensed~~,~~ and labeled and the prescription order is filed in accordance with this Chapter.

R4-23-405. Change of Responsibility

~~**A.**~~ A pharmacist designated as the pharmacist-in-charge for a pharmacy, manufacturer, or other establishment shall give immediate ~~written~~ notice, as defined in R4-23-110, when:

1. ~~of the termination of such~~ The pharmacist's responsibility as a pharmacist-in-charge is terminated; or
2. ~~shall make such a notification~~ The pharmacist knows of a pending termination ~~whenever he has such information~~ of the pharmacist's responsibility as a pharmacist-in-charge.

~~**B.** "Immediate notice" means a notice sent to the executive director within 24 hours of such termination or knowledge of pending termination.~~

R4-23-406. Substitution for Prescription Drugs

~~**A.** All drugs shall comply with federal law.~~

~~**B.** Exclusions:~~

~~1. The following dosage forms shall not be substituted:~~
~~a. Injectable suspensions other than antibiotics,~~
~~b. Suppositories containing active ingredients of which systemic absorption is necessary for therapeutic activity, and~~
~~c. Different delivery systems for aerosol and nebulizer drugs.~~
~~2. The following are not interchangeable:~~
~~a. Creams for ointments or ointments for creams;~~
~~b. Tablets for capsules or capsules for tablets; and~~
~~c. Elixirs for syrups or syrups for elixirs.~~

~~**C.**~~**A.** Approved abbreviations. Whenever a substitution is made pursuant to A.R.S. § 32-1963.01, a pharmacist may use the approved abbreviation that accompanies the name of the manufacturer or distributor listed in subsection (~~D~~B) of this Section.

~~**D.**~~**B.** Manufacturers and distributors. The names of manufacturers and distributors ~~which~~ that have met the requirements of A.R.S. § 32-1963.01(~~I~~H) are recorded and available as a list at the Board office or on the Board's web page.

R4-23-407. Prescription Requirements

A. Prescription orders. A pharmacist shall ensure that:

1. A prescription order dispensed by the pharmacist ~~shall include~~ includes the following information:
   a. Date of issuance;
   b. Name and address of the person to whom, patient for whom, or the owner of the animal for which the drug or device is dispensed;
   c. ~~Name of~~ Drug name, strength, and dosage form or device name;
   d. Name of the drug's or device's manufacturer or distributor when written generically or a substitution is made;
   e. ~~Strength~~ Prescribing medical practitioner's directions for use;
   f. Date of dispensing;
   g. Quantity prescribed and if different quantity, dispensed;
   h. ~~Name or initials of the pharmacists or medical practitioner dispensing the drug, and~~ For a prescription order for a controlled substance, the medical practitioner's address and D.E.A. number;
   ~~i. In the case of an oral prescription, the prescriber's instructions written on the face of the prescription by the pharmacist.~~
   i. For a written prescription order, the medical practitioner's signature;

j. For an oral prescription order, the medical practitioner's name and telephone number; and
k. Name or initials of the dispensing pharmacist.

2. ~~Records of dispensing prescription-only drugs shall be made and kept for three years by wholesalers, manufacturers, pharmacies, and, except when administered to a patient upon whom the medical practitioner personally attends, by medical practitioners.~~ A record of the dispensing of a drug or device is kept for three years from the date the drug or device is dispensed, except for a drug or device personally administered by a medical practitioner to the medical practitioner's patient; and
3. The ~~direct~~ dispensing of a ~~prescription medication shall comply~~ drug or device complies with the packaging requirements of the United States Pharmacopeia and of the Consumer Product Safety Commission.

B. Prescription refills. A pharmacist shall ensure that the following information ~~shall be~~ is recorded on the back of a prescription order when it is refilled:
1. Date refilled~~;~~,
2. Quantity dispensed~~;~~,
3. Name or approved abbreviation of the manufacturer or distributor when written generically or a substitution is made~~;~~, and
4. The name or initials of the dispensing pharmacist ~~or intern~~.

C. ~~A copy of a prescription order is not a valid prescription order and may not be dispensed.~~ A pharmacist may furnish a copy of a prescription order to the patient for whom it was prescribed or to the authorized representative of such patient if such copy is clearly marked "COPY FOR REFERENCE PURPOSES ONLY". A copy of a prescription order is not a valid prescription order and a drug or device shall not be dispensed from the information on a copy.

D. Transfer of prescription order information. For a transfer of prescription order information to be valid, a pharmacy permittee or pharmacist-in-charge shall ensure that the following occur:
1. Both the original and the transferred prescription ~~must be~~ order are maintained for a period of three years ~~from the date of~~ after the last ~~refill~~ dispensing date.
~~2.~~ ~~Pharmacies electronically accessing the same prescription record must satisfy all the information requirements of a manual mode for the prescription transferral.~~
~~3.~~2. Original prescription order information ~~may be~~ is transferred only:
   a. ~~one time during the life of the~~ as As specified in 21 CFR 1306.25, published April 1, 2001, and no future amendments or editions, incorporated by reference and on file with the Board and the office of the Secretary of State, on a prescription ~~in the case of~~ for a Schedule III, IV, ~~and~~ or V controlled ~~substances~~ substance; and
   b. ~~without~~ Without limitation up to the number of originally authorized refills ~~in the case of~~ on a prescription for a non-controlled ~~prescription-only drugs~~ substance drug.

~~4.~~3. Transfer within Arizona.
   a. ~~Transfer~~ The transfer of original prescription order information for a non-controlled ~~prescription-only drugs~~ substance drug ~~must meet~~ meets the following conditions:
      i. ~~Transfer~~ The transfer of information is communicated directly between two licensed pharmacists, a licensed pharmacist and a licensed pharmacy or graduate intern, or two licensed pharmacy or graduate interns;
      ii. The following information is recorded by the transferring pharmacist or pharmacy or graduate intern:
         (1) The word "void" is written on the face of the invalidated prescription unless an electronic transfer occurs or an oral transfer occurs and the transferred prescription order information is invalidated in the transferring pharmacy's computer system; and
         (2) The name and address of the pharmacy to which the prescription ~~was~~ is transferred, the name of the receiving pharmacist or pharmacy or graduate intern ~~receiving the prescription information~~, the date of transfer, and the name of the transferring pharmacist or pharmacy or graduate intern ~~who transfers the information~~ is written on the back of the prescription~~.~~ or entered into the transferring pharmacys computer system; and
      iii. The following information is recorded by the receiving pharmacist or pharmacy or graduate intern ~~receiving the transferred prescription~~:
         (1) The word "transfer" is written on the face of the transferred prescription; and
         (2) The following information is recorded on the transferred prescription:
            (a) Date of issuance of the original prescription;
            (b) Original number of refills authorized on the original prescription;
            (c) Date of original dispensing;
            (d) Number of valid refills remaining and the date of the last refill;
            (e) Name, address, and original prescription number of the pharmacy from which the prescription ~~was~~ is transferred;
            (f) Name of the transferring pharmacist or pharmacy or graduate intern; and
            (g) Name of the receiving pharmacist or pharmacy or graduate intern ~~receiving the prescription~~.
   b. ~~Transfer~~ The transfer of original prescription order information for a Schedule III, IV, ~~and~~ or V controlled ~~substances must meet~~ substance meets the following conditions:

i. ~~Transfer~~ The transfer of information is communicated directly between two licensed pharmacists;
ii. The following information is recorded by the transferring pharmacist:
(1) The word "void" is written on the face of the invalidated prescription unless an electronic transfer occurs or an oral transfer occurs and the transferred prescription order information is invalidated in the transferring pharmacys computer system; and
(2) The name, address, and DEA number of the pharmacy to which the prescription ~~was~~ is transferred, the name of the receiving pharmacist ~~receiving the prescription information~~, the date of transfer, and the name of the transferring pharmacist ~~who transfers the information~~ is written on the back of the prescription~~.~~ or entered into the transferring pharmacys computer system; and
iii. The following information is recorded by the receiving pharmacist ~~receiving the transferred prescription~~:
(1) The word "transfer" is written on the face of the transferred prescription~~.~~; and
(2) The following information is recorded on the transferred prescription:
(a) Date of issuance of original prescription;
(b) Original number of refills authorized on the original prescription;
(c) Date of original dispensing;
(d) Number of valid refills remaining and the date of the last refill;
(e) Name, address, DEA number, and original prescription number of the pharmacy from which the prescription ~~was~~ is transferred;
(f) Name of the transferring pharmacist; and
(g) Name of the receiving pharmacist.

~~5.~~4. Transfer from out of state~~:~~.
a. ~~Transfer~~ The transfer of original prescription order information for a non-controlled ~~prescription only drugs must meet~~ substance drug meets the conditions ~~set forth~~ in subsections (D)(~~4~~3)(a)(i) and (D)(~~4~~3)(a)(iii) of this ~~rule~~ Section.
b. ~~Transfer~~ The transfer of original prescription order information for a Schedule III, IV, ~~and~~ or V controlled ~~substances must meet~~ substance meets the conditions ~~set forth~~ in subsection (D)(~~4~~3)(b)(i) and (D)(~~4~~3)(b)(iii) of this ~~rule~~ Section.

5. Electronic transfer. The electronic transfer of original prescription order information meets the following conditions:
a. The electronic transfer is between pharmacies owned by the same company using a common or shared database;
b. The electronic transfer of original prescription order information for a non-controlled substance drug is performed by a pharmacist or a pharmacy or graduate intern, or pharmacy technician under the supervision of a pharmacist;
c. The electronic transfer of original prescription order information for a controlled substance is performed by two licensed pharmacists;
d. The electronic transfer of original prescription order information for a non-controlled substance drug meets the following conditions:
i. The transferring pharmacys computer system:
(1) Invalidates the transferred original prescription order information;
(2) Records the identification code, number, or address of the pharmacy to which the prescription order information is transferred;
(3) Records the name or identification code of the receiving pharmacist, pharmacy or graduate intern, or pharmacy technician;
(4) Records the date of transfer; and
(5) Records the name or identification code of the transferring pharmacist, pharmacy or graduate intern, or pharmacy technician; and
ii. The electronic prescription order information received by the computer system of the receiving pharmacy includes the information required in subsection (D)(3)(a)(iii) of this Section;
e. The electronic transfer of original prescription order information for a controlled substance meets the following conditions:
i. The transferring pharmacys computer system:
(1) Invalidates the transferred original prescription order information;
(2) Records the identification code, number, or address, and DEA number of the pharmacy to which the prescription order information is transferred;
(3) Records the name or identification code of the receiving pharmacist;
(4) Records the date of transfer; and
(5) Records the name or identification code of the transferring pharmacist; and
ii. The electronic prescription order information received by the computer system of the receiving pharmacy includes the information required in subsection (D)(3)(b)(iii) of this Section; and
f. In addition to electronic documentation of a transferred prescription order in the computer system, an original prescription order containing the requirements of this Section is filed in compliance with A.R.S. § 32-1964.

R4-23-409. Returning Drugs and Devices

A. After ~~it has been~~ a drug is taken from the premises where sold, distributed, or dispensed, ~~no~~ the drug shall not be accepted for return or exchange for the purpose of resale unless the following conditions ~~have been~~ are met:
1. ~~It~~ The drug is in ~~the~~ its original, manufacturers, unopened container; and
2. The drug or its container has not been subjected to contamination or deterioration.

B. The provisions of subsection (A) of this Section do not apply to ~~drugs~~ a drug dispensed to:
1. A hospital ~~inpatients (see R4-23-659(B))~~ inpatient; or
2. ~~To nursing home~~ A resident~~s~~ of a long-term care facility where a licensed health care professional administers the drug, if a pharmacist is satisfied that the drug:
   a. Has been stored in compliance with the requirements of the official compendium; and
   b. Is not obviously contaminated or deteriorated.

C. After ~~it has left~~ a device is taken from the premises ~~of the seller~~ where sold, distributed, or dispensed, ~~no~~ the device shall not be accepted for return or exchange for the purpose of resale or reuse unless the following conditions ~~have been~~ are met:
1. ~~It~~ The device is found to be free of defects after inspection;
2. ~~It~~ The device is rendered incapable of transferring disease; and
3. ~~It~~ The device is not claimed to be new or unused.