NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R04-545]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R4-23-110	Amend
R4-23-402	Amend

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

Authorizing statute: A.R.S. § 32-1904(A)(1)

Implementing statute: A.R.S. § 32-1904(B)(5)

3. A list of all previous notices appearing in the Register addressing the proposed rules:

Notice of Rulemaking Docket Opening: 10 A.A.R. 3762, September 10, 2004

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

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@cox.net

5. An explanation of the rules, including the agency's reasons for initiating the rules:

At the May 12, 2004 Board meeting, Board President Dennis McAllister formed a Patient Counseling Task Force. The task force was charged with reviewing the exiting counseling rule and then to seek methods to improve and increase patient counseling by amending the rule. The proposed rules contain the final recommendations presented by the task force at the August 11, 2004 Board meeting. R4-23-110 will be amended by adding a new definition for "care-giver." R4-23-402 will be amended with the recommendations of the task force. The recommendations include: replacing the term "patient's agent" with "patient's care-giver;" reducing the number of specific circumstances that require counseling to occur from five to three; modifying the four required aspects of oral consultation; adding a new subsection requiring documentation that oral consultation did or did not occur and providing an exception for not providing oral consultation; minor changes to the subsection that specifies those aspects of patient consultation that may be provided to a patient through exercise of a pharmacist's professional judgment; and changes to the subsection that details what a pharmacist shall do if a patient refuses oral consultation. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public, pharmacists, pharmacy interns, and pharmacies by clearly establishing the standards for patient counseling by pharmacists and pharmacy interns under pharmacist supervision.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rules and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and

other supporting material:
None

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:
Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:
The proposed rules will impact the Board, pharmacists, pharmacy interns, and pharmacies. The proposed rules' impact on the Board will be the usual rulemaking-related costs which are minimal. The proposed rules will have no economic impact on pharmacists or pharmacy interns. The changes to the rules will increase the amount of documentation a pharmacist or pharmacy intern is required to maintain in relation to patient counseling. The proposed rules will require documentation whether or not counseling occurs. The proposed rules may increase pharmacy costs. Because documentation requires time, either pharmacist, pharmacy intern, or pharmacy technician time, a pharmacy might have increased costs to comply with the proposed rules. The proposed rules will actually decrease the number of times in a day a pharmacist must counsel which may offset some of the minor increase in costs attributed to the additional documentation required for each prescription. The Board estimates that any increased costs for pharmacies to comply with the proposed rules will be minimal. The proposed rules have no economic impact on the public. The public benefits from rules that ensure that a patient receives necessary and adequate counseling while reducing possible breaches in confidentiality.

The public, Board, pharmacists, pharmacy interns, and pharmacies benefit from rules that are clear, concise, and, understandable. The proposed rules benefit the public, the Board, and the pharmacy community by clearly establishing the standards for patient counseling by pharmacists and pharmacy interns under pharmacist supervision.

9. 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@cox.net

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:
Comments may be written or presented orally. Written comments must be received by 5 p.m., Tuesday, February 22, 2005. An oral proceeding is scheduled for:

Date:	February 22, 2005
Time:	10:00 a.m.
Location:	4425 W. Olive Ave., Suite 140 Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed in item #9.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:
Not applicable

12. Incorporations by reference and their location in the rules:
None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section

R4-23-110. Definitions

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to A.A.C. Title 4 Chapter 23:

"Active ingredient" No change
"Alternate physician" No change
"Approved course in pharmacy law" No change
"Approved Provider" means an individual, institution, organization, association, corporation, or agency that is approved by the ~~American~~ Accreditation Council ~~on Pharmaceutical~~ for Pharmacy Education (ACPE) in accordance with ACPE's policy and procedures or by the Board as meeting criteria indicative of the ability to provide quality continuing education.
"Authentication of product history" No change
"AZPLEX" No change
"Batch" No change
"Beyond-use date" No change
"Biological safety cabinet" No change
"Care-giver" means a person who cares for someone who is sick or disabled or an adult who cares for an infant or child and includes a patient's husband, wife, son, daughter, mother, father, sister, brother, legal guardian, nurse, or medical practitioner.
"Class 100 environment" No change
"Community pharmacy" No change
"Component" No change
"Compounding and dispensing counter" No change
"Computer system" No change
"Computer system audit" No change
"Contact hour" No change
"Container" No change
"Continuing education" No change
"Continuing education activity" No change
"Continuing education unit" or "CEU" No change
"Correctional facility" No change
"CRT" No change
"Current good compounding practices" No change
"Current good manufacturing practice" No change
"Cytotoxic" No change
"Day" No change
"DEA" No change
"Delinquent license" No change
"Dietary supplement" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Drug therapy management agreement" No change
"Extreme emergency" No change
"FDA" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"Limited-service correctional pharmacy" No change
"Limited-service long-term care pharmacy" No change
"Limited-service mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Limited-service pharmacy permittee" No change

"Limited-service sterile pharmaceutical products pharmacy" No change
"Long-term care consultant pharmacist" No change
"Long-term care facility" or "LTCF" No change
"Lot" No change
"Lot number" or "control number" No change
"Materials approval unit" No change
"Mediated instruction" No change
"MPJE" No change
"NABP" No change
"NABPLEX" No change
"NAPLEX" No change
"Other designated personnel" No change
"Outpatient" No change
"Outpatient setting" No change
"Patient profile" No change
"Pharmaceutical patient care services" No change
"Pharmaceutical product" No change
"Pharmacy counter working area" No change
"Pharmacy law continuing education" No change
"Prepackaged drug" No change
"Provider pharmacy" No change
"Radiopharmaceutical" No change
"Radiopharmaceutical quality assurance" No change
"Radiopharmaceutical services" No change
"Red C stamp" No change
"Refill" means other than the original dispensing of the prescription order, dispensing a prescription order in the same quantity originally ordered or in multiples of the originally ordered quantity when specifically authorized by the prescriber, if the refill is authorized by the prescriber either:
In the original prescription order;
By an electronically transmitted refill order that is documented promptly and filed by the pharmacist; or
By an oral refill order that is documented promptly and filed by the pharmacist.
"Remodel" means to alter structurally the pharmacy area or location.
"Remote drug storage area" No change
"Resident" No change
"Responsible person" No change
"Score transfer" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change
"Sterile pharmaceutical product" No change
"Strength" No change
"Supervision" No change
"Supervisory physician" No change
"Supplying" No change
"Support personnel" No change
"Transfill" No change
"Wholesale distribution" No change
"Wholesale distributor" No change

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

A. No change

B. Only a pharmacist, graduate intern, or pharmacy intern shall provide oral consultation about a prescription medication to a patient or patient's ~~agent~~ care-giver in an outpatient setting, including a patient discharged from a hospital. The oral consultation is required whenever the following occurs:

~~1. The prescription medication has not been previously dispensed to the patient;~~
~~2. A new prescription number is assigned to a previously dispensed prescription medication;~~
~~3.~~1. The prescription medication has not been previously dispensed to the patient in the same strength or dosage form or

with the same directions;

~~4.~~2. The pharmacist, through the exercise of professional judgment, determines that oral consultation is warranted; or

~~5.~~3. The patient or patient's ~~agent~~ care-giver requests oral consultation.

C. Oral consultation shall include:

1. ~~The~~ Reviewing or verifying the name~~, strength,~~ and ~~dosage form~~ strength of a prescription medication or name of a prescription-only device and the patient's or care-giver's understanding of what the medical practitioner indicated the prescription medication or prescription-only device is intended for;
2. ~~The directions for use~~ Reviewing or verifying the patient's or care-giver's understanding of how the medical practitioner indicated the prescription medication or prescription-only device is to be used;
3. ~~The route of administration~~ Reviewing or verifying the patient's or care-giver's understanding of what the medical practitioner indicated the patient should expect while taking the prescription medication or using the prescription-only device; and
4. ~~Special instructions, precautions,~~ Providing oral information regarding special instructions and written information regarding side effects, procedures for missed doses, or storage requirements.

D. When, in the professional judgement of the pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist, or when circumstance precludes it, oral consultation may be omitted if the pharmacist, graduate intern, or pharmacy intern:

1. Personally provides written information to the patient or patient's care-giver that summarizes the information that would normally be orally communicated;
2. Documents, or assumes responsibility for documenting, the circumstance and reason for not providing oral consultation; and
3. Offers the patient or patient's care-giver the opportunity to communicate with a pharmacist, graduate intern, or pharmacy intern at a later time and provides a method for the patient or patient's care-giver to contact a pharmacist, graduate intern, or pharmacy intern at the pharmacy.

~~D.~~**E.** The pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist, through the exercise of professional judgment, may provide oral consultation that includes:

1. Common severe adverse effects, interactions, or therapeutic contraindications, and the action required if they occur;
2. Techniques of self-monitoring drug therapy;
3. The duration of the drug therapy; and
4. Prescription refill information~~; and~~
5. ~~Action to be taken if a dose is missed~~.

~~E.~~**F.** Nothing in subsection (B) shall be construed as requiring a pharmacist, graduate intern, or pharmacy intern to provide oral consultation if a patient or patient's ~~agent~~ care-giver refuses the consultation. Using a method approved by the Board or its designee, a pharmacist, graduate intern, or pharmacy intern shall:

1. Document, or assume responsibility to document, that oral consultation is or is not provided; and
2. If oral consultation is not provided, document, or assume responsibility to document, the circumstance and reason that oral consultation is not provided.

~~1. Only a pharmacist, graduate intern, or pharmacy intern shall accept a refusal for consultation.~~

~~2. A pharmacist, graduate intern, or pharmacy intern shall document, or assume responsibility to document, a refusal for consultation on the original prescription order or document by alternative methods approved by the Board or its designee.~~

~~F.~~**G.** When a prescription is delivered to the patient or patient's ~~agent~~ care-giver outside the immediate area of a pharmacy and a pharmacist is not present, the prescription shall be accompanied by written or printed patient medication information that, in addition to the requirements in subsection (C), includes:

1. Approved use for the prescription medication;
2. Possible adverse reactions;
3. Drug-drug, food-drug, or disease-drug interactions;
4. Missed dose information; and
5. Telephone number of the dispensing pharmacy or another method approved by the Board or its designee that allows a patient or patient's care-giver to consult with a pharmacist.

~~G.~~**H.** No change

~~H.~~**I.** No change

~~I.~~**J.** No change