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

[R07-411]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-110	Amend
ARTICLE 5	New Article
R4-23-501	New Section
R4-23-502	New Section
R4-23-503	New Section
R4-23-504	New Section
R4-23-505	New Section

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

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and 36-2602

Implementing statutes: A.R.S. §§ 36-2603, 36-2604, 36-2605, 36-2606, 36-2607, 36-2608, 36-2609, and 36-2610

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

Notice of Rulemaking Docket Opening: 13 A.A.R. 3155, September 14, 2007

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
1700 W. Washington St., Suite 250
Phoenix, AZ 85007

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

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

During the 48th Legislative Session, the Legislature passed H.B. 2136. The bill requires the Board to adopt rules establishing a controlled substances prescription monitoring program that includes a computerized central database tracking system to track the prescribing, dispensing, and consumption of Schedule II, III, and IV controlled substances that are dispensed by a medical practitioner or pharmacy that holds a valid license or permit issued under A.R.S. Title 32. Any necessary new definitions will be place in R4-23-110 (Definitions). The new rules will be placed in a new Article 5 (Controlled Substances Prescription Monitoring Program) with new Sections for: program registration, requirements for data format and transmission, access to program data, computerized central database tracking system task force, and reports. 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 the rules benefits the public and the pharmacy and medical communities by establishing a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances in Arizona. The program will improve the state's ability to identify controlled substance abusers or misusers and refer

them to treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

7. 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

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

The proposed rules will impact the Board, medical practitioners, pharmacies, pharmacists, and the public. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal. The Board estimates the cost of the program will be from $200,000 to $400,000 per year. The costs of the program will be borne by the Board through an annual appropriation of $395,795 from the Board's Pharmacy Fund. The Board will seek additional federal grants when available to help pay the costs of the program.

The Board estimates the proposed rules will have minimal to moderate economic impact on pharmacies or pharmacists. The cost to pharmacies will be to prepare and transmit the prescription data to the Board. The majority of pharmacies already transmit similar data in other states with monitoring program. The few Arizona pharmacies that do not have a computer will be required to transmit the data through use of a universal claim form. There will be a cost in man-hours to manually prepare and transmit the data. The Board estimates this cost will be from $0 to $10 per day equaling an annual additional cost of from $0 to $2,600.

The Board estimates the proposed rules will have minimal to moderate economic impact on medical practitioners. Those medical practitioners who dispense Schedule II, III, and IV controlled substances to patients will be required to transmit prescription data to the Board. Those medical practitioners without computers will be required to manually transmit the data, which will require a staff person to complete a type of universal claim form. There will be a cost in man-hours to prepare and transmit the data. The Board estimates this additional cost may apply to approximately 2,000 of the estimated 24,000 medical practitioners licensed to practice medicine in Arizona. The Board estimates an average medical practice will need an additional one to two man-hours to process the prescription data at a cost of from $0 to $25 per day, equaling an additional annual cost of from $0 to $6,500.

The public, Board, and pharmacists benefit from rules that are clear, concise, and understandable. The Board rules benefit the public and the pharmacy and medical communities by establishing a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances in Arizona. The program will improve the state's ability to identify controlled substance abusers or misusers and refer them to treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

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 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

10. The time, place, and nature of the proceedings for the making, 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, January 14, 2008. An oral proceeding is scheduled for:

Date:	January 14, 2008
Time:	11:00 a.m.
Location:	1700 W. Washington St., 3rd Floor Board Room Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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 rule:
None

13. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 5. CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM

Section
R4-23-501. ~~Recodified~~ Controlled Substances Prescription Monitoring Program Registration
R4-23-502. ~~Recodified~~ Requirements for Data Format and Transmission
R4-23-503. ~~Repealed~~ Access to Controlled Substances Prescription Monitoring Program Data
R4-23-504. ~~Repealed~~ Computerized Central Database Tracking System Task Force
R4-23-505. ~~Repealed~~ Reports

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions
In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" No change

"Alternate physician" No change

"Approved course in pharmacy law" No change

"Approved Provider" No change

"Authentication of product history" No change

"Automated storage and distribution system" No change

"Batch" No change

"Beyond-use date" No change

"Biological safety cabinet" No change

"Care-giver" No change

"Community pharmacy" No change

"Component" 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

"CSPMP" means the Controlled Substances Prescription Monitoring Program established under Arizona Revised Statutes Title 36, Chapter 28.

"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
"Digital signature" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Electronic signature" No change
"Eligible patient" No change
"Extreme emergency" No change
"FDA" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"ISO Class 5 environment" No change
"ISO Class 7 environment" 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
"Mechanical counting device for a drug in solid, oral dosage form" No change
"Mechanical storage and counting device for a drug in solid, oral dosage form" No change
"Mediated instruction" No change
"MPJE" No change
"NABP" No change
"NABPLEX" No change
"NAPLEX" No change
"Order" 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
"Pharmacist-administered immunizations training program" No change
"Pharmacy counter working area" No change

"Pharmacy law continuing education" No change

"Pharmacy permittee" No change

"Prepackaged drug" No change

"Prep area" No change

"Proprietor" No change

"Provider pharmacy" No change

"Radiopharmaceutical" No change

"Radiopharmaceutical quality assurance" No change

"Radiopharmaceutical services" No change

"Red C stamp" No change

"Refill" No change

"Remodel" No change

"Remote drug storage area" No change

"Resident" No change

"Responsible person" No change

"Score transfer" No change

"Security ~~paper~~ features" means the attributes incorporated into the paper of a prescription order, referenced in A.R.S. § 32-1968(A)(4), that ~~is~~ are approved by the Board or its staff and that includes one or more of the following features that attempt to prevent duplication or aid the authentication of a paper document: laid lines, enhanced laid lines, thermochromic ink, artificial watermark, fluorescent ink, chemical void, persistent void, penetrating numbers, high-resolution border, high-resolution latent images, micro-printing, prismatic printing, embossed images, abrasion ink, holograms, and foil stamping.

"Shared order filling" No change

"Shared order processing" No change

"Shared services" No change

"Sight-readable" No change

"Single-drug audit" No change

"Single-drug usage report" No change

"Standard-risk sterile pharmaceutical product" No change

"Sterile pharmaceutical product" No change

"Strength" No change

"Substantial-risk sterile pharmaceutical product" No change

"Supervision" No change

"Supervisory physician" No change

"Supplying" No change

"Support personnel" No change

"Transfill" No change

"Verified signature" or "signature verifying" No change

"Wholesale distribution" No change

"Wholesale distributor" No change

ARTICLE 5. CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM

R4-23-501. ~~Recodified~~ Controlled Substances Prescription Monitoring Program Registration

A. Under A.R.S. § 36-2606, a medical practitioner who is issued a license under A.R.S. Title 32, Chapters 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29 and possesses a current DEA registration under the Federal Controlled Substances Act shall have a current CSPMP registration issued by the Board.

B. Application. To obtain a CSPMP registration, a person shall submit a completed application on a form furnished by the Board that includes:

1. Applicant's name, address, mailing address, if different, e-mail address, telephone number, facsimile number, license

number issued under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29, and DEA registration number;

2. Whether the applicant's license and DEA registration listed in subsection (B)(1) are current and in good standing, and if not, the status of the license and registration; and
3. Date signed and applicant's verified signature.

C. Registration. Within seven business days of receipt of a completed application specified in subsection (B), the Board office shall determine whether an application is complete. If the application is complete, the Board office shall issue a registration number and mail a current renewal receipt to the applicant. If the application is incomplete, the Board office shall issue a notice of incompleteness. An applicant with an incomplete application shall comply with the requirements of R4-23-202(F)(2) and (3).

D. Registration renewal. As specified in A.R.S. § 36-2606(C), the Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before May 1 of the year in which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.

E. Pharmacy registration and renewal. Each pharmacy with a current Board-issued pharmacy permit and a current DEA registration is automatically registered in the CSPMP. Existing pharmacy permittees who possess a current DEA registration will receive a registration receipt before the implementation date of the CSPMP. For pharmacy permits issued on or after the CSPMP implementation date, the Board will issue a registration receipt when issuing the pharmacy's permit. Each pharmacy shall renew the CSPMP registration on or before May 1 of the year in which the renewal is due. The Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before the date on which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.

F. CSPMP database access. A medical practitioner or pharmacy that chooses to use the CSPMP database shall request a user name and password in writing from the CSPMP Director. Upon receipt of the request, the CSPMP Director or designee shall issue a user name and password provided the medical practitioner or pharmacy is in compliance with the registration requirements of this Section.

R4-23-502. ~~Recodified~~ Requirements for Data Format and Transmission

A. Each dispenser shall submit to the Board by electronic means information regarding each prescription dispensed for a controlled substance listed in Schedules II, III, and IV of A.R.S. Title 36, Chapter 27, the Arizona Uniform Controlled Substances Act. The information reported shall conform to the August 31, 2005 Version 003, Release 000 ASAP Rules-based Standard Implementation Guide for Prescription Monitoring Programs published by the American Society for Automation in Pharmacy as specified in A.R.S. § 36-2608(B). The information submitted for each prescription shall include:

1. The name, address, telephone number, prescription number, and DEA registration number of the dispenser;
2. The name, address, and date of birth of the person or, if for an animal, the owner of the animal for whom the prescription is written;
3. The name, strength, quantity, dosage form, and National Drug Code (NDC) number of the Schedule II, III, or IV controlled substance dispensed;
4. The date the prescription was dispensed;
5. The number of refills, if any, authorized by the medical practitioner;
6. The date the prescription was issued;
7. The method of payment; and
8. Whether the prescription is new or a refill.

B. A dispenser shall submit the required information electronically unless the Board approves a waiver as specified in subsection (D).

C. A dispenser's electronic data transfer equipment including hardware, software, and Internet connections shall meet the privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and A.R.S. § 12-2292, in addition to common Internet industry standards for privacy and security. A dispenser shall ensure that each electronic transmission meets the following data protection requirements:

1. Data shall be at least 128 bit encryption in transmission and at rest; and
2. Data shall be transmitted via secure e-mail, telephone modem, diskette, CD-ROM, tape, secure File Transfer Protocol (FTP), Virtual Private Network (VPN), or other Board-approved media.

D. A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the Board established format may request a waiver from electronic reporting by submitting a written request to the Board. The Board shall grant the request if the dispenser agrees in writing to report the data by submitting a completed universal claim form supplied by the Board or its designee.

E. A dispenser shall report by close of business on each Friday the required information for the previous week, Sunday through Saturday. If a Friday falls on a state holiday, the dispenser shall report the information on the following business day.

R4-23-503. ~~Repealed~~ Access to Controlled Substances Prescription Monitoring Program Data

A. Except as provided in A.R.S. § 36-2604(B) and (C) and this Section, prescription information submitted to the Board is confidential and is not subject to public inspection.

B. The Board or its designee shall review the prescription information collected under A.R.S. Title 36, Chapter 28 and R4-23-502. If the Board or its designee has reason to believe an act of unprofessional or illegal conduct has occurred, the Board or its designee shall notify the appropriate professional licensing board or law enforcement or criminal justice agency and provide the prescription information required for an investigation.

C. The Board or its designee is authorized to release data collected by the program to the following:

1. A person who is authorized to prescribe or dispense a controlled substance to assist that person to provide medical or pharmaceutical care to a patient or to evaluate a patient;
2. An individual who requests the individual's own controlled substance prescription information under A.R.S. § 12-2293;
3. A professional licensing board established under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 21, 25, or 26. Except as required under subsection (B), the Board shall provide this information only if the requesting board states in writing that the information is necessary for an open investigation or complaint;
4. A local, state, or federal law enforcement or criminal justice agency. Except as required under subsection (B), the Board shall provide this information only if the requesting agency states in writing that the information is necessary for an open investigation or complaint;
5. The Arizona Health Care Cost Containment System Administration regarding persons who are receiving services under A.R.S. Title 36, Chapter 29. Except as required under subsection (B), the Board shall provide this information only if the Administration states in writing that the information is necessary for an open investigation or complaint;
6. A person serving a lawful order of a court of competent jurisdiction; and
7. The Board staff for purposes of administration and enforcement of A.R.S. § Title 36, Chapter 28 and this Article.

D. The Board or its designee may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients or persons who received prescriptions from dispensers.

R4-23-504. ~~Repealed~~ Computerized Central Database Tracking System Task Force

A. The Board shall appoint a task force to help it administer the computerized central database tracking system as specified in A.R.S. § 36-2603.

B. The Task Force shall meet at least once each year and at the call of the chairperson to establish the procedures and conditions relating to the release of prescription information specified in A.R.S. § 36-2604 and R4-23-503.

C. The Task Force shall determine:

1. The information to be screened;
2. The frequency and thresholds for screening; and
3. The parameters for using the information to notify medical practitioners, patients, and pharmacies to educate and provide for patient management and treatment options.

D. The Board shall review and approve the procedures and conditions established by the Task Force as needed but at least once every calendar year.

R4-23-505. ~~Repealed~~ Reports

A. Before releasing prescription monitoring program data, the Board or its designee shall receive a written request for controlled substance prescription information.

B. A person authorized to access CSPMP data under R4-23-503(C)(1) through (6) shall submit a written request that:

1. Specifies the information requested for the report;
2. For a medical practitioner, provides a statement that the report's purpose is to provide medical or pharmaceutical care to a patient or to evaluate a patient;
3. For an individual obtaining the individual's own controlled substance prescription information, provides a form of non-expired government-issued identification;
4. For a professional licensing board, states that the information is necessary for an open investigation or complaint;
5. For a local, state, or federal law enforcement or criminal justice agency, states that the information is necessary for an open investigation or complaint;
6. For the AHCCCS Administration, states that the information is necessary for an open investigation or complaint; and
7. For a person serving a lawful order of a court of competent jurisdiction, provides a copy of the court order.

C. The Board may provide reports through U.S. mail, other common carrier, facsimile, or secured electronic media or may allow reports to be picked up in-person at the Board office.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R07-410]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R4-23-404 Amend

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

Authorizing statutes: A.R.S. §§ 32-1901.01(B)(11), (12), (24), (25), (26), and (27) and 32-1904(A)(1)

Implementing statutes: A.R.S. §§ 32-1904(B)(5) and 32-1968(D)

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

Notice of Rulemaking Docket Opening: 13 A.A.R. 1279, April 6, 2007

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
1700 W. Washington St., Suite 250
Phoenix, AZ 85007

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

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

A.R.S. § 32-1968(D) specifies that any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or the Internet is misbranded. A.R.S. § 32-1965(1) states that selling any drug that is misbranded is prohibited. According to A.R.S. § 32-1996(A), a person who sells a misbranded drug is guilty of either a class 2 misdemeanor or a class 5 felony based on intent. A.R.S. § 32-1901.01(B)(12) states that a pharmacist or intern is guilty of unprofessional conduct for knowingly dispensing a drug on a prescription order that was issued in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or the Internet. The Board intends to amend R4-23-404 (Unethical Practices) by adding language to specifically address the issue of dispensing prescriptions received from a business conducted by mail or the Internet, specifically prescription orders based on an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting medical practitioner-patient relationship. 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 this rule benefits the public and the pharmacy community by clearly establishing the standards for professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

7. 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

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

The proposed rule will impact the Board, pharmacists, and the public. The proposed rules' impact on the Board will be the usual rulemaking-related costs which are minimal. The Board estimates the proposed rule will have no economic impact on pharmacies or pharmacists, because the rule change is simply clarifying the statutory language that has been in place for over 12 years.

The public, Board, and pharmacists benefit from rules that are clear, concise, and understandable. The proposed rule benefits the public and the pharmacy community by clearly establishing the standards for professional conduct appro-

priate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

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
1700 W. Washington St., Suite 250
Phoenix, AZ 85007

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

10. The time, place, and nature of the proceedings for the making, 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, January 14, 2008. An oral proceeding is scheduled for:

Date: January 14, 2008

Time: 10:00 a.m.

Location: 1700 W. Washington St., 3rd Floor Board Room
Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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 rule:

None

13. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-404. Unethical Practices

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-404. Unethical Practices

A. No change
1. No change
2. No change
   a. No change
   b. No change

B. No change
1. No change
2. No change

C. No change

D. No change
1. No change
2. No change
3. No change

E. No change
1. No change
2. No change

3. No change

F. Drugs dispensed in the course of the conduct of a business of dispensing drugs through diagnosis by mail or the Internet.

1. A pharmacist shall make a reasonable effort to ensure that any prescription order received by the pharmacist, regardless of the means of transmission, is issued for a legitimate medical purpose by an authorized medical practitioner. A pharmacist shall not dispense a drug from a prescription order if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting medical practitioner-patient relationship.
2. If a pharmacist has reasons to suspect that a prescription was authorized solely on the results of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and in the absence of a documented patient evaluation including a physical examination, the pharmacist shall ascertain if that medical practitioner's standard of practice allows that medical practitioner to authorize a prescription under such circumstances. Reasons to suspect that a prescription may have been authorized in the absence of a valid medical practitioner-patient relationship, or in violation of the medical practitioner's standard of practice, include:
   a. The number of prescriptions authorized on a daily basis by the medical practitioner;
   b. The manner in which the prescriptions are authorized by the medical practitioner or received by the pharmacy, i.e., electronically;
   c. The geographical distance between the medical practitioner and the patient;
   d. Knowledge by the pharmacist that the prescription was issued solely as a result of answers to an electronic questionnaire; or
   e. Knowledge by the pharmacist that the pharmacy the pharmacist works for directly or indirectly participates in an Internet site that markets prescription drugs to the public.
3. A pharmacist who has reasons to suspect that a prescription may have been authorized in the absence of a valid medical practitioner-patient relationship, or otherwise in violation of the medical practitioner's standard of practice, shall not fill such prescription until the pharmacist has obtained proof to a reasonable certainty of the validity of such prescription.
4. A pharmacist who dispenses prescription drugs in violation of this Section is not acting in the best interest of the patient and is dispensing outside the course of the professional practice of pharmacy.

NOTICE OF PROPOSED RULEMAKING

TITLE 15. REVENUE

CHAPTER 5. DEPARTMENT OF REVENUE
TRANSACTION PRIVILEGE AND USE TAX SECTION

[R07-407]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R15-5-2214 Amend

2. 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. §§ 42-1005 and 42-5008

Implementing statute: A.R.S. § 42-5009

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

Notice of Rulemaking Docket Opening: 13 A.A.R. 4413, December 14, 2007 *(in this issue)*

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

Name: Len Heugly, Tax Analyst

Address: Tax Policy and Research Division
Department of Revenue
1600 W. Monroe, Room 810
Phoenix, AZ 85007

Telephone: (602) 716-6039

Fax: (602) 716-7995

E-mail: LHeugly@azdor.gov

Please visit the ADOR web site to track the progress of these rules and other agency rulemaking matters at www.azdor.gov/ResearchStats/Proposedrulesmainmenu.htm.

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

The amendment to A.A.C. R15-5-2214 will impose time limitations on when taxpayers may issue exemption certificates. Currently, the rules are silent as to when exemption certificates, whether created by the Department or otherwise, may be issued. This omission has allowed taxpayers to issue exemption certificates well after the transaction or event occurred and apply them retroactively.

A retroactive exemption certificate does not automatically exempt the transaction from transaction privilege tax and the transaction must still be shown to be exempt to the satisfaction of the Department. Nevertheless, retroactive exemption certificates do affect the burden of proof requirements. Without an exemption certificate, the burden of proof remains on the vendor to prove entitlement to the exemption per A.R.S. § 42-5009(B). If the vendor accepts a certificate other than a departmental certificate, the burden of proof will also remain with the vendor. A.A.C. R15-5-2214(D). This changes when the vendor accepts in good faith an exemption certificate created by the Department. Here, according to A.R.S. § 42-5009(D), the vendor is relieved of any tax liability and the Department must take action against the purchaser and the burden of proof is now on the Department per A.A.C. R15-5-2214(B)(7).

This burden of proof shift is problematic to the Department because it allows taxpayers under audit to issue retroactive exemption certificates after the fact and place the burden on the Department to prove the accuracy of the information on the certificates. The Department feels that taxpayers who have had every opportunity to obtain an exemption certificate prior to audit should still carry the burden of proving the transaction is exempt during audit.

The proposed amendment to A.A.C. R15-5-2214 ensures that the burden of proof shift will not occur by providing certain deadlines for when exemption certificates must be issued. The proposed rules provide two deadlines: the time of purchase or when the vendor's transaction privilege or use tax return is due.

Finally, the amendment serves to remind taxpayers that have not obtained exemption certificates within the proscribed deadlines that they can still prove that they are entitled to the exemption pursuant to A.R.S. § 42-5009(B).

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each 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 rule primarily reduces an existing administrative burden of the agency. The Department may have decreased costs by imposing deadlines for issuance of exemption certificates. This is because the rule may impact the amount of disputed cases that eventually go before the Office of Administrative Hearings. The rule will clarify the requirements for accepting exception certificates and promote better bookkeeping for vendors.

Imposing deadlines will not affect internal departmental procedures used in determining the validity of an exemption certificate. It may mean that the Department is more likely to challenge exemption certificates that appear to be issued after the deadlines. The Department will still have the burden of proving that all other information aside from the date of issuance is incomplete, inaccurate or that the exemption claimed is not based on statutory provisions.

The economic impact is primarily born by the vendors (taxpayers). Taxpayers will no longer be able to prove entitlement to a statutory exemption merely by obtaining an exemption certificate at any time during the course of an audit. This requirement may cause taxpayers to concede cases where exemptions questionably apply. It also may cost the taxpayer more manpower, consultation, or representation to prove entitlement to an exemption or that the exemption certificate was issued within the proscribed time-frames. This may affect small businesses by increasing the amount of time taxpayers spend timely maintaining proper books and records.

Despite these costs to taxpayers, the Department believes that the benefit of this rule outweighs its comparatively small burden. The rule curbs taxpayer abuse of exemption certificates by more appropriately requiring taxpayers to obtain exemption certificates within a time-frame closer to the transaction and not years removed from it. Consequently, the administrative burden on the Department is diminished by placing the burden of proof on the party whose neglect to obtain proper documentation created the exception. The rule requirements to timely and adequately keep company books and records evidencing the exempt transactions will require taxpayers to more carefully consider the applicability of an exemption to a transaction.

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: Len Heugly, Tax Analyst

Address: Tax Policy and Research Division
Department of Revenue
1600 W. Monroe, Room 810
Phoenix, AZ 85007

Telephone: (602) 716-6039

Fax: (602) 716-7995

E-mail: LHeugly@azdor.gov

10. 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 rules:

No oral proceeding is scheduled. Under A.R.S. § 41-1023(C), an oral proceeding will be scheduled if a written request is submitted to the person identified in item 4 within 30 days after publication of this notice.

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

None

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

None

13. The full text of the rules follows:

TITLE 15. REVENUE

CHAPTER 5. DEPARTMENT OF REVENUE
TRANSACTION PRIVILEGE AND USE TAX SECTION

ARTICLE 22. TRANSACTION PRIVILEGE TAX ADMINISTRATION

Section
R15-5-2214. Establishing the Right to a Deduction by Use of a Certificate or Other Documentation

ARTICLE 22. TRANSACTION PRIVILEGE TAX ADMINISTRATION

R15-5-2214. Establishing the Right to a Deduction by Use of a Certificate or Other Documentation

A. The vendor is responsible for the payment of tax and therefore shall provide sufficient documentation in support of all deductions.

B. The vendor may establish a deduction or exclusion from the tax base pursuant to A.R.S. § ~~42-1316~~ 42-5009 or ~~42-1328~~ 42-5022.

1. If the purchaser does not have a valid license number, the purchaser shall indicate the reason on any certificate.
2. Marking an invoice may be done either by recording the purchaser's transaction privilege tax license number on the invoice or by cross referencing the specific transaction to the specific exemption certificate of the specific purchaser.
3. The Department has prescribed a certificate for establishing entitlement to statutory deductions. Reproductions of the blank prescribed original certificate shall be acceptable for use.
4. The appropriate certificate shall be accurately and fully completed by the purchaser.
5. If the vendor has reason to believe that the information contained in the certificate is not accurate, complete, or applicable to the transaction, the vendor may refuse to accept the certificate.
6. If at any time the vendor has reason to believe that the certificate is not applicable to a transaction, the vendor may refuse to honor the certificate for that transaction.
7. The Department may challenge the certificate as accepted by the vendor if the Department has reason to believe that the information in the certificate is incomplete, inaccurate, or if the exemption claimed is not based on statutory provisions. The burden of proof lies with the Department when a vendor accepts a completed departmental certificate and marks the applicable invoice pursuant to statute.
8. Fully completed exemption certificates, whether in departmental form or otherwise, shall be obtained by the vendor before or at the time of the purchase or by the date the vendor's return is due.
9. If the vendor has not obtained the necessary exemption certificate before the return is due, the vendor may prove the sale is exempt from tax pursuant to A.R.S. § 42-5009(B).

C. A blanket certificate may be accepted if the vendor and purchaser agree. The blanket certificate may continue in force, for

applicable transactions, for a period of time as set forth on the certificate. For purposes of this rule, a blanket certificate is one which covers the indicated type of transaction over a specified period of time.

1. The vendor may refuse to honor a blanket certificate and shall cancel such a certificate if, at any time, the vendor has reason to believe that the information contained in the certificate is no longer accurate or complete or no longer applies.
2. A new, accurate, and complete certificate may then be accepted.

D. Documentation, including a certificate other than a departmental certificate, may be accepted by the vendor to establish the right to a deduction.

1. If the vendor accepts a form of documentation other than a completed departmental certificate, the burden of proof remains with the vendor to establish the right to the deduction.
2. Other documentation necessary to establish a deduction from the tax base shall contain the information required by A.R.S. § ~~42-1316(A)~~ 42-5009(A).

E. Documentation or a certificate to establish a deduction from the tax base shall be provided for each transaction or if a blanket certificate is used for each different exemption category.

F. The vendor shall retain all documentation for the required statutory period pursuant to A.R.S. § ~~42-113~~ 42-1104.