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

Editor's Note: The following Notice of Proposed Rulemaking was exempt from Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 1045.)

[R12-55]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

R4-23-110	Amend
R4-23-1005	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. §§ 32-1904(A)(1) and 36-2521

Implementing statute: A.R.S. §§ 36-2512(B), 36-2513(B), 36-2514(B), 36-2515(B), and 36-2523

3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 18 A.A.R. 5, January 6, 2012

4. The agency's contact person who can answer questions about the rulemaking:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

During the Board's five-year rule review approved September 14, 2010, the Board determined that R4-23-1005 Substances Excepted from the Schedules of Controlled Substances needed to be amended to update citations in subsections (A), (B), and (C).

The proposed rulemaking will include amending definitions in R4-23-110 (Definitions) that the Board has identified as due for update, such as, "continuing education" and "adult-administered immunizations training program." The rulemaking will delete definitions identified after the repeal of the Drug Therapy Management rules in December 2011 that only relate to the repealed Drug Therapy Management rules and are no longer necessary. The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing those substances that are excepted from the schedules of 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 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, and pharmacies. The proposed rules' impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the proposed rules will have no economic impact on pharmacist and pharmacies. The rulemaking is necessary to update citations in subsections (A), (B), and (C) of R4-23-1005 (Substances Excepted from the Schedules of Controlled Substances). The citations to federal law last updated in August 2000, need to be updated. The proposed rulemaking will include amending definitions in R4-23-110 (Definitions) that the Board has identified as due for update, such as, "continuing education" and "adult-administered immunizations training program." The rulemaking will delete definitions identified after the repeal of the Drug Therapy Management rules in December 2011 that only relate to the repealed Drug Therapy Management rules and are no longer necessary. The amending of these definitions will have no economic impact on pharmacists or pharmacies.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing those substances that are excepted from the schedules of controlled substances.

9. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy P.O. Box 18520 Phoenix, AZ 85005
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber 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., Tuesday, June 5, 2012. An oral proceeding is scheduled for:

Date:	June 5, 2012
Time:	10:00 a.m.
Location:	1616 W. Adams St., 1st Floor, Board Room Phoenix, AZ 85007

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

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

Not applicable

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rule does not require a permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Yes, the rule is a citation to federal regulations. The rule is not more stringent than the federal regulations. The rule incorporates the federal regulations by reference.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

21 CFR 1308.22 April 1, 2012 in R4-23-1005(A)

21 CFR 1308.24 April 1, 2012 in R4-23-1005(B)

21 CFR 1308.32 April 1, 2012 in R4-23-1005(C)

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 10. UNIFORMED CONTROLLED SUBSTANCES AND DRUG OFFENSES

Section
R4-23-1005. Substances Excepted from the Schedules of Controlled Substances

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" means any component that furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or that affects the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug, that are present in the finished drug product in a modified form, and that furnish the specified activity or effect.

"AHCCCS" means the Arizona Health Care Cost Containment System.

~~"Alternate physician" means a physician licensed under A.R.S. Title 32 Chapter 13 or 17 who signs a drug therapy management agreement to temporarily assume responsibility for supervision and evaluation of the drug therapy management performed by a pharmacist when the supervisory physician is unavailable by direct telecommunication or physical presence at the practice site.~~

"Annual family income" means the combined yearly gross earned income and unearned income of all adult individuals within a family unit.

"Approved course in pharmacy law" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations.

"Approved Provider" means an individual, institution, organization, association, corporation, or agency that is approved by the Accreditation Council 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" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"Automated storage and distribution system" means a mechanical system that performs operations or activities other than counting, compounding, or administration, relative to the storage, packaging, or distributing of drugs or devices and that collects, controls, and maintains all transaction information.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means:

A date determined by a pharmacist and placed on a prescription label at the time of dispensing to indicate a time beyond which the contents of the prescription are not recommended to be used; or

A date determined by a pharmacist and placed on a compounded pharmaceutical product's label at the time of preparation as specified in R4-23-410(B)(3)(d), ~~R4-23-410(I)(6)(e)~~ (I)(6)(e), or ~~R4-23-410(J)(1)(d)~~ (J)(1)(d) to indicate a time beyond which the compounded pharmaceutical product is not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents when

there is a need for protection of the product, personnel, and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, NSF International P. O. Box 130140, Ann Arbor, MI, revised June 1987 edition, (and no future amendments or editions), incorporated by reference and on file with the Board.

"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.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

"Component" means any ingredient used in compounding or manufacturing drugs in dosage form, including an ingredient that may not appear in the finished product.

"Compounding and dispensing counter" means a pharmacy counter working area defined in this Section where a pharmacist or a graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist compounds, mixes, combines, counts, pours, or prepares and packages a prescription medication to dispense an individual prescription order or prepackages a drug for future dispensing.

"Computer system" means an automated data-processing system that uses a programmable electronic device to store, retrieve, and process data.

"Computer system audit" means an accounting method, involving multiple single-drug usage reports and audits, used to determine a computer system's ability to store, retrieve, and process original and refill prescription dispensing information.

"Contact hour" means 50 minutes of participation in a continuing education activity sponsored by an Approved Provider.

"Container" means:

A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or

A metal receptacle designed to contain liquefied or vaporized compressed medical gas and used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.

"Continuing education" means a structured learning process required of a ~~licensed pharmacist~~ licensee to maintain licensure that includes study in the general areas of socio-economic and legal aspects of health care; the properties and actions of drugs and dosage forms; etiology, characteristics and therapeutics of disease status; or pharmacy practice.

"Continuing education activity" means continuing education obtained through an institute, seminar, lecture, conference, workshop, mediated instruction, programmed learning course, or postgraduate study in an accredited college or school of pharmacy.

"Continuing education unit" or "CEU" means 10 contact hours of participation in a continuing education activity sponsored by an Approved Provider.

"Correctional facility" has the same meaning as in A.R.S. §§ 13-2501 and 31-341.

"CRT" means a cathode ray tube or other mechanism used to view information produced or stored by a computer system.

"CSPMP" means the Controlled Substances Prescription Monitoring Program established under A.R.S. Title 36, Chapter 28.

"Current good compounding practices" means the minimum standards for methods used in, and facilities or controls used for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Current good manufacturing practice" means the minimum standard for methods used in, and facilities or controls used for manufacturing, processing, packing, or holding a drug to ensure that the drug meets the requirements of the federal act as to safety, and has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Cytotoxic" means a pharmaceutical that is capable of killing living cells.

"Day" means a calendar day unless otherwise specified.

"DEA" means the Drug Enforcement Administration as defined in A.R.S. § 32-1901.

"Declared disaster areas" means areas designated by the governor or by a county, city, or town under A.R.S. § 32-

1910 as those areas that have been adversely affected by a natural disaster or terrorist attack and require extraordinary measures to provide adequate, safe, and effective health care for the affected population.

"Delinquent license" means a pharmacist, pharmacy intern, graduate intern, or pharmacy technician license the Board suspends for failure to renew or pay all required fees on or before the date the renewal is due.

"Dietary supplement" means a product (other than tobacco) that:

Is intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;

Is intended for ingestion in pill, capsule, tablet, or liquid form;

Is not represented for use as a conventional food or as the sole item of a meal or diet; and

Is labeled as a "dietary supplement."

"Digital signature" has the same meaning as in A.R.S. § 41-132(E).

"Dispensing pharmacist" means a pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the prescription medication label, as required in R4-23-402(A).

"Drug sample" means a unit of a prescription drug that a manufacturer provides free of charge to promote the sale of the drug.

~~"Drug therapy management" means any act or service provided by a pharmacist in compliance with a Board-approved drug therapy management agreement.~~

~~"Drug therapy management agreement" means a written protocol, approved and signed by a supervisory physician, alternate physician, and pharmacist that specifies the conditions under which a pharmacist:~~

~~Assesses patient status;~~

~~Orders and interprets laboratory tests; and~~

~~Modifies, implements, or monitors patient drug therapy.~~

"Earned income" means monetary payments received by an individual as a result of work performed or rental property owned or leased by the individual, including:

Wages,

Commissions and fees,

Salaries and tips,

Profit from self-employment,

Profit from rent received from a tenant or boarder, and

Any other monetary payments received by an individual for work performed or rental of property.

"Electronic signature" has the same meaning as in A.R.S. § 44-7002.

"Eligible patient" means a patient who a pharmacist determines is eligible to receive an immunization using professional judgment after consulting with the patient regarding the patient's current health condition, recent health condition, and allergies.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"Family unit" means:

A group of individuals residing together who are related by birth, marriage, or adoption; or

An individual who:

Does not reside with another individual; or

Resides only with another individual or group of individuals to whom the individual is unrelated by birth, marriage, or adoption.

"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.

"Health care decision maker" has the same meaning as in A.R.S. § 12-2291.

"Health care institution" has the same meaning as in A.R.S. § 36-401.

"Immediate notice" means a required notice sent by mail, facsimile, or electronic mail to the Board Office within 24 hours.

~~"Pharmacist-administered immunizations~~ "Immunizations training program" means an immunization training program for pharmacists, pharmacy interns, and graduate interns that meets the requirements of ~~R4-23-411(C)~~ R4-23-411(E).

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Internal test assessment" means performing quality assurance or other procedures necessary to ensure the integrity of a test.

"ISO Class 5 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.

"ISO Class 7 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.

"Licensed health care professional" means an individual who is licensed and regulated under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 25, 29, or 35.

"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that:

Holds a current Board permit under A.R.S. § 32-1931;

Is located in a correctional facility; and

Uses pharmacists, interns, and support personnel to compound, produce, dispense, and distribute drugs.

"Limited-service long-term care pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board-issued permit and dispenses prescription medication or prescription-only devices to patients in long-term care facilities.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

"Limited-service nuclear pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and provides radiopharmaceutical services.

"Limited-service pharmacy permittee" means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

"Limited-service sterile pharmaceutical products pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices as sterile pharmaceutical products.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Long-term care facility" or "LTCF" means a nursing care institution as defined in A.R.S. § 36-401 or an assisted living facility that:

Provides 24-hour, seven-day a week licensed nursing services to resident patients; and

Is licensed by the Arizona Department of Health Services.

"Lot" means a batch or any portion of a batch of a drug, or if a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity. In either case, a lot is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.

"Low-income subsidy" means Medicare-provided assistance that may partially or fully cover the costs of drugs and is based on the income of an individual and, if applicable, the individual's spouse.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

"Mechanical counting device for a drug in solid, oral dosage form" means a mechanical device that counts drugs in solid, oral dosage forms for dispensing and includes an electronic balance when used to count drugs.

"Mechanical storage and counting device for a drug in solid, oral dosage form" means a mechanical device that stores and counts and may package or label drugs in solid, oral dosage forms for dispensing.

"Mediated instruction" means information transmitted via intermediate mechanisms such as audio or video tape or telephone transmission.

"Medical practitioner-patient relationship" means that before prescribing, dispensing, or administering a prescription-only drug, prescription-only device, or controlled substance to a person, a medical practitioner, as defined in A.R.S. § 32-1901, shall first conduct a physical examination of that person or have previously conducted a physical examination. This subdivision does not apply to:

A medical practitioner who provides temporary patient supervision on behalf of the patient's regular treating medical practitioner;

Emergency medical situations as defined in A.R.S. § 41-1831;

Prescriptions written to prepare a patient for a medical examination; or

Prescriptions written, prescription-only drugs, prescription-only devices, or controlled substances issued for use by a county or tribal public health department for immunization programs, emergency treatment, in response to an infectious disease investigation, public health emergency, infectious disease outbreak or act of bioterrorism. For purposes of this subsection, "bioterrorism" has the same meaning as in A.R.S. § 36-781.

"Medicare" means a federal health insurance program established under Title XVIII of the Social Security Act.

"Mobile pharmacy" means a pharmacy that is self propelled or movable by another vehicle that is self propelled.

"MPJE" means Multistate Pharmacy Jurisprudence Examination, a Board-approved national pharmacy law examination written and administered in cooperation with NABP.

"NABP" means National Association of Boards of Pharmacy.

"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.

"NAPLEX" means North American Pharmacist Licensure Examination.

"Order" means either of the following:

A prescription order as defined in A.R.S. § 32-1901~~.~~, or

A medication order as defined in A.A.C. R4-23-651.

"Other designated personnel" means a non-pharmacist individual who is permitted in the pharmacy area, for a limited time, under the direct supervision of a pharmacist, to perform non-pharmacy related duties, such as trash removal, floor maintenance, and telephone or computer repair.

"Outpatient" means an individual who is not a residential patient in a health care institution.

"Outpatient setting" means a location that provides medical treatment to an outpatient.

"Patient profile" means a readily retrievable, centrally located information record that contains patient demographics, allergies, and medication profile.

"Pharmaceutical patient care services" means the provision of drug selection, drug utilization review, drug administration, drug therapy monitoring, and other drug-related patient care services intended to achieve outcomes related to curing or preventing a disease, eliminating or reducing a patient's symptoms, or arresting or slowing a disease process, by identifying and resolving or preventing potential and actual drug-related problems.

"Pharmaceutical product" means a medicinal drug.

"Pharmacy counter working area" means a clear and continuous working area that contains no major obstacles such as a desktop computer, computer monitor, computer keyboard, external computer drive device, printer, facsimile machine, pharmacy balance, typewriter, or pill-counting machine, but may contain individual documents or prescription labels, pens, prescription blanks, refill log, pill-counting tray, spatula, stapler, or other similar items necessary for the prescription-filling process.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations, offered by an Approved Provider.

"Pharmacy permittee" means a person who holds a current pharmacy permit that complies with A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1934, and A.A.C. R4-23-606 and R4-23-652.

"Physician" means a medical practitioner licensed under A.R.S. Title 32, Chapter 13 or 17.

"Physician-in-charge" means a physician who is responsible to the Board for all aspects of a prescription medication

donation program required in A.R.S. § 32-1909 and operated in the physician's office or in a health care institution.

"Poverty level" means the annual family income for a family unit of a particular size, as specified in the poverty guidelines updated annually in the *Federal Register* by the U.S. Department of Health and Human Services.

"Precursor chemical" means a precursor chemical I as defined in A.R.S. § 13-3401(26) and a precursor chemical II as defined in A.R.S. § 13-3401(27).

"Prepackaged drug" means a drug that is packaged in a frequently prescribed quantity, labeled in compliance with A.R.S. §§ 32-1967 and 32-1968, stored, and subsequently dispensed by a pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist, who verifies at the time of dispensing that the drug container is properly labeled, in compliance with A.R.S. § 32-1968, for the patient.

"Prep area" means a specified area either within an ISO class 7 environment or adjacent to but outside an ISO class 7 environment that:

Allows the assembling of necessary drugs, supplies, and equipment for compounding sterile pharmaceutical products, but does not allow the use of paper products such as boxes or bulk drug storage;

Allows personnel to don personnel protective clothing, such as gown, gloves, head cover, and booties before entering the clean compounding area; and

Is a room or a specified area within a room, such as an area specified by a line on the floor.

"Primary care provider" means the medical practitioner who is treating an individual for a disease or medical condition.

"Proprietor" means the owner of a business permitted by the Board under A.R.S. §§ 32-1929, 32-1930, 32-1931, and 32-1934.

"Provider pharmacy" means a pharmacy that contracts with a long-term care facility to supply prescription medication or other services for residents of a long-term care facility.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of a radiopharmaceutical, but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and

Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means performing and interpreting appropriate chemical, biological, and physical tests on radiopharmaceuticals to determine the suitability of the radiopharmaceutical for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and appropriate record retention.

"Radiopharmaceutical services" means procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, recordkeeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs. Radiopharmaceutical services include quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Red C stamp" means a device used with red ink to imprint an invoice with a red letter C at least one inch high, to make an invoice of a Schedule III through IV controlled substance, as defined in A.R.S. § 36-2501, readily retrievable, as required by state and federal rules.

"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~~.~~ ~~In~~ in the original prescription order~~.~~:

By an electronically transmitted refill order that the pharmacist promptly documents and files~~.~~, or

By an oral refill order that the pharmacist promptly documents and files.

"Regulated chemical" means the same as in A.R.S. § 13-3401(30).

"Remodel" means to alter structurally the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means:

An individual admitted to and living in a long-term care facility,

An individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist, or

A person who owns or operates a place of business in Arizona.

"Responsible person" means the owner, manager, or other employee who is responsible to the Board for a permitted establishment's compliance with the laws and administrative rules of this state and of the federal government pertaining to distribution of drugs, devices, precursor chemicals, and regulated chemicals. Nothing in this definition relieves other individuals from the responsibility to comply with state and federal laws and administrative rules.

"Score transfer" means the process that enables an applicant to take the NAPLEX in a jurisdiction and be eligible for licensure by examination in other jurisdictions.

"Security features" means the attributes incorporated into the paper of a prescription order, referenced in A.R.S. § 32-1968(A)(4), that 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" means the following:

Preparing, packaging, compounding, or labeling an order, or any combination of these functions, that are performed by:

A person with a current Arizona Board license, located at an Arizona pharmacy, on behalf of and at the request of another resident or nonresident pharmacy; or

A person, located at a nonresident pharmacy, on behalf of and at the request of an Arizona pharmacy; and

Returning the filled order to the requesting pharmacy for delivery to the patient or patient's care-giver or, at the request of this pharmacy, directly delivering the filled order to the patient.

"Shared order processing" means the following:

Interpreting the order, performing order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, and when necessary, therapeutic intervention, or any combination of these order processing functions, that are performed by:

A pharmacist or intern, under pharmacist supervision, with a current Arizona Board license, located at an Arizona pharmacy, on behalf of and at the request of another resident or nonresident pharmacy: or

A pharmacist or intern, under pharmacist supervision, located at a nonresident pharmacy, on behalf of and at the request of an Arizona pharmacy; and

After order processing is completed, returning the processed order to the requesting pharmacy for order filling and delivery to the patient or patient's care-giver or, at the request of this pharmacy, returning the processed order to another pharmacy for order filling and delivery to the patient or patient's care-giver.

"Shared services" means shared order filling or shared order processing, or both.

"Sight-readable" means that an authorized individual is able to examine a record and read its information from a CRT, microfiche, microfilm, printout, or other method acceptable to the Board or its designee.

"Single-drug audit" means an accounting method that determines the numerical and percentage difference between a drug's beginning inventory plus purchases and ending inventory plus sales.

"Single-drug usage report" means a computer system printout of original and refill prescription order usage information for a single drug.

"Standard-risk sterile pharmaceutical product" means a sterile pharmaceutical product compounded from sterile commercial drugs using sterile commercial devices or a sterile pharmaceutical otic or ophthalmic product compounded from non-sterile ingredients.

"State of emergency" means a governmental declaration issued under A.R.S. § 32-1910 as a result of a natural disaster or terrorist attack that results in individuals being unable to refill existing prescriptions.

"Sterile pharmaceutical product" means a medicinal drug free from living biological organisms.

"Strength" means:

The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis); or

The potency, that is, the therapeutic activity of a drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Substantial-risk sterile pharmaceutical product" means a sterile pharmaceutical product compounded as a parenteral or injectable dosage form from non-sterile ingredients.

"Supervision" means a pharmacist is present, assumes legal responsibility, and has direct oversight of activities relating to acquiring, preparing, distributing, administering, and selling prescription medications by pharmacy interns, graduate interns, pharmacy technicians, or pharmacy technician trainees and when used in connection with the intern training requirements means that, in a pharmacy where intern training occurs, a pharmacy intern preceptor assumes the primary responsibility of teaching the intern during the entire period of the training.

~~"Supervisory physician" means a physician licensed under A.R.S. Title 32 Chapter 13 or 17 who:~~

~~Writes an order in a patient's medical record and signs a drug therapy management agreement authorizing a pharmacist to provide patient-specific drug therapy management, and~~

~~Assumes responsibility for the on-going supervision and evaluation of the drug therapy management performed by the pharmacist.~~

"Supplying" means selling, transferring, or delivering to a patient or a patient's agent one or more doses of:

A nonprescription drug in the manufacturer's original container for subsequent use by the patient, or

A compressed medical gas in the manufacturer's or compressed medical gas distributor's original container for subsequent use by the patient.

"Support personnel" means an individual, working under the supervision of a pharmacist, trained to perform clerical duties associated with the practice of pharmacy, including cashiering, bookkeeping, pricing, stocking, delivering, answering non-professional telephone inquiries, and documenting third-party reimbursement. Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee.

"Temporary pharmacy facility" means a facility established as a result of a declared state of emergency to temporarily provide pharmacy services within or adjacent to declared disaster areas.

"Tourist" means an individual who is living in Arizona but maintains a place of habitation outside of Arizona and lives outside of Arizona for more than six months during a calendar year.

"Transfill" means a manufacturing process by which one or more compressed medical gases are transferred from a bulk container to a properly labeled container for subsequent distribution or supply.

"Unearned income" means monetary payment received by an individual that is not compensation for work performed or rental of property owned or leased by the individual, including:

Unemployment insurance,

Workers' compensation,

Disability payments,

Payments from the Social Security Administration,

Payments from public assistance,

Periodic insurance or annuity payments,

Retirement or pension payments,

Strike benefits from union funds,

Training stipends,

Child support payments,

Alimony payments,

Military family allotments,

Regular support payments from a relative or other individual not residing in the household,

Investment income,

Royalty payments,

Periodic payments from estates or trusts, and

Any other monetary payments received by an individual that are not:

As a result of work performed or rental of property owned by the individual,

Gifts,

Lump-sum capital gains payments,

Lump-sum inheritance payments,

Lump-sum insurance payments, or

Payments made to compensate for personal injury.

"Verified signature" or "signature verifying" means in relation to a Board license or permit application or report, form, or agreement, the hand-written or electronic signature of an individual who, by placing a hand-written or electronic signature on a hard-copy or electronic license or permit application or report, form, or agreement agrees with and verifies that the statements and information within or attached to the license or permit application or report, form, or agreement are true in every respect and that inaccurate reporting can result in denial or loss of a license or permit or report, form, or agreement.

"Veteran" means an individual who has served in the United States Armed Forces.

"Wholesale distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

Selling, purchasing, or trading a drug or offering to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Section, "emergency medical reasons" includes transferring a prescription drug by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage;

Selling, purchasing, or trading a drug, offering to sell, purchase, or trade a drug, or dispensing a drug as specified in a prescription;

Distributing a drug sample by a manufacturers' or distributors' representative; or

Selling, purchasing, or trading blood or blood components intended for transfusion.

"Wholesale distributor" means any person engaged in wholesale distribution of drugs, including: manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least 5% of gross sales.

ARTICLE 10. UNIFORMED CONTROLLED SUBSTANCES AND DRUG OFFENSES

R4-23-1005. Substances Excepted from the Schedules of Controlled Substances

A. All over-the-counter non-narcotic substances containing limited amounts of controlled substances that are excluded from all controlled substance schedules by 21 CFR ~~§~~ 1308.22 ~~April 1, 1999~~ April 1, 2012, and no future editions or amendments, incorporated by reference and on file with the Board ~~and the Office of the Secretary of State~~, are excluded from all controlled substance schedules in Arizona.

B. All chemical preparations or mixtures containing one or more controlled substances listed in any schedule that are exempted from all controlled substance schedules by 21 CFR ~~§~~ 1308.24 ~~April 1, 1999~~ April 1, 2012, and no future editions or amendments, incorporated by reference and on file with the Board ~~and the Office of the Secretary of State~~, are exempted from all controlled substance schedules in Arizona.

C. All prescription-only drugs that are exempted by 21 CFR ~~§~~ 1308.32 ~~April 1, 1999~~ April 1, 2012, and no future editions or amendments, incorporated by reference and on file with the Board ~~and the Office of the Secretary of State~~, are exempted from all controlled substance schedules in Arizona.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 46. BOARD OF APPRAISAL

Editor's Note: The following Notice of Proposed Rulemaking was exempt from Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 1045.)

[R12-57]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) **Rulemaking Action**
R4-46-401 Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):
Authorizing statute: A.R.S. § 32-3605(A)

Implementing statutes: A.R.S. §§ 32-3605(B)(1) and 32-3635(A)

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

Notice of Rulemaking Docket Opening: 18 A.A.R. 1041, May 4, 2012 *(in this issue)*

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

Name: Dan Pietropaulo, Executive Director

Address: 1400 W. Washington St., Suite 360
Phoenix, AZ 85007

Telephone: (602) 542-1566

Fax: (602) 542-1598

E-mail: daniel.pietropaulo@appraisal.state.az.us

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

The change in the rule is to comply with Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, which requires state licensing boards to recognize and enforce the *Uniform Standards of Professional Appraisal Practice* (USPAP); and A.R.S. § 32-3605(B)(1), which requires the Board to adopt standards for professional appraisal practice that are at least equal to USPAP. The amended rule incorporates by reference the 2012-2013 edition of USPAP.

The goal of the *Uniform Standards of Professional Appraisal Practice* is to promote and maintain a high level of public trust in appraisal practice by establishing requirements for appraisers. All potential changes and additions to USPAP are evaluated in light of this goal. The adopted changes are intended to improve the clarity, understanding and enforcement of USPAP, thereby furthering the goal of promoting and maintaining public trust in appraisal practice.

In reviewing comment letters received on the exposure drafts, the ASB's primary focus is the reasoning and insight presented in the letters, rather than the source or authorship. The ASB is guided by the quality, relevancy, and accuracy of the points made, and not their frequency.

On April 8, 2011, the Appraisal Standards Board (ASB) approved and adopted modifications to the *Uniform Standards of Professional Appraisal Practice* (USPAP). The changes to USPAP that were adopted by the ASB were the result of five exposure drafts, which were issued on January 5, 2010, May 27, 2010, September 29, 2010, December 10, 2010, and February 11, 2011. The following changes were adopted by the ASB on April 8, 2011, and will be incorporated in the 2012-13 edition of USPAP and associated guidance material with an effective date of January 1, 2012:

- Revisions to DEFINITIONS of "Client," "Extraordinary Assumption," "Hypothetical Condition," and a new definition, "Exposure Time"
- Revisions Relating to Development and Disclosure of Exposure Time Opinion
- Revisions to Standards Rules 2-3, 3-6, 5-3, 6-9, 8-3 and 10-3
- Creation of a new RECORD KEEPING RULE and Related Edits to the Conduct Section of the ETHICS RULE
- Revisions to Advisory Opinion 21, *USPAP Compliance*
- Revisions to STANDARDS 7 and 8: PERSONAL PROPERTY APPRAISAL, DEVELOPMENT and REPORTING

In a separate action, on May 10, 2011 the Board adopted an additional revision related to Advisory opinion 13 (AO-13), *Performing Evaluations of Real Property Collateral to Conform with USPAP******

The key features of the 2012-2013 edition are:

(1) The definition of Client was changed to: CLIENT: the party or parties who engage, by employment or contract, an appraiser in a specific assignment. Comment: The client may be an individual, group, or entity, and may engage and communicate with the appraiser directly or through an agent. The definition was revised to further clarify the proper application of the term client and to facilitate in the proper identification of the client in assignments. NOTE: Corresponding edits regarding the definition of Client will be made to STATEMENT ON APPRAISAL STANDARDS NO. 9 (SMT-9).

(2) A new definition of Exposure Time was developed from STATEMENT ON APPRAISAL STANDARDS NO. 6 (SMT-6): EXPOSURE TIME: estimated length of time that the property interest being appraised would have been offered on the market prior to the hypothetical consummation of a sale at market value on the effective date of the appraisal. Comment: Exposure time is a retrospective opinion based on an analysis of past events assuming a competitive and open market. The new definition is substantially the same as the definition currently in SMT-6, but it has been somewhat reformatted to be consistent with the rest of the DEFINITIONS. With the adoption of this definition, minor edits to SMT-6 will be made. The extent of those edits will be replacing the current paragraph that includes the definition with a copy of the new definition and a reference to its location in the DEFINITIONS. Moving this definition to the DEFINITIONS will enhance the usability of USPAP.

(3) The definition of Extraordinary Assumption was changed to: EXTRAORDINARY ASSUMPTION: an assumption, directly related to a specific assignment, as of the effective date of the assignment results, which, if found to be

false, could alter the appraiser's opinions or conclusions. Comment: Extraordinary assumptions presume as fact otherwise uncertain information about physical, legal, or economic characteristics of the subject property; or about conditions external to the property, such as market conditions or trends; or about the integrity of data used in an analysis. The current definition of extraordinary assumption is often misunderstood by appraisers, clients and other intended users. This misunderstanding can result in misapplication by appraisers, increasing the probability of misleading assignment results. The ASB believes that adding the concept of the effective date of the assignment results to the definition will reduce misunderstanding and misapplication of this term.

(4) The definition of Hypothetical Condition was changed to: HYPOTHETICAL CONDITION: a condition, directly related to a specific assignment, which is contrary to what is known by the appraiser to exist on the effective date of the assignment results, but is used for the purpose of analysis. Comment: Hypothetical conditions are contrary to known facts about physical, legal, or economic characteristics of the subject property; or about conditions external to the property, such as market conditions or trends; or about the integrity of data used in an analysis. The current definition of hypothetical condition is often misunderstood by appraisers, clients and other intended users. This misunderstanding can result in misapplication by appraisers, increasing the probability of misleading assignment results. The ASB believes that adding the concept of the effective date of the assignment results to the definition will reduce misunderstanding and misapplication of this term.

(5) The Board adopted the revisions proposed in the Fifth Exposure Draft related to the Comment to Standards Rules 1-2(c)(iv), 2-2(a)(v), 2-2(b)(v), 2-2(c)(v), 8-2(a)(v), 8-2(b)(v), and 8-2(c)(v). In addition, the Board updated STATEMENT ON APPRAISAL STANDARDS NO. 6 (SMT-6) to reflect that *exposure time* is now included in the DEFINITIONS section of USPAP.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on in its evaluation of or justification for the rule or proposes 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:

Not applicable

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 rule is being amended to adopt the latest standards of practice in the profession, as required by federal and state law. The primary groups that will be affected are the Board, licensed or certified appraisers, trainees and the public. The Board adopts the latest standards for professional appraisal practice as they are adopted by the ASB and there should be no appreciable changes in the economic impact. However, USPAP prior to the 2006 edition was revised annually, the 2006 edition was effective for 18 months, and the 2012-2013 edition is effective for two years, which results in USPAP having to be purchased less often. The cost for the new edition, which now includes Frequently Asked Questions, is $55. Not all appraisers will find it necessary to own a copy. Some offices share copies. The cost is a deductible business expense.

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:	Dan Pietropaulo, Executive Director
Address:	1400 W. Washington St., Suite 360 Phoenix, AZ 85007
Telephone:	(602) 542-1566
Fax:	(602) 542-1598
E-mail:	daniel.pietropaulo@appraisal.state.az.us

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:

Oral and written comments are accepted at the address listed in items 4 and 9 above and between the hours of 8:00-4:30 p.m., Monday through Friday, except for state holidays.

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

None

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

Not applicable

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Federal law is applicable to the subject of the rule, and the rule is not more stringent than the federal law.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis was submitted.

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

The *Uniform Standards of Professional Appraisal Practice* (USPAP), 2012-2013 Edition, published by The Appraisal Foundation, 1155 15th St., NW, Suite 1111, Washington, DC 20005, phone (202) 347-7722, fax (202) 347-7727, or web site www.appraisalfoundation.org and effective nationally January 1, 2012. The location in the rules is R4-46-401.

13. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 46. BOARD OF APPRAISAL

ARTICLE 4. STANDARDS OF PRACTICE

Section
R4-46-401. Standards of Appraisal Practice

ARTICLE 4. STANDARDS OF PRACTICE

R4-46-401. Standards of Appraisal Practice

Every appraiser, in performing the acts and services of an appraiser, shall comply with the Uniform Standards of Professional Appraisal Practice (USPAP), ~~2008-2009~~ 2012-2013 edition, published by The Appraisal Foundation, which is incorporated by reference and on file with the Board. This incorporation by reference contains no future editions or amendments. A copy of the USPAP ~~2010-2011~~ 2012-2013 edition may be obtained from The Appraisal Foundation, 1155 15th St., NW, Suite 1111, Washington, DC 20005; (202) 347-7722; fax (202) 347-7727; or web site www.appraisalfoundation.org.