



Arizona State Board of Pharmacy
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SMALL BUSINESS BILL OF RIGHTS

YOU ARE ENTITLED TO ALL OF THE RIGHTS ESTABLISHED IN A.R.S. §41-1001.01 AND A.R.S. §41-1009 (A)(1)-(7). COPIES OF THESE STATUTES AND RULES ARE ATTACHED HERETO. IF YOU HAVE ANY QUESTIONS OR CONCERNS REGARDING THIS INSPECTION PLEASE CONTACT THE FOLLOWING AGENCY-DESIGNATED EMPLOYEE (IN WRITING OR BY E-MAIL):

ARIZONA BOARD OF PHARMACY
ATTN: DEPUTY DIRECTOR CHERYL FRUSH
P.O. BOX 18520
PHOENIX, AZ 85005

CFRUSH@AZPHARMACY.GOV

IN THE EVENT THAT YOU HAVE MADE A REASONABLE EFFORT TO RESOLVE ANY PROBLEMS REGARDING THIS INSPECTION WITH THE AGENCY AND HAVE NOT BEEN SUCCESSFUL, YOU MAY CONTACT THE OFFICE OF OMBUDSMAN-CITIZENS AIDE:

ARIZONA OMBUDSMAN-CITIZENS' AIDE
3737 N. 7TH STREET, SUITE 209
PHOENIX AZ 85014
(602) 277-7292

1-800-872-2879
(ARIZONA OUTSIDE PHOENIX METRO AREA)

FAX: (602) 277-7312

E-MAIL AT: OMBUDS@AZOCA.GOV

41-1001.01. Regulatory bill of rights; small businesses

A. To ensure fair and open regulation by state agencies, a person

1. Is eligible for reimbursement of fees and other expenses if the person prevails by adjudication on the merits against an agency in a court proceeding regarding an agency decision as provided in section 12-348.
2. Is eligible for reimbursement of the person's costs and fees if the person prevails against any agency in an administrative hearing as provided in section 41-1007.
3. Is entitled to have an agency not charge the person a fee unless the fee for the specific activity is expressly authorized as provided in section 41-1008.
4. Is entitled to receive the information and notice regarding inspections and audits prescribed in section 41-1009.
5. May review the full text or summary of all rulemaking activity, the summary of substantive policy statements and the full text of executive orders in the register as provided in article 2 of this chapter.
6. May participate in the rulemaking process as provided in articles 3, 4, 4.1 and 5 of this chapter, including:
 - (a) Providing written comments or testimony on proposed rules to an agency as provided in section 41-1023 and having the agency adequately address those comments as provided in section 41-1052, subsection D, including comments or testimony concerning the information contained in the economic, small business and consumer impact statement.
 - (b) Filing an early review petition with the governor's regulatory review council as provided in article 5 of this chapter.
 - (c) Providing written comments or testimony on rules to the governor's regulatory review council during the mandatory sixty-day comment period as provided in article 5 of this chapter.
7. Is entitled to have an agency not base a licensing decision in whole or in part on licensing conditions or requirements that are not specifically authorized by statute, rule or state tribal gaming compact as provided in section 41-1030, subsection B.
8. Is entitled to have an agency not make a rule under a specific grant of rulemaking authority that exceeds the subject matter areas listed in the specific statute or not make a rule under a general grant of rulemaking authority to supplement a more specific grant of rulemaking authority as provided in section 41-1030, subsection C.
9. May allege that an existing agency practice or substantive policy statement constitutes a rule and have that agency practice or substantive policy statement declared void because the practice or substantive policy statement constitutes a rule as provided in section 41-1033.
10. May file a complaint with the administrative rules oversight committee concerning:
 - (a) A rule's, practice's or substantive policy statement's lack of conformity with statute or legislative intent as provided in section 41-1047.
 - (b) An existing statute, rule, practice alleged to constitute a rule or substantive policy statement that is alleged to be duplicative or onerous as provided in section 41-1048.
11. May have the person's administrative hearing on contested cases and appealable agency actions heard by an independent administrative law judge as provided in articles 6 and 10 of this chapter.
12. May have administrative hearings governed by uniform administrative appeal procedures as provided in articles 6 and 10 of this chapter and may appeal a final administrative decision by filing a notice of appeal pursuant to title 12, chapter 7, article 6.
13. May have an agency approve or deny the person's license application within a predetermined period of time as provided in article 7.1 of this chapter.
14. Is entitled to receive written notice from an agency on denial of a license application:
 - (a) That justifies the denial with references to the statutes or rules on which the denial is based as provided in section 41-1076.
 - (b) That explains the applicant's right to appeal the denial as provided in section 41-1076.
15. Is entitled to receive information regarding the license application process before or at the time the person obtains an application for a license as provided in sections 41-1001.02 and 41-1079.
16. May receive public notice and participate in the adoption or amendment of agreements to delegate agency functions, powers or duties to political subdivisions as provided in section 41-1026.01 and article 8 of this chapter.
17. May inspect all rules and substantive policy statements of an agency, including a directory of documents, in the office of the agency director as provided in section 41-1091.

- May file a complaint with the office of the ombudsman-citizens aide to investigate administrative acts of agencies as provided in chapter 8, article 5 of this title.
- Unless specifically authorized by statute, may expect state agencies to avoid duplication of other laws that do not enhance regulatory clarity and to avoid dual permitting to the extent practicable as prescribed in section 41-1002.
- May have the person's administrative hearing on contested cases pursuant to title 23, chapter 2 or 4 heard by an independent administrative law judge as prescribed by title 23, chapter 2 or 4.

The enumeration of the rights listed in subsection A of this section does not grant any additional rights that are not prescribed in the sections referenced in subsection A of this section.

Each state agency that conducts audits, inspections or other regulatory enforcement actions pursuant to section 41-1009 shall create and clearly post on the agency's website a small business bill of rights. The agency shall create the small business bill of rights by selecting the applicable rights prescribed in this section and section 41-1009 and any other agency-specific statutes and rules. At the request of an authorized on-site representative of the regulated small business, the agency shall provide a written document of the small business bill of rights. In addition to the rights listed in this section and section 41-1009, the agency notice of the small business bill of rights shall include the process by which a small business may file a complaint with the agency employees who are designated to assist members of the public or regulated community pursuant to section 41-1006. The notice must provide the contact information of the agency's designated employees. The agency notice must also state that if the regulated person has already made a reasonable effort with the agency to resolve the problem and still has not been successful, the regulated person may contact the office of ombudsman-citizens aide.

41-1009. Inspections and audits; applicability; annual report

An agency inspector, auditor or regulator who enters any premises of a regulated person for the purpose of conducting an inspection or audit shall, unless otherwise provided by law:

Present photo identification on entry of the premises.

On initiation of the inspection or audit, state the purpose of the inspection or audit and the legal authority for conducting the inspection or audit.

Disclose any applicable inspection or audit fees.

Afford an opportunity to have an authorized on-site representative of the regulated person accompany the agency inspector, auditor or regulator on the premises, except during confidential interviews.

Provide notice of the right to have on request:

Copies of any original documents taken by the agency during the inspection or audit if the agency is permitted by law to take original documents.

A split of any samples taken during the inspection if the split of any samples would not prohibit an analysis from being conducted or render an analysis inconclusive.

Copies of any analysis performed on samples taken during the inspection.

Copies of any documents to be relied on to determine compliance with licensure or regulatory requirements if the agency is otherwise permitted by law to do so.

Inform each person whose conversation with the agency inspector, auditor or regulator during the inspection or audit is tape recorded that the conversation is being tape recorded.

Inform each person interviewed during the inspection or audit that statements made by the person may be included in the inspection or audit report.