

Pharmacy Law/Regulatory Affairs/Public Policy

Background

This profile is a compilation of three different groups, however they are related in many ways. They are occupied with laws and regulations as well as the population-based impact of their work. Pharmacy law looks specifically at those laws and regulations that govern pharmacists, the pharmaceutical industry, and the profession. These pharmacist lawyers work in the areas of patent law, academia, medication-related litigation, boards of pharmacy, and related careers. The American Society for Pharmacy Law is an organization that provides insights for its members regarding food, drug, and medical device policies.

Regulatory affairs pharmacists are concerned with the regulations and guidelines for clinical trials and other aspects of human research. As most countries require some type of government approval for a product to reach the market, there are regulations that must be followed in conducting a clinical trial. A career in regulatory affairs would involve pharmacists working through a variety of processes that are designed to protect human subjects participating in a trial. Pharmacists in this field can earn the professional credential of Regulatory Affairs Certification (RAC).

A pharmacist in public policy works to determine how regulations, guidelines, and laws affect the patients for whom pharmacists provide care. In addition, professionals in this field may reach beyond pharmacy to population-based analysis not only in the United States but across the globe.

Characteristics

Thirty-seven pharmacy law, regulatory affairs, and public policy pharmacists responded to the 2012 *APhA Career Pathway Evaluation Program* survey. Seventy-five percent of respondents held an entry-level BS pharmacy degree; 30% held the PharmD degree; and 55% indicated an advanced degree (MA, MS, MBS, JD, PhD, or other).

Twenty percent had been through a residency program, 15% had been through a certificate training program, and 20% reported having been through some form of other training.

Respondents' average age was 51 years old (one of the oldest average ages for the *APhA Career Pathway Evaluation Program* survey). Fifty-five percent of respondents were female. Income data show 21% earn between \$80,000–\$100,000, while 74% earn \$100,000 or more per year, with 37% earning greater than \$150,000. The average time worked per week was 35 hours.

An overwhelming majority of respondents indicated that they were satisfied with their job, with 63% indicating “extremely satisfied” and 34% indicating “somewhat satisfied.” Similarly, most respondents indicated that they felt the job was challenging, with 51% indicating “extremely challenging” and 37% indicating “somewhat challenging.”

Insider's Perspective

What aspects of the job are most appealing?

Because of the variety of the roles in pharmacy law, regulatory affairs, and public policy, the most and least appealing aspects can overlap. One of the most appealing aspects of these roles, cited by 25% of pharmacist respondents, was their impact on public and patient safety. Many pharmacists working in these areas make decisions that affect the overall process for clinical research, patient care, and public safety relative to medications.

Nineteen percent of the respondents cited the diversity of issues that they work on as one of the most appealing aspects of their jobs. Flexible work hours also were indicated as an appealing aspect by 19% of respondents. The daily challenges and changes in the field were cited by 16% of respondents as some of the most appealing aspects of their work. Several respondents also mentioned travel as a plus (although this was also a least appealing factor for other respondents).

One respondent stated that the job requires “always dealing with current ‘hot’ issues. New challenges every day.” Another respondent indicated having the opportunity for “international travel/exposure to multiple cultures,” which this individual found appealing.

Finally, one respondent provided insight into the diversity of issues by stating that “the work is always varied, and provides an opportunity to support large scale changes in health care systems.”

What aspects of the job are least appealing?

Administration (bureaucracy) and politics were cited by 25% of pharmacists as one of the least appealing aspects of their role. These pharmacists are very satisfied with the work they perform, but do not enjoy dealing with the politics in their work. One respondent summed up this aspect when stating having a hard time “dealing with company management that does not understand the difference between sales and marketing and regulatory affairs and public policy.”

Interestingly, travel was cited by 16% of the respondents. As noted earlier, what is an appealing aspect of a role to one pharmacist may be unappealing to another. The international travel quoted above by one respondent as appealing is countered by another who states having “excessive travel and time away from home” as a least appealing aspect.

What advice should students and practitioners consider when selecting the option of becoming a pharmacy law, regulatory affairs, or public policy pharmacist?

One respondent provided a broad-based statement that captured what many were also saying: student pharmacists “need the ability to study and understand federal and state regulations and apply them to diverse practice settings in addition to various accreditation program criteria while keeping public and patient safety top of mind.”

Another respondent summed up the patient and public safety side that is appealing to the group: “always question what is in the best interest for patients.”

Critical Factor Ratings

Interaction With People

Interaction with people was a mid-range response for this group. Of interest is that less than 1% indicate that they work in patient care services areas.

= 4.9



Conducting Physical Assessments

Conducting physical assessments was the lowest-rated critical factor by the respondents. There was no mention of any respondent conducting physical assessment in their roles.

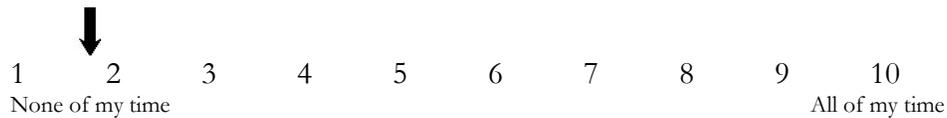
= 1.3



Interpreting Laboratory Values

Interpreting lab values was the second lowest critical factor. Some respondents indirectly get lab values through the clinical trials where they work but rarely are asked to interpret them.

= 1.7



Continuity of Relationships

The extent to which these respondents have ongoing or long-term relationships with patients varies by practice setting. Those in roles that have an impact on patients also may be involved in patient advocacy groups and thereby have some ongoing relationships.

= 4.3



Helping People

Pharmacists working in these areas see more indirect effect on people than direct effect. Those in public policy are looking at populations that they impact primarily indirectly. One respondent stated, "Develop health-related policy to protect patient safety. Can impact large groups of people with work that we accomplish." This is an indirect impact. Another stated, "I have opportunities each day to positively impact the health care of millions of citizens."

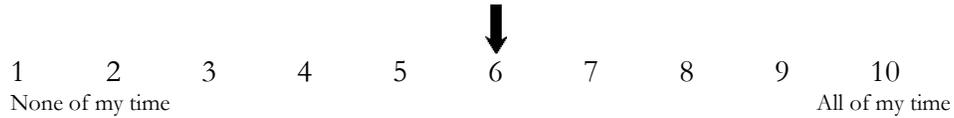
= 3.5



Collaboration With Other Professionals

These respondents indicated that they are mid-range for collaboration with other professionals. Again, this is setting specific. One respondent indicated, “Work with the various agencies and monitoring compliance with laws and regulations.” This is when they collaborate with other professionals.

= 6.0



Educating Other Professionals

Pharmacist respondents spend time educating other health professionals. The response was mid-range for this critical factor. A pharmacist who listed this as an appealing aspect stated, “I am allowed to serve as an educational resource for the pharmacists and technicians that I regulate.”

= 5.4



Variety of Daily Activities

The day-to-day workload of these pharmacists often depends on which issues are “hot” at the moment. This was one of the more appealing aspects of the work that they perform. As a result, there is a good deal of variation in their practices.

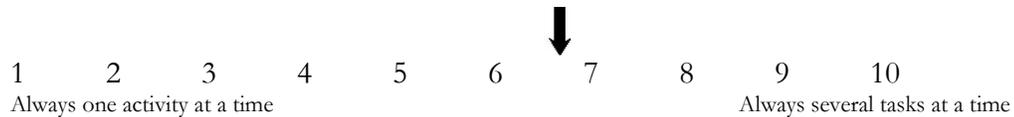
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Multiple Task Handling

There was fairly good agreement among respondent pharmacists that they often deal with more than one task at a time.

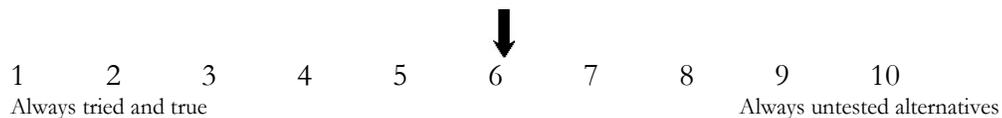
= 6.8



Problem Solving

Pharmacists responding to the survey indicated that they are mid-range in applying tried and true solutions compared with untested alternatives.

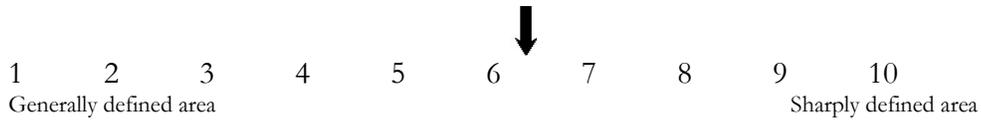
= 6.1



Focus of Expertise

Because these pharmacists tend to be specialized in their field, they lean slightly toward having more of a sharply defined area of expertise.

= 6.3



Innovative Thinking

Some settings are well established and have highly defined expectations, duties, and responsibilities, whereas others will require innovative thinking to help shape and define the practice. These respondents lean toward the upper mid-range responses for this factor.

= 7.7



Applying Scientific Knowledge

Pharmacists spend a portion of their time applying scientific knowledge in their area of expertise, giving this factor a rating of 4.9. Applying legal and regulatory knowledge rates much higher.

= 4.9



Applying Medical Knowledge

As noted in applying scientific knowledge, respondents were low mid-range in applying medical knowledge in their field for similar reasons.

= 4.6



Creating New Knowledge by Conducting Research

There is little opportunity to conduct research; it occupies only 8% of their time.

= 3.4



Management/Supervision of Others

A low mid-range response shows that pharmacists in this group are not very involved in the management and supervisory responsibilities of others. Depending on the practice setting, these pharmacists generally work with peers and other health professionals. Their level of supervision of others depends upon support personnel staffing levels.

= 3.4



Management/Supervision of a Business

Respondents indicated that they spend 8% of their time managing business-related activities.

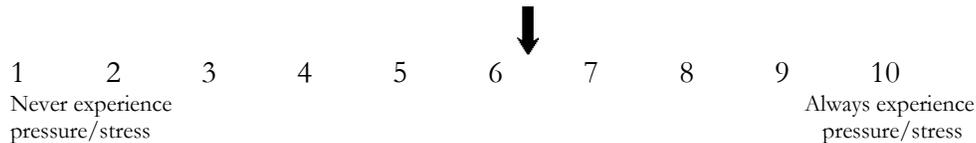
= 3.6



Pressure/Stress

Respondents indicated that they experience pressure/stress at the mid-range level. All pharmacists experience some stress in their workday, which comes with responsibility. The types of pressures and stresses vary depending upon the practice environment.

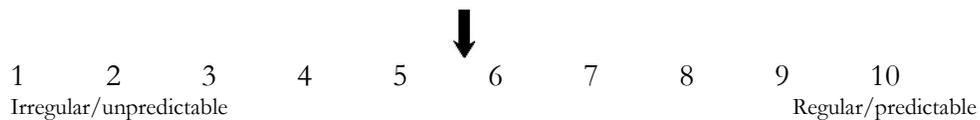
= 6.3



Work Schedule

Although these pharmacists are mid-range in their responses, they indicated that the work schedule is one of the most appealing aspects of their role.

= 5.7



Part-Time Opportunities

Part-time opportunities are available in these areas, but these opportunities are limited.

= 4.1



Job-Sharing Opportunities

Job sharing is not a common practice in this field as reinforced by the low range rating of this factor. This critical factor was the third lowest for this group.

= 2.8



Exit/Re-entry Opportunities

Exit/re-entry opportunities are mid-range for this group.

= 5.3



Parental Leave Opportunities

Parental leave opportunities rated higher than others in the areas of work-related options. Most employers provide the opportunity for parental leave. These respondents rated this in the high range.

= 8.0



Leisure/Family Time

Respondents indicated that they do have leisure and family time available.

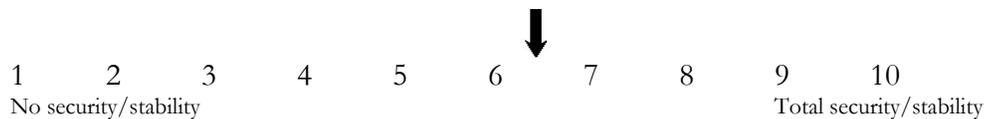
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Job Security

Legal and regulatory areas are in demand even as the health system continues to change and increased pressures for accountability in many areas of patient care continue to rise.

= 6.4

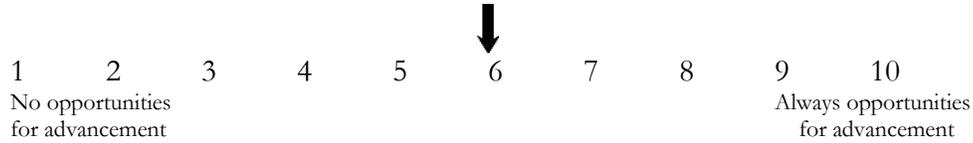


Opportunities for Advancement

Pharmacists had mixed opinions on opportunities for advancement as many enter at a high level in these areas. As an example, a patent attorney is already at the level needed.

Experience over the years is important but there are not many levels for advancement.

= 5.9



Opportunities for Leadership Development

Pharmacists indicated an upper mid-range response of 7.1 regarding opportunities for leadership development.

= 7.1



Community Prestige

Pharmacists are well-respected health professionals. The extent to which their practice directly influences their prestige in the community depends on the visibility of their role to the general public.

= 7.1



Professional Involvement

Active involvement in pharmacy meetings and events creates opportunities for professional development and the sharing of ideas and knowledge among peers. The extent to which a pharmacist gets involved is largely a personal decision.

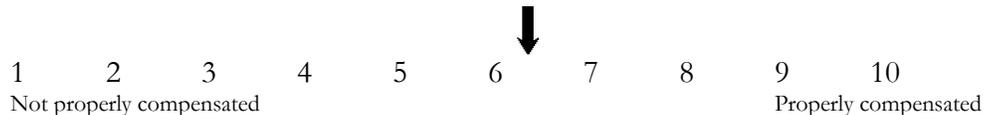
= 7.7



Income

Respondents were mid-range regarding income.

= 6.3



Additional Training

As noted earlier in the advanced degree critical factor, it is clear that additional training is required for pharmacists in these roles. Certificate training programs are available as mentioned earlier in the profile.

= 7.3



Interacting With Colleagues

Respondents indicated that they tend to interact with coworkers on a regular basis. This critical factor is tied as the second highest for this group.

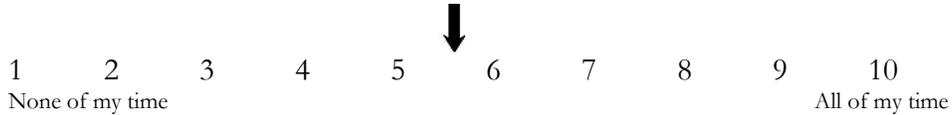
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Travel

Respondents are almost exactly mid-range. Based on the most and least appealing aspects of these roles, this reinforces their earlier statements.

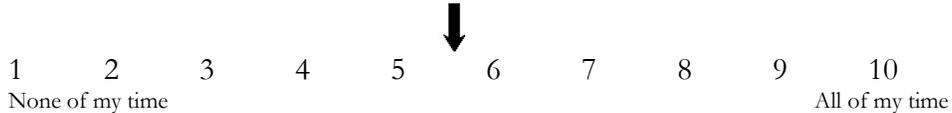
= 5.6



Writing

Respondents were mid-range regarding writing as part of their role.

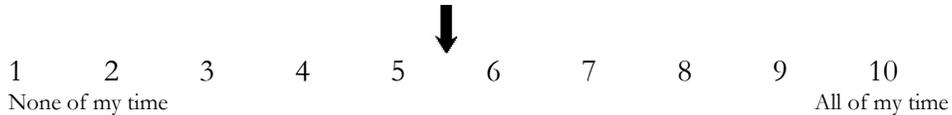
= 5.6



Working With Teams

Respondents tend to have some team-related projects and are exactly mid-range.

= 5.5



Mean Scores for Critical Factors

1. Interaction With People	4.9
2. Performing Physical Assessments	1.3
3. Interpreting Laboratory Values	1.7
4. Continuity of Relationships	4.3
5. Helping People	3.5
6. Collaboration With Other Professionals	6.0
7. Educating Other Professionals	5.4
8. Variety of Daily Activities	7.0
9. Multiple Task Handling	6.8
10. Problem Solving	6.1
11. Focus of Expertise	6.3
12. Innovative Thinking	7.7
13. Applying Scientific Knowledge	4.9
14. Applying Medical Knowledge	4.6
15. Creating New Knowledge by Conducting Research	3.4
16. Management/Supervision of Others	3.4
17. Management/Supervision of a Business	3.6
18. Pressure/Stress	6.3
19. Work Schedule	5.7
20. Part-Time Opportunities	4.1
21. Job-Sharing Opportunities	2.8
22. Exit/Re-entry Opportunities	5.3
23. Parental Leave Opportunities	8.0
24. Leisure/Family Time	7.1
25. Job Security	6.4
26. Opportunities for Advancement	5.9
27. Opportunities for Leadership Development	7.1
28. Community Prestige	7.1
29. Professional Involvement	7.7
30. Income	6.3
31. Benefits (vacation, health, retirement)	7.7
32. Geographic Location	5.2
33. Working Remotely	6.3
34. Autonomy	7.0
35. Self-Worth	8.2
36. Future Focus	7.6
37. Professional Prestige	7.6
38. Unique Practice Environment	8.1
39. Advanced Degree	5.2
40. Entrepreneurial Opportunity	4.5
41. Additional Training	7.3
42. Interacting With Colleagues	8.1
43. Travel	5.6
44. Writing	5.6
45. Working With Teams	5.5

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U.S. Public Health Service. Commissioned Corps. Pharmacists. Available at: <http://www.usphs.gov/profession/pharmacist/>

Professional Organizations

American College of Clinical Pharmacy (ACCP)

3101 Broadway, Suite 650, Kansas City, MO 64111
Tel: 816-531-2177 Fax: 816-531-4990
www.accp.com

American Pharmacists Association (APhA)

2215 Constitution Avenue NW, Washington, DC 20037
Tel: 800-237-APhA Fax: 202-783-2351
www.pharmacist.com

American Public Health Association (APHA)

800 I Street NW, Washington, DC 20001-3710
Tel: 202-777-APHA Fax: 202-777-2534
<http://apha.org>

American Society of Health-System Pharmacists (ASHP)

7272 Wisconsin Avenue, Bethesda, MD 20814
Tel: 301-657-3000
www.ashp.com

American Society for Pharmacy Law (ASPL)

3085 Stevenson Drive, Suite 200, Springfield, IL 62703
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National Community Pharmacists Association (NCPA)

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www.ncpanet.org

Regulatory Affairs Professionals Society (RAPS)

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