

# Pharmacy Law/Regulatory Affairs/Public Policy

## Holland Code: EIC

### 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.”

Adapted from the American Pharmacists Association