STATEMENT

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**In Opposition to Rhode Island House Bill 7041 (Representative Potter)**

**February 28, 2024**

**Position: PhRMA respectfully opposes House Bill 7041, which seeks to establish a registration mechanism for pharmaceutical sales representatives that is administratively burdensome and largely duplicative of federal reporting requirements. This type of activity is heavily regulated at the federal level and a patchwork of state laws will create a complex regulatory structure unnecessarily.**

PhRMA believes that ethical relationships with health care professionals are critical to its mission of helping patients by developing and marketing new medicines. A cornerstone to achieving this mission is ensuring that health care professionals have the latest, most accurate information available regarding prescription medicines, which play an increasingly important role in patient health care.

This bill is unnecessary as pharmaceutical sales and marketing practices are broadly regulated by the federal government in a number of ways. Additionally, industry practice and extensive training serve to further regulate interactions. For example:

- **The U.S. Food and Drug Administration ("FDA") regulates advertising and promotional materials distributed about a prescription medicine.** Before a new drug may be marketed, FDA approves the labeling for that medicine, which contains the scientific information needed for the safe and effective use of the medicine. Pharmaceutical manufacturers have strict processes for developing promotional materials that are consistent with the labeling for the drug. These materials are submitted to FDA by the date of first use and companies may submit certain materials for FDA review prior to use. Sales representatives are not permitted to discuss information that is not consistent with the FDA-approved labeling and must use approved promotional materials. All sales representatives must adhere to this standard.

- **The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, requires prescription drug manufacturers to annually report payments and transfers of value provided to prescribers and teaching hospitals.** Reportable payments and transfers of value include meals, travel, and fee-for-service payments. Reported data are posted on a public website. The Sunshine Act preempts state laws that require reporting of the same information.

- **Pharmaceutical companies and their representatives are subject to criminal anti-kickback statutes and other federal criminal and civil laws, enforced by the U.S. Department of Justice, that govern relationships with health care providers.** The U.S Department of Health and Human Services ("HHS") Office of Inspector General has published detailed guidance for pharmaceutical companies designed to deter violations of these federal laws. These guidelines prohibit *quid pro quos* between drug makers and health care professionals.

- **The PhRMA Code on Interactions with Health Care Professionals (the "Code") offers guidance about appropriate interactions between pharmaceutical manufacturers and health**

**care providers.** Pharmaceutical manufacturers may offer items primarily for the education of patients or health care professionals (items that are $100 or less).

- **Company representatives receive extensive training about their company's medicines and the conditions that their medicines treat.** Pharmaceutical companies employ many physicians, pharmacists, and other scientists who work with others to create the information that is provided to healthcare professionals.

- **FDA has long-established statutory authority under which it has issued regulations that cover all aspects of the packaging, distribution and accounting for prescription drug samples.** Only the manufacturer and an authorized distributor may distribute drug samples, and they may be distributed only to a healthcare provider who is licensed to prescribe in the state where the provider's practice is located. A provider must request samples, and the request must include the practitioner's address; state license number; the drug, the drug's manufacturer and the quantity of samples requested; the date of the request; and the practitioner's signature. Once the manufacturer or authorized distributor has received the request, the samples may be delivered by mail, a common carrier, or a pharmaceutical representative. Regardless of the method of delivery, the manufacturer must receive a signed receipt from the prescriber. The manufacturer must keep both the request and the receipt for 3 years.

In addition to requiring duplicative reporting, this legislation places further administrative burden on manufacturers and the state by requiring the population and maintenance of a fully public list of pharmaceutical sales representatives as well as an annual report that is largely duplicative of reports already available under the Sunshine Act.

**For the foregoing reasons, we urge a no vote on House Bill 7041.**

*The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.*