This policy establishes the decision of the Pharmacy Quality Assurance Commission (commission) related to the licensing of pharmaceutical virtual manufacturers and virtual wholesalers, made at the June 8, 2018, regularly scheduled business meeting.

The commission interprets the definition of “manufacturer” under RCW 18.64.011(22) to include in-state virtual manufacturers. The commission further interprets the definition of “wholesaler” under RCW 18.64.011(33) to include out-of-state virtual manufacturers and both in-state and out-of-state virtual wholesalers. The commission intends to incorporate this interpretation in rule.

BACKGROUND:
Under RCW 18.64.005 and 18.64.165, the commission has regulatory authority over manufacturers and can commence legal action if a manufacturer violates applicable law. RCW 18.64.011(22) defines a manufacturer as a “person, corporation, or other entity engaged in the manufacture of drugs and devices”. RCW 18.64.045, requires businesses engaged in the manufacturing of drugs to be licensed as a manufacturer in Washington state.

Under RCW 18.64.165, the Commission has regulatory authority over wholesalers and can commence legal action if a wholesaler violates applicable law. RCW 18.64.011(33) defines wholesaler as a “corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.” WAC 246-879-010(11) also defines wholesale distributor as “anyone engaged in wholesale distribution of
drugs, including but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.” **RCW 18.64.046** requires businesses that sell legend drugs and nonprescription drugs, or nonprescription drugs at wholesale to be licensed as wholesalers in Washington state, and failure to obtain licensure amounts to a misdemeanor.

**CONCLUSION:**
By meeting the definitions under **RCW 18.64.011**, the Commission will license in-state virtual manufacturers as manufacturers under **RCW 18.64.045**; and will license out-of-state virtual manufacturers, as well as in-state and out-of-state virtual wholesalers as wholesalers under **RCW 18.64.046**. The Commission intends to adopt rules regarding licensure of virtual manufacturers and virtual wholesalers through its rules rewrite project.