Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Alicyn Carrel, Ohio Department of Health

FROM: Jacob Ritzenthaler, Regulatory Policy Advocate

DATE: November 13, 2019

RE: **CSI Review – Medical Use of Radioactive Materials (OAC 3701:1-40-16, 3701:1-46-43, 3701:1-58-01, 3701:1-58-07 through 3701:1-58-10, 3701:1-58-12, 3701:1-58-15, 3701:1-58-16, 3701:1-58-18 through 3701:1-58-21, 3701:1-58-26, 3701:1-58-33, 3701:1-58-35, 3701:1-58-36, 3701:1-58-37, 3701:1-58-40 through 3701:1-58-43, 3701:1-58-49, 3701:1-58-51 through 3701:1-58-55, 3701:1-58-58, 3701:1-58-69, 3701:1-58-71, 3701:1-58-73, 3701:1-58-86, 3701:1-58-100, 3701:1-58-101, 3701:1-58-104, and 3701:1-58-105)**

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This rule package consists of 37 amended rules and one new rule proposed by the Ohio Department of Health (ODH). This rule package was submitted to the CSI Office on August 14, 2019 and the public comment period was held open through September 12, 2019. No comments were received during this time. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI office on August 14, 2019.

The rules contained in this package establish requirements for the possession and use of radioactive material for medical use. Ohio Administrative Code (OAC) 3701:1-40-16 sets forth the terms and conditions for radioactive material licenses and is being amended to include requirements for licensees to report instances of generator breakthrough or contamination. OAC

3701:1-46-43 provides guidelines for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs and includes provisions that ensure registration status, labeling, and pharmacist designation. OAC Chapter 3701:1-58 establishes requirements for medical use of radioactive materials. OAC 3701:1-58-01 describes the definitions used throughout the Chapter and is being amended to include new definitions for "Associate Radiation Safety Officer" and "Ophthalmic Physicist." OAC 3701:1-58-07 details the application and renewal processes for licensure and is being amended to clarify the information required on an application. OAC 3701:1-58-08, 3701:1-58-09, and 3701:1-58-10 set forth requirements for license amendments, notification, and exemptions and are largely being amended to reflect the inclusion of associate radiation safety officers and ophthalmic physicists. OAC 3701:1-58-12 establishes the authority and responsibility of the radiation protection program and is being amended to allow for the appointment of associate radiation safety officers.

OAC 3701:1-58-15 and 3701:1-58-16 set forth guidelines for written directives and procedures authorized by written directive and includes updates that address permanent brachytherapy. OAC 3701:1-58-18 through 3701:1-58-21 set forth training requirements for radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, and other personnel. The rules are being amended to introduce training requirements for associate radiation safety officers and update the requirements for other personnel. OAC 3701:1-58-26 regards the use of radioactive material for calibration, transmission, and reference use and includes amendments that concern sealed sources of radioactive material. OAC 3701:1-58-33 through 3701:1-58-72 establish training and safety requirements for various treatments, including the use of unsealed radioactive material, administration of radioactive medication, and safety procedures for equipment. OAC 3701:1-58-73, 3701:1-58-86, and 3701:1-58-100 establish record keeping requirements for radiation protection program authority, safety instruction, and servicing for teletherapy and gamma stereotactic radiosurgery units, which include amendments that clarify the requirements. OAC 3701:1-58-104 sets forth standards for training for the parenteral administration of unsealed radioactive material and is being amended to clarify and update the requirements for identifying individuals qualified to conduct administration. OAC 3701:1-58-105 is a new rule that is proposed to require businesses to contact the Department in the event of a breakthrough in a generator.

During early stakeholder outreach, ODH reviewed the rules with both the Radiation Advisory Council and the Department's Radioactive Material Committee. Relevant stakeholders were also invited to comment on the rules. During this time, ODH implemented changes and updates to the rules suggested by the Radioactive Material Committee. No comments were received during the CSI public comment period.

The business community impacted by these rules includes all individuals licensed to handle

radioactive material. ODH states that there are 300 licensees currently operating in Ohio. The adverse costs created by the rules include the time and effort spent by licensees to comply with the training and handling requirements of the rules. ODH states in the BIA that many of the amendments made to the rules increase flexibility for licensees.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the Ohio Department of Health should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.