ACTION: No Change

DATE: 03/09/2017 10:48 AM



MEMORANDUM

TO: Kaye Norton, Ohio Department of Health

FROM: Chris Smyke, Executive Assistant

DATE: November 30, 2016

RE: CSI Review – Medical Use of Radioactive Materials (OAC 3701:1-58-01, -08, -09,

-16 thru -22, -26, -30, -33, -36, -40 thru -42, -51, -52, -54, -71, -104)

On behalf of Lt. Governor Mary Taylor, 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 22 no-change rules submitted by the Ohio Department of Health (ODH) as part of its statutorily-required five-year review. The rule package was submitted to the CSI Office on September 27, 2016, and the comment period remained open until October 27, 2016.

Ohio Administrative Code (OAC) Chapter 3701:1-58 establishes the requirements to possess and utilize radioactive material for medical purposes in Ohio. These rules include relevant definitions, license amendment procedures, notifications to the Department, procedures for administering radioactive material and personnel training. Per ORC 3748.03 Ohio must comply with federal regulations set forth in Title 10, part 35, (10 CFR 35). Compliance with these regulations is a stipulation of Ohio's status as an "agreement state" under the Nuclear Regulatory Commission (NRC), which allows Ohio to assume regulatory control over the possession and use of radioactive material in the state.

The rule impacts the 300 radioactive material licensees in Ohio. ODH assesses fees based on the quantity and scope of the licensee's operation, so they can cost between \$1,993 and \$18,116. In addition, the BIA estimates the cost of bringing operating procedures into compliance to be 40

hours at \$31.58 per hour; the cost of maintaining compliance is estimated to be 10 hours each month at a rate of \$31.58 per hour.¹

ODH justifies this rule in its BIA by citing the need to ensure safe handling and licensing requirements of radioactive material in order to protect the environment and the public. In addition, these regulations are necessary to keep Ohio in line with federal requirements in order to maintain Ohio's "agreement state" status under the NRC.

ODH conducted stakeholder outreach via the Governor-appointed Radiation Advisory Council (RAC), which provides technical input on any rulemaking activities concerning radiological issues. In addition, the RAC formed the Radioactive Material Committee (RMC), which is comprised of experts in the field of radiation safety who represent stakeholders in industrial, academic, medical and research facilities. The BIA indicates that the RAC and RMC conducted meetings that were open to the public and posted the draft rules for public comment on the ODH website. No additional comments were submitted indicating that the rules are overly burdensome, and the CSI Office has determined the purpose of the rules to be justified.

Recommendations

For the reasons discussed above, the CSI Office does not have any recommendations for this rule package.

Conclusion

Based on the above comments, the CSI Office concludes that the Ohio Department of Health should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.

cc: Mark Hamlin, Lt. Governor's Office

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¹ The BIA draws these estimates from the U.S Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2014, code 29-2033 for nuclear medical technologists.