NOTICE OF PUBLIC RULES HEARING

DATE: Thursday, December 17, 2020
TIME: 2:00 p.m.
LOCATION: Via Electronic Teleconference
CALL-IN INFO: Microsoft Teams meeting
Join on your computer or mobile app
Click here to join the meeting
Or call in (audio only)
+1 614-721-2972,,875048671# United States, Columbus
Phone Conference ID: 875 048 671#

In accordance with *Chapter 119* of the Revised Code (R.C.), the Director of the Ohio Department of Health announces a Public Hearing at the date and time listed above to hear comments regarding the following action:

Ohio Revised Code (O.A.C.) Chapter 3701-04 – Ohio Cancer Incidence Surveillance System

The proposed rules are under review as required by Ohio Revised Code 3702, these rules cover types of cancer and other tumorous or precancerous diseases that must be reported to the Ohio Cancer Incidence Surveillance System (OCISS). Also, the rules establish reporting requirements for diagnosed cases of cancer and the required standards for researchers to obtain OCISS data. Amendments to the rules include the mandatory, rather than as-available, reporting of a patient's social security number.

Information regarding rule package proposed:

This rule package consists of one amended and two no-change rules. It was submitted to the CSI Office on March 3, 2020 as part of the statutory five-year review, and the public comment period was open through April 2, 2020. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on March 3, 2020.

The rules impact all physicians, dentists, hospitals, and others that provide diagnostic and treatment services to cancer patients, as well as researchers that want to obtain OCISS data. Adverse impacts of the rules include information required to be reported about patients with cancer within six months of diagnosis. Researchers wishing to obtain OCISS data must complete an application for consideration by the Department's Institutional Review Board prior to gaining access to the requested data. As part of the application, researchers must submit information regarding their credentials, the purpose of the research, the nature of the data to be collected, the records sought for review, and any safeguards that will be taken to protect a patient's identity. Researchers will be furnished the requested information only for the purpose of reducing morbidity or mortality of cancer. The Department estimates that it takes one to two hours to report the required information, depending on the complexity of a patient's case. For researchers, the time to complete an application is estimated at approximately four hours. Failure to comply with the rules may result in a monetary fine. The Department states that the proposed rules are necessary to accurately determine the burden of cancer and to plan, target, and evaluate interventions for cancer prevention and control.

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Ohio Revised Code (O.A.C.) Chapter 3701:1-40-16, 3701:1-46-43, 3701:1-58 – Medical Use of Radioactive Materials

The proposed rules are under review as required by Ohio Revised Code 3702, these rules 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.

Information regarding rule package proposed:

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.

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.

Hearing and Contact Information:

Information about the hearing, people affected by the proposed action may appear via teleconference and be heard or in tandem with an attorney. They may present their positions, arguments, or contentions orally or in writing; may offer witnesses; and may present evidence showing that the proposed rule, if adopted or effectuated, will be unreasonable or unlawful.

To aid in getting the call to be organized and go as smooth as possible, any persons intending to testify on the tele-Public Hearing or planning to observe are encouraged to email Alicyn.Carrel@odh.ohio.gov immediately.

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Copies of the proposed rules will be available on the Register of Ohio website: http://www.registerofohio.state.oh.us/rules/search approximately one day after the rule is filed, or from the Office of the General Counsel, Ohio Department of Health (https://odh.ohio.gov/wps/portal/gov/odh/about-us/offices-bureaus-and-departments/Office-of-General-Counsel/laws-and-rules/).

Please e-mail any written comments to ODHRules@odh.ohio.gov by 5:00 p.m. on Tuesday, December 15, 2020.