

# NOTICE OF PUBLIC RULES HEARING

DATE: Friday, September 11, 2015  
TIME: 10:30 a.m.  
PLACE: OHIO DEPARTMENT OF HEALTH  
35 E. Chestnut Street  
Columbus, Ohio 43215  
ROOM: Basement Training Room A

In accordance with Chapter 119 of the Revised Code (R.C.), the Director (Director) of the Ohio Department of Health (ODH), or his designee, shall conduct a public hearing at the date, time, and place listed above to consider the following rules:

## **O.A.C. Chapter 3701-4 – OHIO CANCER INCIDENCE SURVEILLANCE SYSTEM**

By authority of R.C. 3701.262 and in fulfillment of five-year review requirements, the Director proposes changes to the following rules:

3701-4-01	Definitions	Amend
3701-4-02	Responsibility for reporting	Rescind/New
3701-4-03	Confidentiality; research	Rescind/New

O.A.C. rules 3701-4-01 and 3701-4-02 specify the types of cancer and other tumorous and precancerous diseases that are to be reported to the Ohio Cancer Incidence Surveillance System (OCISS) and establish reporting requirements for diagnosed cancer cases to include who is required to report, the mechanism and timeline for reporting and what information must be reported. Rule 3701-4-03 establishes the standards that must be met by researchers to receive OCISS data for research projects.

Amendments to rule 3701-4-01 update the definition of cancer, and add two more definitions. Rules 3701-4-02 and 3701-4-03 are proposed for rescission and are being replaced with new versions of the rules. Some changes to 3701-4-02 (1) remove language that is already in statute; (2) clarify the mechanism for reporting to OCISS; and (3) clarify that reports are to be made on all persons diagnosed and treated in Ohio, regardless whether they are Ohio residents. Some changes to 3701-4-03 (1) remove language that is already in statute; (2) clarify the process for access to confidential OCISS data to align with Ohio Department of Health Institutional Review Board processes; and (3) allow researchers to directly contact patients to request additional information for research purposes or to solicit a patient's participation in a research project if the patient's managing physician has not informed the researcher within a reasonable time that the patient should not be contacted.

## **O.A.C. Chapter 3701-12 – CERTIFICATE OF NEED PROGRAM**

By authority of R.C. 3702.57, to incorporate statutory requirements from House Bill 483 of the 130<sup>th</sup> General Assembly, and to satisfy five-year rule review requirements, the Director proposes the following changes to Certificate of Need Program rules:

3701-12-01	Definitions	Amend
3701-12-05	Scope of review: reviewable activities	Amend
3701-12-08	Certificate of need application and completeness process; public notice; certificate of need review and decision process; appeals	Amend
3701-12-09	Certificate of need application and completeness process for applications filed under section 3702.593 of the Revised Code; comparative review; review and decision process	Amend
3701-12-10	Replacement certificate of need	Amend
3701-12-11	Opportunity to submit written comments during the course of a certificate of need review.	New/Rescind
3701-12-18	Validity requirements, follow-up and withdrawal of certificates of need	Amend
3701-12-19	Monitoring of activities determined to not be reviewable activities	Amend
3701-12-20	General certificate of need review criteria	Amend
3701-12-23	Long-term care facilities and beds and bed review; State and county bed need	Amend
3701-12-23.2	Replacement of long-term care facilities and relocation of long-term care beds	Amend
3701-12-24	Monitoring of hospital beds recategorized as skilled Nursing beds	Amend

The proposed amendments include, but are not limited to, changes to: (1) Increase the deadline for affected parties to submit written comments regarding a CON application from 30 to 45 days; (2) Require the Director to review, approve, or deny an application for a replacement CON in the same manner as the approved application; (3) Modify the requirements pertaining to reviewable activities and “substantial compliance”; and (4) Make minor technical and formatting changes to the rules.

### **Hearing and Comment Procedure:**

At the hearing, people affected by the proposed actions may appear and be heard in person, by an attorney or both; may present their positions, arguments, or contentions orally or in writing; may offer witnesses; and may present evidence tending to show that the proposed rules, if adopted or effectuated, will be unreasonable or unlawful. To aid in getting visitors through building security, both persons intending to testify at the hearing and those simply intending to observe are encouraged to pre-register by writing to the Office of the General Counsel, Ohio Department of Health, 246 North High Street, Columbus, Ohio 43215, by phoning (614) 466-4882, or by sending an e-mail to [odhrules@odh.ohio.gov](mailto:odhrules@odh.ohio.gov). Copies of the proposed rules are available on the Register of Ohio website: <http://www.registerofohio.state.oh.us/jsps/publicdisplayrules/searchRuleNumber.jsp>, or from the Office of the General Counsel, Ohio Department of Health (address listed above). Please FAX [(614) 564-2509], mail, or e-mail any written comments by 5:00 p.m. on September 10, 2015.

*August 4, 2015*