

Chapter DHS 157

APPENDIX M

Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening

Persons requesting that the department approve a healing arts screening program shall submit the following information and evaluation. Mammography screening, ~~and~~ bone density screening and National Cancer Institute approved low dose CT lung screening are exempt from this requirement unless persons under age 18 are involved:

- a. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.
- b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.
- c. A detailed description of the x-ray examinations proposed in the screening program.
- d. A description of the population to be examined in the screening program, which is age, sex, physical condition, and other appropriate information. If the study involves women of reproductive age and the exam involves the trunk of the body, what precautions are being taken to ensure the subjects are not pregnant.
- e. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.
- f. An evaluation by a medical physicist of the x-ray system to be used in the screening program. The evaluation by the medical physicist shall show that the system satisfies all requirements of this chapter. The evaluation shall include a measurement of patient exposures from the x-ray examinations to be performed. This exposure information must be included in the informed consent papers signed by the subject. An explanation of the risk from the radiation exposure shall be included in the informed consent if the head, neck or trunk is involved in the procedure.
- g. The name and address of the individual who will interpret the radiograph or images if any are produced. The interpreting physicians must be licensed in Wisconsin.
- h. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
- i. A description of the procedures for the retention or disposition of the radiographs, images, graphs and other records pertaining to the x-ray examinations.
- j. An indication of the frequency of screening and the duration of the entire screening program.
- k. Human-use committee approval of the screening program if one is required by local policy.
- l. A copy of the informed consent information being provided to the subjects.
- m. If minors are involved, parental consent is required.