Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986

House Bill 5647 (Substitute H-1 as passed by the House)
Sponsor: Representative Ben Frederick
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 12-11-18

CONTENT

The bill would amend the Public Health Code to prohibit the use of a handheld dental x-ray system unless the machine was registered with the Department of Licensing and Regulatory Affairs (LARA), and the system, the personnel operating it, and the facilities in which it was used met certain requirements.

Under the bill, a person could not use a handheld dental x-ray system to perform dental radiography unless the machine was registered with LARA under Department rules for registration of radiation machines, and the system, the personnel operating the system, and the facilities in which the system is used met all of the following requirements:

-- The system had been approved for human use by the United States Food and Drug Administration.
-- The system had a backscatter shield that met certain requirements (described below).
-- The system was calibrated by its manufacturer before its first use and was recalibrated at least every 24 months after the date of the last calibration.
-- When not in use, the system was stored in a manner that restricted access to it, such as by storing it in a locked area of the facility.
-- The system was not used if the backscatter shield was broken, missing, or malfunctioning.

The backscatter shield described above would have to meet the following requirements:

-- The shield was composed of a leaded polymer or a lead-equivalent substance that had a substantially equivalent protective capacity.
-- The shield had at least 0.5 millimeters of lead or lead-equivalent shielding, as determined by LARA.
-- The shield was permanently affixed to the handheld dental x-ray system.

Additionally, each individual who operated the system would have to be authorized to operate a dental radiography machine pursuant to rules promulgated under Part 166 (Dentistry) of the Code. An individual operating the system would not be required to wear a lead apron or other personal monitoring equipment while operating the system if it were determined that the use of the system was in compliance with Parts 381 (Ionizing Radiation) and of the Michigan Occupational Safety and Health Administration Occupational Health Standards of the Administrative Code, or equivalent Federal occupational health and safety standards, and other rules. Upon request, a registrant would have to make a lead apron or other personal monitoring equipment available to an individual who operated the system.

A handheld dental x-ray system that met the requirements described in the bill could be used for routine dental radiography in a dental office or a situation in which it was impractical to transfer a patient to a radiation machine that was stationary.

"Handheld dental x-ray system" or "system" would mean an x-ray system that is used to take radiographs, is designated to be handheld during its operation, and is portable.

The bill would take effect 90 days after its enactment.

MCL 333.13521 Legislative Analyst: Stephen Jackson

FISCAL IMPACT

The bill would have no fiscal impact on the Department of Licensing and Regulatory Affairs or local government units. Departmental rules already require the registration of radiation devices.

Fiscal Analyst: Abbey Frazier
Elizabeth Raczkowski

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