4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.

Subpart 1. **Report required.** A licensee must report any event as a medical event, except for an event that results from patient intervention, in which:

A. the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

(1) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dose by more than five rems (0.05 Sv) effective dose equivalent, 50 rems (0.5 Sv) to an organ or tissue, or 50 rems (0.5 Sv) shallow dose equivalent to the skin and:

(a) the total dose delivered differs from the prescribed dose by 20 percent or more;

(b) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(c) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

(2) a dose that exceeds five rems (0.05 Sv) effective dose equivalent, 50 rems (0.5 Sv) to an organ or tissue, or 50 rems (0.5 Sv) shallow dose equivalent to the skin from:

(a) an administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

(b) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

(c) an administration of a dose or dosage to the wrong individual or human research subject;

(d) an administration of a dose or dosage delivered by the wrong mode of treatment; or

(e) a leaking sealed source; or

(3) a dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(a) 50 rems (0.5 Sv) or more from the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(b) 50 percent or more from the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

B. for permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material excluding sources that were implanted in the correct site but migrated outside the treatment site that results in:

(1) the total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(2) the total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(3) an administration that includes any of the following:

(a) the wrong radionuclide;

(b) the wrong individual or human research subject;

(c) sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(d) a leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

Subp. 2. **Events from patient intervention.** A licensee must report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Subp. 3. **24-hour notification required.** A licensee must notify the commissioner within 24 hours after discovery of a medical event.

Subp. 4. **Written report.** A licensee must submit a written report to the commissioner within 15 days after discovery of a medical event. The report must not contain an individual's name or any other information that could lead to identification of an individual. The report must include:

A. the licensee's name;

B. the name of the prescribing physician;

C. a brief description of the event;

D. why the event occurred;

E. the effect, if any, on the individual who received the administration;

F. what actions, if any, have been taken or are planned to prevent recurrence; and

G. certification that the licensee notified the individual or the individual's responsible relative or guardian and, if not, why.

Subp. 5. **Notification of individual.**

A. A licensee must provide notification of a medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that the physician

will inform the individual or that, based on medical judgment, telling the individual would be harmful.

B. A licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter.

C. A licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification.

D. To meet the notification requirements in this subpart, notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian.

E. If a verbal notification is made, the licensee must inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee must provide a written description if requested.

Subp. 6. **Construction.** Aside from the notification requirement, nothing in this part affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by a medical event, or to that individual's responsible relatives or guardians.

Subp. 7. **Individual identification.** A licensee must:

A. annotate a copy of the report provided to the commissioner with:

(1) the name of the individual who is the subject of the event; and

(2) the identification number or, if no other identification number is available, the Social Security number of the individual who is the subject of the event; and

B. provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the medical event.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 36 SR 74; 46 SR 791*

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