

# STATE OF COLORADO

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Colorado Department  
of Public Health  
and Environment

To: Dialysis Treatment Clinic Advisory  
From: Lorraine Dixon-Jones, Policy Analyst  
Date: March 13, 2014  
Re: Types of Reportable Events (Occurrences) in Other States

Below is a listing of the types of reportable events in various states established for dialysis treatment clinics along with the state agency response to such information. This listing is based on a preliminary review of state statutes, regulations and reports. (Attachment A shows the reportable events in Colorado state statute.)

## Definition of Reportable Events

States generally require the reporting of events that resulted in harm, although some have requirements for “near misses.” The way of defining events that resulted in harm may be fairly broad or it may identify specific events. An example of a broad brush definition reads as follows:

Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.<sup>1</sup> This only includes events not related to the natural course of the patients’ illness or underlying condition.

Examples of specific events identified as reportable events include:

- Assault: any sexual or physical assault of or by a patient which is alleged to have occurred in the facility.
- Allergic reaction to medication and/or to dialyzer and other substance.
- Exsanguination. Blood loss greater than 275 ml: to include blood loss occurring from vascular access, dialyzer leak or system separation.
- Contamination: contaminated drugs, devices, biologics, or water (including chlorine/chloramine exposure or pyrogenic reaction).
- Dialysate with an incorrect pH or conductivity issue.

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<sup>1</sup> Instead of physical injury, it might read “serious disability” to include both a physical or mental impairment.

- Equipment: malfunction or misuse of equipment resulting in serious injury or death.
- Falls: that result in serious injury or death.
- Hemolytic reaction, including those due to disinfectant exposure, dialysate temperature, mechanical failure, or other cause.
- Infection: those related to Central Venous Catheter (CVC), CVC tunnel/exit site, AV fistula, AV graft, HERO device, or septicemia.
- Intra-dialytic event: any event that stops treatment including loss of consciousness, cardiac arrest, or seizure.
- Medication errors.
- Patient suicide, or attempted suicide, resulting in serious disability or death while being cared for in a healthcare facility.
- Patient elopement (disappearance).
- Vascular access problems: such as AVF or AVG clotting during the dialysis procedure, bleeding greater than 30 minutes for 3 consecutive treatments, or difficulty resulting in inability to initiate or complete dialysis treatment.
- Weight: variance for greater than or equal to 3 consecutive treatments (specifically either 2kg above or below the target weight).

### **State Agency Action in Response to Reportable Events**

State agency response to reportable events includes:

- Review and monitoring of facility corrective action plans.
- Dissemination to the public of facility specific information.
- Dissemination to the public of aggregated facility information and trending.
- Technical assistance to facilities regarding the reduction of reportable events based on in-depth analysis of confidential facility data, including root cause analyses. (This type of response is often conducted by a non-regulatory body.)

## Attachment A

### Colorado's Occurrence Reporting Statute: C.R.S. § 25-1-124

#### 25-1-124. Health care facilities - consumer information - reporting - release

(1) The general assembly hereby finds that an increasing number of people are faced with the difficult task of choosing a health care facility for themselves and their family members. This task may be made less difficult by improved access to reliable, helpful, and unbiased information concerning the quality of care and the safety of the environment offered by each health care facility. The general assembly further finds that it is appropriate that the department, in keeping with its role of protecting and improving the public health, solicit this information from health care facilities and disseminate it to the public in a form that will assist people in making informed choices among health care facilities.

(2) Each health care facility licensed pursuant to [section 25-3-101](#) or certified pursuant to [section 25-1.5-103 \(1\) \(a\) \(II\)](#) shall report to the department all of the following occurrences:

(a) Any occurrence that results in the death of a patient or resident of the facility and is required to be reported to the coroner pursuant to [section 30-10-606, C.R.S.](#), as arising from an unexplained cause or under suspicious circumstances;

(b) Any occurrence that results in any of the following serious injuries to a patient or resident:

(I) Brain or spinal cord injuries;

(II) Life-threatening complications of anesthesia or life-threatening transfusion errors or reactions;

(III) Second- or third-degree burns involving twenty percent or more of the body surface area of an adult patient or resident or fifteen percent or more of the body surface area of a child patient or resident;

(c) Any time that a resident or patient of the facility cannot be located following a search of the facility, the facility grounds, and the area surrounding the facility and there are circumstances that place the resident's health, safety, or welfare at risk or, regardless of whether such circumstances exist, the patient or resident has been missing for eight hours;

(d) Any occurrence involving physical, sexual, or verbal abuse of a patient or resident, as described in [section 18-3-202](#), [18-3-203](#), [18-3-204](#), [18-3-206](#), [18-3-402](#), [18-3-403](#), as it existed prior to July 1, 2000, [18-3-404](#), or [18-3-405, C.R.S.](#), by another patient or resident, an employee of the facility, or a visitor to the facility;

(e) Any occurrence involving caretaker neglect of a patient or resident, as described in [section 26-3.1-101 \(2.3\), C.R.S.](#);

(f) Any occurrence involving misappropriation of a patient's or resident's property. For purposes of this paragraph (f), "misappropriation of a patient's or resident's property" means a pattern of or deliberately misplacing, exploiting, or wrongfully using, either temporarily or permanently, a patient's or resident's belongings or money without the patient's or resident's consent.

(g) Any occurrence in which drugs intended for use by patients or residents are diverted to use by other persons. If the diverted drugs are injectable, the health care facility shall also report the full name and date of birth of any individual who diverted the injectable drugs, if known.

(h) Any occurrence involving the malfunction or intentional or accidental misuse of patient or resident care equipment that occurs during treatment or diagnosis of a patient or resident and that significantly adversely affects or if not averted would have significantly adversely affected a patient or resident of the facility.

(2.5) (a) In addition to the reports required by subsection (2) of this section, if the Colorado attorney general, the division for developmental disabilities in the department of human services, a community centered board, an adult protection service, or a law enforcement agency makes a report of an occurrence as described in subsection (2) of this section involving a licensed long-term care facility, that report shall be provided to the department and shall be made available for inspection consistent with the provisions of subsection (6) of this section. Any reports concerning an adult protection service shall be in compliance with the confidentiality requirements of [section 26-3.1-102 \(7\), C.R.S.](#)

(b) For purposes of this subsection (2.5), a "licensed long-term care facility" means a licensed community residential or group home, a licensed intermediate care facility for individuals with intellectual disabilities, and a licensed facility for persons with developmental disabilities.

(3) The board by rule shall specify the manner, time period, and form in which the reports required pursuant to subsection (2) of this section shall be made.

(4) Any report submitted pursuant to subsection (2) of this section shall be strictly confidential; except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions. The information in such reports shall not be made public upon subpoena, search warrant, discovery proceedings, or otherwise, except as provided in subsection (6) of this section.

(5) The department shall investigate each report submitted pursuant to subsection (2) of this section that it determines was appropriately submitted. For each report investigated, the department shall prepare a summary of its findings, including the department's conclusions and whether there was a violation of licensing standards or a deficiency or whether the facility acted appropriately in response to the occurrence. If the investigation is not conducted on site, the department shall specify in the summary how the investigation was conducted. Any investigation conducted pursuant to this subsection (5) shall be in addition to and not in lieu of any inspection required to be conducted pursuant to [section 25-1.5-103 \(1\) \(a\)](#) with regard to licensing.

(6) (a) The department shall make the following information available to the public:

(I) Any investigation summaries prepared pursuant to subsection (5) of this section;

(II) Any complaints against a health care facility that have been filed with the department and that the department has investigated, including the conclusions reached by the department and whether there was a violation of licensing standards or a deficiency or whether the facility acted appropriately in response to the subject of the complaint; and

(III) A listing of any deficiency citations issued against each health care facility.

(b) The information released pursuant to this subsection (6) shall not identify the patient or resident or the health care professional involved in the report.

(7) Prior to the completion of an investigation pursuant to this section, the department may respond to any inquiry regarding a report received pursuant to subsection (2) of this section by confirming that it has received such report and that an investigation is pending.

(8) In addition to the report to the department for an occurrence described in paragraph (d) of subsection (2) of this section, the occurrence shall be reported to a law enforcement agency.