

Fiscal Year 2010-2011 Adverse Events Addendum

The data for the following four tables were obtained from the federal Automated Survey Processing Environment (ASPEN) database on December 10, 2009. ASPEN processes and tracks reported adverse events and complaints reported by health care facilities. ASPEN is a dynamic database, being updated constantly. The dynamic nature of ASPEN yields different results from the same analysis on different dates. The differing totals of adverse events between the table on page 16 of the 2010-11 Health Facility License Fees Annual Report and the following tables are due to data being obtained from ASPEN on different dates.

Table 1. Adverse Event Report Category and Type by State Fiscal Year

Table 1 displays the 2,446 adverse events that were reported in California from July 01, 2007, through December 31, 2009. There have been 937 and 1,509 events reported for State Fiscal Years 2007-08 and 2008-09, respectively.

Among all reported events, "Stage 3 or 4 decubitus ulcers (pressure ulcers) acquired after admission" represents the largest number of any single type of event reported during these two years. For both years, 1,585 of these events were reported. This represents 65 percent of all events reported for both years and 61 percent and 67 percent of the events for each respective year of reporting.

The second largest type of adverse event reported in California for both years of reporting is the "Retention of a Foreign Object in a Patient" event.

There were no adverse events reported for the event types titled, "Infants discharged to the wrong person" and "Death or disability associated with hyperbilirubinemia in neonates."

Table 1. Adverse Event Report Category and Type by State Fiscal Year

Adverse Event Categories and Types*	State Fiscal Year		All
	2007-08	2008-09	
Surgical Events	223	283	506
Surgery performed on a wrong body part	29	26	55
Surgery performed on the wrong patient	2	4	6
Wrong surgical procedure performed on a patient	7	16	23
Retention of a foreign object in a patient	153	197	350
Death during or up to 24 hours after induction of anesthesia after surgery	32	40	72
Product or Device Events	4	6	10
Death or serious disability associated with the use of contaminated drug, device, or biologic	1	0	1
Death or serious disability associated with the use or function of a device in which the device is used for or functions other than as intended	1	3	4
Death or serious disability associated with intravascular air embolism	2	3	5

Table 1, Continued

Adverse Event Categories and Types	State Fiscal Year		All
	2007-08	2008-09	
Patient Protection Events	15	16	31
Infant discharged to wrong person	0	0	0
Death or serious disability associated with disappearance for more than four hours	2	4	6
Suicide or attempted suicide resulting in serious disability due to patient actions after admission to the health facility	13	12	25
Care Management Events	614	1,061	1,675
Death or serious disability associated with a medication error	32	30	62
Death or serious disability associated with incompatible blood or blood products	1	1	2
Maternal death or serious disability associated with labor or delivery in a low risk pregnancy	11	8	19
Death or serious disability directly related to hypoglycemia	0	6	6
Death or serious disability associated with hyperbilirubinemia in neonates	0	0	0
Stage 3 or 4 ulcer acquired after admission	570	1,015	1,585
Death or serious disability due to spinal manipulation therapy	0	1	1
Environmental Events	36	55	91
Death or serious disability associated with electric shock	0	1	1
Oxygen line contains wrong or toxic gas	1	0	1
Death or serious disability associated with a burn	1	5	6
Death associated with a fall	31	42	73
Death or serious disability associated with the use of restraints or bedrails	3	7	10
Criminal Events	18	38	56
Care ordered or provided by someone impersonating a licensed health provider	1	2	3
Abduction of a patient of any age	0	1	1
Sexual assault on a patient	13	30	43
Death or significant injury of a patient or staff member resulting from a physical assault	4	5	9
Other	27	50	77
Adverse event or series of adverse events that caused the death or serious disability of a patient, personnel, or visitor	27	50	77
Total Adverse Events	937	1,509	2,446

* See Health and Safety Code Section 1279.1 for specific description of each adverse event.

Table 2. Volume and Percent of Adverse Events by Category

Table 2 shows that the top three ranking adverse event categories for all state fiscal years were Category 4, Care Management Events; Category 1, Surgical Events; and Category 5, Environmental Events, respectively. The Care Management Category represents the largest percent of events reported for all years. For SFY 2007-08, this category represented 65.3% for all events reported and increased to 70.3% during SFY 2008-09.

State Fiscal Years 2007-08 and 2008-09 provide complete annual accountings of adverse events. For these years, the volume of reported adverse events increased for all categories.

The volume of events reported for Category 2, Product or Device Events, represent the least amount of change.

Table 2: Volume and Percent of Adverse Events by Category

Adverse Event Category	SFY 2007-08	%	SFY 2008-09	%	Total	%
1. Surgical Events	223	23.8%	283	18.8%	506	20.7%
2. Product or Device Events	4	0.4%	6	0.4%	10	0.4%
3. Patient Protection Events	15	1.6%	16	1.1%	31	1.3%
4. Care Management Events	614	65.5%	1061	70.3%	1,675	68.5%
5. Environmental Events	36	3.8%	55	3.6%	91	3.7%
6. Criminal Events	18	1.9%	38	2.5%	56	2.3%
7. Other	27	2.9%	50	3.3%	77	3.1%
Total	937		1,509		2,446	

Table 3. Volume of Adverse Events by Severity

Reported adverse events are categorized based on the severity and the risk of harm to patients or residents. Senate Bill (SB) 1301 distinguishes between adverse events that involve “an ongoing threat of imminent danger of death or serious bodily harm” and others that do not involve such an ongoing threat. For the former, the department is required to begin an investigation “within 48 hours or two business days” (HSC § 1279.2 (a) (1)). Such adverse events are distinguished from others where “there is no threat of imminent danger of death or serious bodily harm” in HSC § 1279.2 (b).

During SFY 2008-09, the overall volume of events meeting this definition of an ongoing threat of imminent danger decreased significantly in all categories except one (Category 3, Patient Protection Events). Conversely, during the same year, there was a significant increase in the overall volume of other adverse events.

Table 3: Annual Count of Adverse Events that involve an ongoing threat of imminent danger by Event Category

Adverse Event Report Type by Urgency	Urgency				Total		Adverse Events requiring inspection within 48 hours as percent of total	
	Adverse Events requiring inspection within 48 hours*		Other Adverse Events**					
	SFY 2007-2008	SFY 2008-2009	SFY 2007-2008	SFY 2008-2009	SFY 2007-2008	SFY 2008-2009	SFY 2007-2008	SFY 2008-2009
1. Surgical Events	30	8	193	275	223	283	13.5%	2.8%
2. Product or Device Events	3	2	1	4	4	6	75.0%	33.3%
3. Patient Protection Events	5	5	10	11	15	16	33.3%	31.3%
4. Care Management Events	82	14	532	1047	614	1061	13.4%	1.3%
5. Environmental Events	10	4	26	51	36	55	27.8%	7.3%
6. Criminal Events	3	2	15	36	18	38	16.7%	5.3%
7. Other	6	3	21	47	27	50	22.2%	6.0%
Total	139	38	798	1471	937	1509	14.8%	2.5%

* HSC § 1279.2 (a)(1)

** HSC § 1279.2 (b)

Table 4. Failure to Report Adverse Events Statistics

Table 4 shows the total counts of failure to report adverse events and the penalty amounts sanctioned against the licenses of acute care facilities during the period of July 01, 2007 through June 30, 2009.

Table 4: Failure to Report Adverse Events Statistics by State Fiscal Year

Events and Penalties	SFY 2007 - 2008	SFY 2008-2009	Totals
Failure to Report Adverse Events	94	153	247
Penalties Assessed	\$283,900	\$673,000	\$956,900