

Federal Regimes for Mandatory Adverse Event Reporting

	A	B	C	D	E	F	G
	Regime	Subject	Agency	Applies to	What to report	When to report	Reporting to whom
1	Medical Device Reporting Act	Adverse events during use of approved medical devices	FDA	Device Manufacturers and Hospitals	Serious injuries, deaths	Device user facilities: 10 work days; submit annual reports Manufacturers: 30 calendar days, or 5 days for events requiring remedial action/events for which FDA has made specific information request; submit annual baseline reports and supplemental reports for incomplete initial reports	Center for Devices and Radiological Health (CDRH)
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3	Vaccine Adverse Event Report System(VAERS)	Adverse events during use of vaccines	FDA, CDC	Health care providers, manufacturers, packers, distributors, shared manufacturers, joint manufacturers, or any other participant involved in divided manufacturing	See Table, sheet 2	See Table, sheet 2	
4	National Nosocomial Infections Surveillance(NNIS) database	Healthcare-Associated Infections	CDC	Hospitals voluntarily submitting	Any infection occurring during patient treatment	no set time-frame	NNIS
5	Dialysis Surveillance Network	Recording and tracking of vascular access infections, other bacterial infections, and intravenous antimicrobial starts.	CDC	Hemodialysis Centers	Any infection occurring during patient treatment	no set time-frame	DSN

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	Department of Veterans Affairs Adverse Event Reporting System	Adverse Events during medical treatment	Department of Veterans Affairs, Veterans' Health Administration	VA Hospitals	adverse events (untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences) "close calls" (events which might have become "adverse events but did not as a result of chance or timely intervention) and "sentinel events" (unexpected occurrences involving death, serious physical or psychological injury, or risk thereof.)	Unspecified	The National Center for Patient Safety, local Veterans' Integrated Service Network (if applicable)
6	Current Good Tissue Practice (CGTP) regulations	Communicable disease transmittal via tissue transplantation	FDA	Healthcare organizations which recover, process, store, label, package, manufacture, or distribute human cells, tissues, and cellular or tissue-based products (HCT/Ps)	Any serious "adverse reactions" (requiring medical or surgical intervention, or involving death, permanent impairment, or the threat thereof) involving a communicable disease; Any HCT/P deviation relating to the core CGTP requirements, if the HCT/P deviation occurred in manufacturer's facility or in a facility that performed a manufacturing step for the manufacturer under contract, agreement, or other arrangement.	Within 15 days of initial receipt of the information; must provide follow-up report within 15 days of receipt of new information; Within 45 days of any HCT/P deviation from core CGTP requirements	Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (HFM-600), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448
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8	Blood and Blood product manufacturing errors	errors and accidents associated with the manufacture, processing, and distribution of blood and blood products	FDA	licensed manufacturers of blood and blood components; unlicensed registered blood establishments; transfusion services	<p>Any event, and information relevant to the event, associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of blood or blood products which:</p> <p>(i) Represents a deviation from current good manufacturing practice, regulations, standards, specifications affecting the safety, purity, or potency of that product; or</p> <p>(ii) Represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product; and</p> <p>(2) Occurs in the (manufacturer/unlicensed registered blood establishment/transfusion service)'s facility or another facility under contract with the (manufacturer/unlicensed registered blood establishment/transfusion service); and</p> <p>(3) Involves distributed blood or blood components. (fatalities must be reported within 7 days to the CBER)</p>	<p>as soon as possible; but (manufacturer/unlicensed registered blood establishment/transfusion service)s must report at a date not to exceed 45-calendar days from the date the (manufacturer/unlicensed registered blood establishment/transfusion service) or its agent acquires information reasonably suggesting that a reportable event has occurred. *Note: fatalities are required under 21 C.F.R 606.170 to be reported within 7 days.</p>	Center for Biologics Evaluation and Research (CBER)

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	Other actions	Sanction	Statutory Authority	Applicable Regulation(s)	Exemptions/Other
1	Manufacturers: Must obtain and submit information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters to the FDA; must investigate each event and evaluate the cause of the event. If the manufacturer cannot submit complete information on a report, it must provide a statement explaining why this information was incomplete and the steps taken to obtain the information. If any required information that was not available at the time of filing the initial report is obtained, it must be submitted in a supplemental report.	21 U.S.C. 333(f)(1)(A) (Section 303, Federal Food Drug and Cosmetic Act)- Civil liability of up to \$15,000 for each violation (not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding) *Note: Penalties do not apply to violations unless the violation constitutes a "significant or knowing departure from such requirements" OR "a risk to public health".	21 U.S.C. 360(i)	21 CFR 600.80; 21 CFR 803	21 CFR 803.19 (Licensed practitioner utilizing device for treatment/diagnosis of patient with whom physician patient relationship exists; Manufacturers fabricating devices for research/testing only and not for sale; dental/optical laboratories; "investigational devices" (See 21 C.F.R. 812) (devices, including transitional devices, that are the object of a clinical investigation or research involving one or more subjects to determine its safety or effectiveness- 21 CFR 812.3))
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1	Other actions	Sanction	Statutory Authority	Applicable Regulation(s)	Exemptions/Other
3		None	Section 2125, Public Health Service Act, 42 USCS § 300aa-25 ("National Childhood Vaccine Injury Act")	42 CFR 100.3	
4	Maintenance of sufficient personnel/facilities/other resources to monitor treatment-related infections	None- participation is voluntary	42 USC §§ 241, 242b, 242k, and 242m(d)		*Slated to be replaced in 2006 by National Health Safety Network (NHSN)
5	Maintenance of sufficient personnel/facilities/other resources to monitor treatment-related infections	None- participation is voluntary	42 USC §§ 241, 242b, 242k, and 242m(d)		*Slated to be replaced in 2006 by National Health Safety Network (NHSN)

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1		none found.	No statutory/regulatory authority found. Mandated by Department of Veterans' Affairs Handbook, and VHA Directive 1051/1	None found	A parallel, completely voluntary system, the Patient Safety Reporting System (PSRS), has been established to accomplish the same functions, utilizing non-punitive review of adverse events and rewards for compliance
6		none found.	42 U.S.C. § 264	21 CFR 1271.350	Note: Does NOT apply to blood, blood products, or blood components (See 21 C.F.R. 1271.330)
7	Must investigate all HCT/P deviations related to a distributed HCT/P for which they performed a manufacturing step. Must investigate any adverse reaction involving a communicable disease relating to an HCT/P they made available for distribution.	none found.			

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1		none found.	42 U.S.C. § 262; 42 U.S.C. § 264	21 CFR 606.171	
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