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Agency	Subagency	CFR Citation	Description	Authority Type	Authority Citation	Mens Rea Type	Mens Rea Source Citation	Penalty Type	Penalty Range	Penalty Source	Add'l Information
Department of Health and Human Services	ACF (Administration for Children and Families)	45 C.F.R. 303.21(f)	Civil monetary penalty for unauthorized access to, disclosure of, or uses of information in the National Directory of New Hires	Statutory and regulatory	42 U.S.C. 653(l); 45 C.F.R. 303.21(f)	Knowingly and willfully	42 U.S.C. 653(l)(2)	Fine	\$1,000 for each act	42 U.S.C. 653(l)(2)	
Department of Health and Human Services	ASPR (Administration for Strategic Preparedness and Response) Defense Production Act and Emergency Response Authorities Office	Health Resource Priorities and Allocation System 45 CFR Part 101 101.74 Violations, penalties, and remedies	Willful violation of the provisions of the DPA, and related statutes may be punished by fine or imprisonment, or both. The maximum penalties provided by the DPA are a \$10,000 fine, or one year in prison, or both.	Statutory	The Defense Production Act of 1950, as amended [50 U.S.C. § 4501 et seq.] Section. 103 Penalties [50 U.S.C. § 4513]	Negligence	Statutory The Defense Production Act of 1950, as amended [50 U.S.C. § 4501 et seq.] Section. 103 Penalties [50 U.S.C. § 4513]	Fine and/or Imprisonment	Fine - up to \$10,000 Imprisonment - up to 1 year.	The Defense Production Act of 1950, as amended [50 U.S.C. § 4501 et seq.] Section. 103 Penalties [50 U.S.C. § 4513]	The HRPAS, like the DPAS and other implementation regulations for Title I authorities, support legislation and are required by Executive Order 13603.
Department of Health and Human Services	CDC (Centers for Disease Control and Prevention)	42 CFR 70.18	Persons or organizations that violate interstate quarantine requirements noted in column F are subject to fines or jail time. DOJ would be responsible for deciding whether to pursue civil penalties and/or criminal charges.	Statutory	Violation of the following sections of 42 CFR 70 can result in the penalties outlined in 42 CFR 70.18: 42 CFR § 70.3 All communicable diseases. 42 CFR § 70.4 Report of disease. 42 CFR § 70.5 Requirements relating to travelers under a federal order of isolation, quarantine, or conditional release. 42 CFR § 70.7 Responsibility with respect to minors, wards, and patients. 42 CFR § 70.11 Report of death or illness onboard aircraft operated by an airline.	not defined	not defined	Imprisonment and/or fine	Persons: A fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law. Organizations: A fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.	Section 368 of the PHSA specifies the penalties for violations of regulations “prescribed under [Section 361]” states: Violators may be subject to statutory penalties of up to one year in jail or a fine of \$1,000, or both. This is codified under and codified under 42 U.S.C. 271(a). Generally applicable criminal statutes on sentencing, however, authorize higher fines which CDC incorporated in this regulation (See 18 U.S.C. § 3559, §3571(b)(5), (c)(5)).	
Department of Health and Human Services	CDC (Centers for Disease Control and Prevention)	42 CFR 71.20	Persons or organizations that violate foreign quarantine requirements noted in column F are subject to fines or jail time. DOJ would be responsible for deciding whether to pursue civil	Statutory	Violation of the following sections of 42 CFR 71 can result in the penalties outlined in 42 CFR 71.20: 42 CFR § 71.4 Requirements relating to the transmission of airline passenger, crew, and flight information for public health purposes.	not defined	not defined	Imprisonment and/or fine	Persons: A fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law. Organizations: A fine of no more than \$200,000	Section 368 of the PHSA specifies the penalties for violations of regulations “prescribed under [Section 361]” states: Violators may be subject to statutory penalties of up to one year in jail or a fine of \$1,000, or both. This is codified under and codified under	
Department of Health and Human Services	CDC (Centers for Disease Control and Prevention)	42 CFR 71.51(gg)	If CDC believes that an importer, broker, or carrier has violated these requirements or otherwise broken the law, CDC may ask CBP to issue additional fines or	Statutory	CDC may refer the matter to CBP if importers, brokers, or carriers violate any of the following paragraphs: 71.51(b); 71.51(f)-(h); 71.51(j) –(q) 71.51(s)-(z); 71.51(bb)-(dd).	not defined	not defined	Imprisonment and/or fine	Not defined, we are only referring to CBP and DOJ for consideration.	Section 365 of the Public Health Service Act provides that it shall be the duty of customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations. Under section 368, HHS/CDC may	Note - we have included 71.51(gg) at HHS's request. However, we do not recommend including in the HHS submission to DOJ; HHS/CDC does not

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Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 312.62	Failure by clinical investigator to maintain adequate or accurate case histories	Statutory	21 USC 355(i)	Strict liability	21 USC 333(a)(1); US v. Dotterweich, 320 US 277 (1943); US v. Park, 421 US 658 (1975).	Imprisonment and/or criminal fine	Maximum one year in prison and/or maximum fine ranging from \$100,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(1); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 312.62	Failure by clinical investigator to maintain adequate or accurate case histories	Statutory	21 USC 355(i)	Specific intent to defraud or mislead or second conviction for violating the	21 USC 333(a)(2)	Imprisonment and/or criminal fine	Maximum three years in prison and/or maximum fine ranging from \$250,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(2); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 201.5	Failure to provide labeling with instructions for a layperson to use the drug safely	Statutory	21 USC 352(f)(1)	Strict liability	21 USC 333(a)(1); US v. Dotterweich, 320 US 277 (1943); US v. Park, 421 US 658 (1975).	Imprisonment and/or criminal fine	Maximum one year in prison and/or maximum fine ranging from \$100,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(1); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 201.5	Failure to provide labeling with instructions for a layperson to use the drug safely	Statutory	21 USC 352(f)(1)	Specific intent to defraud or mislead or second conviction for violating the Federal Food, Drug, and Cosmetic Act	21 USC 333(a)(2)	Imprisonment and/or criminal fine	Maximum three years in prison and/or maximum fine ranging from \$250,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(2); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 814.39	Failure to seek FDA approval for a change to an approved device that affect safety or effectiveness	Statutory	21 USC 360e(c)	Strict liability	21 USC 333(a)(1); US v. Dotterweich, 320 US 277 (1943); US v. Park, 421 US 658 (1975).	Imprisonment and/or criminal fine	Maximum one year in prison and/or maximum fine ranging from \$100,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(1); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 814.39	Failure to seek FDA approval for a change to an approved device that affect safety or effectiveness	Statutory	21 USC 360e(c)	Specific intent to defraud or mislead or second conviction for violating the Federal Food, Drug, and Cosmetic Act	21 USC 333(a)(2)	Imprisonment and/or criminal fine	Maximum three years in prison and/or maximum fine ranging from \$250,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(2); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 807.81	Failure to seek FDA clearance for a change to a cleared device that could affect safety or effectiveness	Statutory	21 USC 360(k)	Strict liability	21 USC 333(a)(1); US v. Dotterweich, 320 US 277 (1943); US v. Park, 421 US 658 (1975).	Imprisonment and/or criminal fine	Maximum one year in prison and/or maximum fine ranging from \$100,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(1); 18 USC 3571	

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Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 807.81	Failure to seek FDA clearance for a change to a cleared device that could affect safety or effectiveness	Statutory	21 USC 360(k)	Specific intent to defraud or mislead or second conviction for violating the Federal Food, Drug, and Cosmetic Act	21 USC 333(a)(2)	Imprisonment and/or criminal fine	Maximum three years in prison and/or maximum fine ranging from \$250,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(2); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 201.15(c)(1)	Foreign language labeling on a drug	Statutory	21 USC 352(c)	Strict liability	21 USC 333(a)(1); US v. Dotterweich, 320 US 277 (1943); US v. Park, 421 US 658 (1975).	Imprisonment and/or criminal fine	Maximum one year in prison and/or maximum fine ranging from \$100,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(1); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 201.15(c)(1)	Foreign language labeling on a drug	Statutory	21 USC 352(c)	Specific intent to defraud or mislead or second conviction for violating the Federal Food, Drug, and Cosmetic Act	21 USC 333(a)(2)	Imprisonment and/or criminal fine	Maximum three years in prison and/or maximum fine ranging from \$100,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(2); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 801.15(c)(1)	Foreign language labeling on a device	Statutory	21 USC 352(c)	Strict liability	21 USC 333(a)(1); US v. Dotterweich, 320 US 277 (1943); US v. Park, 421 US 658 (1975).	Imprisonment and/or criminal fine	Maximum one year in prison and/or maximum fine ranging from \$100,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(1); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 801.15(c)(1)	Foreign language labeling on a device	Statutory	21 USC 352(c)	Specific intent to defraud or mislead or second conviction for violating the Federal Food, Drug, and Cosmetic Act	21 USC 333(a)(2)	Imprisonment and/or criminal fine	Maximum three years in prison and/or maximum fine ranging from \$250,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(2); 18 USC 3571	
Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 801.109	Prescription devices requirements (including valid prescription and cautionary statement)	Statutory	21 USC 352	Strict liability	21 USC 333(a)(1); US v. Dotterweich, 320 US 277 (1943); US v. Park, 421 US 658 (1975).	Imprisonment and/or criminal fine	Maximum one year in prison and/or maximum fine ranging from \$100,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(1); 18 USC 3571	

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Department of Health and Human Services	FDA (Food and Drug Administration)	21 CFR 801.109	Prescription device requirements (including valid prescription and cautionary statement)	Statutory	21 USC 352	Specific intent to defraud or mislead or second conviction for violating the Federal Food, Drug, and Cosmetic Act	21 USC 333(a)(2)	Imprisonment and/or criminal fine	Maximum three years in prison and/or maximum fine ranging from \$250,000-\$500,000 or twice the gross gain or loss	21 USC 333(a)(2); 18 USC 3571	
Department of Health and Human Services	IHS (Indian Health Service)	42 CFR 136.119	In the context of the Indian Self Determination and Education Assistance Act (ISDEAA) this regulation prohibits recipients and related persons from embezzling, willfully misapplying, stealing, or obtaining by fraud federal property which is the subject of a grant or contract. It imposes a penalty of not more than \$10,000 or not more than two years imprisonment, but if the amount so embezzled, misapplied, stolen, or obtained by fraud does not exceed \$100, the maximum fine is \$1,000 or imprisonment for not more than one year, or both.	Statute	25 U.S.C. § 5306	25 U.S.C. § 5306 (willfully as to misapplying)	25 U.S.C. § 5306	Fine, imprisonment	For all sums over \$100, \$0-10,000 fine and 0-2 years of imprisonment. For sums equal to or less than \$100, \$0-1,000 fine and 0-1 year imprisonment.	25 U.S.C.A. § 5306	Offense is enforceable under existing statute(s), with or without this regulation. The regulation restates the penalty contained in 25 U.S.C. § 5306. See also 8 U.S.C. § 666 and 18 U.S.C. § 641 for similar penalties for for same types of offenses.
Department of Health and Human Services	IHS (Indian Health Service)	42 CFR 136.412	This regulation informs applicants for employment with the Indian Health Service of the consequences under federal law (e.g., 18 U.S.C. § 1001) for making false statements in application materials related to the requirements of the Indian Child Protection and Family Violence Prevention Act (see 25 U.S.C. 3207(a)(3)) and the Crime Control Act (34 U.S.C. § 20351)	Statute	18 U.S.C. § 1001	18 U.S.C. § 1001 (knowingly and willfully)	18 U.S.C. § 1001	Fine, imprisonment	Maximum fine of \$10,000; sentence of up to 5 years	18 U.S.C. § 1001	Offense is enforceable under existing statute(s), with or without this regulation. The regulation provides additional notice of this penalty to applicants and the public.

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Department of Health and Human Services	IHS (Indian Health Service)	48 CFR 326.606-2	In the context of responses to solicitations set-aside under the Buy Indian Act, this regulation notifies the public that any false or misleading information may be a violation of the law punishable under 18 U.S.C. 1001. Additionally, the regulation notifies the public that false claims submitted as part of contract performance may be subject to the penalties enumerated in 31 U.S.C. 3729 to 3731 and 18 U.S.C. 287. Except as provided in HHS Acquisition Regulation (HHSAR) 326.602-2, this portion of the HHSARs applies to all acquisitions above the micro-purchase threshold, including simplified acquisitions, made by IHS, and any HHS operating divisions or agency outside of IHS conducting acquisitions on behalf of IHS.	Statutes	18 U.S.C. 1001; 31 U.S.C. 3729 to 3731; and 18 U.S.C. 287	18 U.S.C. 1001: knowledge; 31 U.S.C. 3729 to 3731: knowledge for applicable acts; and 18 U.S.C. 287: knowledge	Statute: 18 U.S.C. 1001(a); 31 U.S.C. 3729(a); 18 U.S.C. 287	18 U.S.C. 1001: fine, imprisonment; 31 U.S.C. 3729 to 3731: civil fine; and 18 U.S.C. 287: fine, imprisonment	N/A	Statute: 18 U.S.C. 1001(a); 31 U.S.C. 3729(a); 18 U.S.C. 287	Offense is enforceable under existing statute(s), with or without this regulation from the HHS Acquisition Regulations; The regulation provides additional notice to the public.
Department of Health and Human Services	NIH/ FDA (National Institutes of Health / Food and Drug Administration)	42 CFR § 11.6	Provision of truthful information for clinical trials registration, results and information submission.	Statutory	21 U.S.C. §§ 331(jj), 333; 42 U.S.C. § 282(j)	See Column L	See Column L	See Column L	See Column L	See Column L	This regulation is managed jointly by NIH and FDA; the enforcement authority belongs to FDA. NIH defers to FDA on the interpretation of its statutory authority.
Department of Health and Human Services	NIH/ FDA (National Institutes of Health / Food and Drug Administration)	42 CFR § 11.66	Potential legal consequences of not complying with provision of truthful information for clinical trials registration, results and information submission.	Statutory	21 U.S.C. §§ 331(jj), 333; 42 U.S.C. § 282(j)	See Column L	See Column L	See Column L	See Column L	See Column L	This regulation is managed jointly by NIH and FDA; the enforcement authority belongs to FDA. NIH defers to FDA on the interpretation of its statutory authority.

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Department of Health and Human Services	OCR (Office for Civil Rights / Justice Department Health Care Fraud Unit)	The HIPAA Privacy Rule, Security Rule, Breach Notification Rule, and Enforcement Rules at 45 C.F.R. Parts 160 and 164	Criminal penalties for certain violations of HIPAA	Statutory	42 U.S.C. § 1320d-6	A person who knowingly (1) uses or causes to be used a unique health identifier; (2) obtains individually identifiable health information relating to an individual; or (3) discloses individually identifiable health information to another person.	42 U.S.C. § 1320d-6(a)&(b)	Criminal Fine/Imprisonment	1) maximum penalty of \$50,000 and/or imprisonment for not more than 1 year; 2) maximum penalty of \$100,000 and/or imprisonment for not more than 5 years for offences committed under false pretenses; 3) maximum penalty of \$250,000 and/or imprisonment for not more than 10 years for offences committed with intent to sell, transfer or use individually identifying health information for commercial advantage, personal gain, or malicious harm.	Statutory- 42 U.S.C. § 1320d-6(b)(1)-(3)	The Attorney General is responsible for the prosecution of criminal violations pursuant to 42 U.S.C. 1320d-6.
Department of Health and Human Services	Office of the Secretary	45 C.F.R. § 101.70(c)	Potential consequences for willful violations of Title I and Section 705 of the Defense Production Act (DPA) and other applicable statutes, the Health Resources Priorities and Allocations System (HRPAS), or an official action taken by HHS under the authority of the DPA, E.O. 13603, and the HRPAS or another regulation under the Federal Priorities and Allocations System (FPAS).	Statutory / Regulatory	50 U.S.C. §§ 4513, 4555(c)-(d); 45 C.F.R. § 101.74(a).	Willfulness	50 U.S.C. §§ 4513, 4555(c)-(d); 45 C.F.R. § 101.74(a).	Fine and/or imprisonment	Up to \$10,000 fine and/or one year in prison	50 U.S.C. §§ 4513, 4555(c)-(d); 45 C.F.R. § 101.74 (a).	