PROPOSED RULE MAKING



By (date) 07/29/2020

CR-102 (December 2017) (Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

Agency: Department of Health and State Board of Health (Joint rules)

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DATE: June 15, 2020

TIME: 3:59 PM

WSR 20-13-062

Supplemental Notice to WSR 20-07-108						
⊠Preproposal Stater	ment of Inqu	uiry was filed as WSR 18-11-089;	or			
Expedited Rule Ma	kingPropo	osed notice was filed as WSR ; or				
☐Proposal is exemp	t under RC\	N 34.05.310(4) or 34.05.330(1).				
☐Proposal is exemp	t under RC\	N.				
Title of rule and other	r identifying	information: (describe subject) C	hapter 246-101 WAC, Notifiable conditions. Supplemental			
		,	ment of Health (department) jointly propose changes to add			
notification and specime	n submission	requirements; change notification and	specimen submission requirements for existing conditions;			
-			ements for veterinarians and the Washington State			
	•		ility of the rule. This supplemental proposal adds Silicosis as			
	-		race and ethnicity to the list of required reportable data			
components; and makes other administrative changes and clarifications.						
Hearing location(s):						
Date:	Time:	Location: (be specific)	Comment:			
8/12/2020	11:30 am	In response to the coronavirus				
		disease 2019 (COVID-19) public				
	health emergency, the Department					
	of Health and State Board of Health					
		will not provide a physical location				
		for this hearing to promote social				
		distancing and the safety of the				
		citizens of Washington State. A				
		virtual public hearing, without a				
		physical meeting space, will be held				
		instead.				
		To access the meeting online:				
		https://attendee.gotowebinar.com/				
		register/2102821893206520331				
		You can also dial-in using your				
		phone: +1 (562) 247-8421, Access				
		Code 260-915-447				
	Date of intended adoption: 08/12/2020 (Note: This is NOT the effective date)					
Submit written comm	ents to:					
Name: Alexandra Monta	ano					
Address: PO Box 4781	1 Olympia W	A 98504-7811				
Email: https://fortress.w	va.gov/doh/p	olicyreview				
Fax: None	= ''					
Other: None						

Assistance for persons with disabilities:

Contact <u>Alexandra Montano</u> Phone: 360-236-4205

Fax: TTY: 711

Email: alexandra.montano@doh.wa.gov

Other:

By (date) 08/07/2020

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose the chapter is to provide critical information to public health authorities to aid them in protecting and improving public health through prevention and control of infectious and noninfectious conditions as required under law. Public health authorities use the information gathered under this chapter to take appropriate action, including, but not limited to: treating ill people; providing preventive therapies for individuals who came into contact with infectious agents; investigating and halting outbreaks; removing harmful health exposures from the environment; assessing broader health-related patterns, including historical trends, geographic clustering, and risk factors; and redirecting program activities and developing policies based on broader health-related patterns. The chapter establishes notification requirements and standards for conditions that pose a threat to public health consistent with this purpose and the authorizing statutes it is adopted under.

The current rules require health care providers, health care facilities, laboratories, veterinarians, food service establishments, child care facilities, and schools to notify public health authorities of cases of notifiable conditions identified in this chapter, cooperate with public health authorities when conducting case investigations, and follow infection control measures when necessary to control the spread of disease.

The proposed rules significantly amend notification requirements applicable to health care providers, health care facilities, laboratories, and veterinarians; create notification requirements for the Washington State Department of Agriculture; and clarify requirements for food service establishments, schools, child care facilities, and the general public. Proposed changes to the rules include: (1) adding or revising notification and specimen submission requirements for 74 new or existing conditions; (2) eliminating three categories of conditions (other rare diseases of public health significance, emerging conditions with outbreak potential and disease of suspected bioterrorism origin); (3) eliminating notification requirements for veterinarians and clarifying requirements for veterinarians to cooperate with public health authorities during case investigations; (4) establishing notification requirements for the Washington State Department of Agriculture; (5) updating Local Health Jurisdiction duties to reflect current technology used for notifying the department, clarifying existing and establishing new notification timelines, and clarifying notification, case report, and outbreak report content requirements; (6) updating reference to the Security and Confidentiality Guidelines developed by the Centers for Disease Control and Prevention; (7) updating statutory references throughout the chapter; and (8) improving overall clarity and usability of the chapter by merging health care provider and facility rules, repealing unnecessary rules, clarifying requirements for suspected cases of notifiable conditions, and revising language consistent with clear rule writing standards.

The board held a public hearing on April 8, 2020. The board determined it would continue its consideration of the proposal until its August 12, 2020 meeting in recognition of interested parties' limited ability to comment on the proposed changes as a result of COVID-19. As a result of public comments, the board and department have made the following changes to the proposed rule since it was filed in March: addition of Silicosis as a notifiable condition for healthcare providers and healthcare facilities; addition of race and ethnicity to the list of data components that must be included in WAC 246-101-105, -246-101-115, 246-101-205, 246-101-215, and 246-101-225; and other administrative changes and clarifications.

Reasons supporting proposal: The rules were last revised in 2011. Since then, there have been a number of advances and developments which can only be addressed in rule. The board and department have proposed changes to chapter 246-101 WAC to better protect public health by improving our understanding of emerging conditions, allowing more thorough case investigations, and improving the public health response to infectious and noninfectious conditions. The public health goals for these changes are to reduce the risk of transmission of disease and prevent serious complications and fatalities.

Statutory authority for adoption: RCW 43.20.050, 70.104.055, 43.70.545, 70.24.125, 70.104.030, 70.24.130, 70.24.380 and 70.28.032

Statute being implemented: RCW 70.104.055, 43.70.545, 70.28.010, and 70.05.060

Is rule necessary	because of a:			
Federal Lav	v?		☐ Yes	⊠ No
Federal Co	urt Decision?		☐ Yes	⊠ No
State Court	Decision?		☐ Yes	⊠ No
If yes, CITATION:				
Agency commen matters: None	ts or recommendations, if	any, as to statutory language, implementation, enfor	cement, a	nd fiscal
Name of propone Department of Heal		Washington State Board of Health and Washington State	☐Private ☐Public ☑Govern	
Name of agency	personnel responsible for:			
	Name	Office Location	Phone	
Drafting:	Alexandra Montano	101 Israel Road S.E., Tumwater, WA, 98504-7990	(360) 236	-4205
Implementation:	Alexandra Montano	101 Israel Road S.E., Tumwater, WA, 98504-7990	(360) 236	-4205
Enforcement:	Alexandra Montano	101 Israel Road S.E., Tumwater, WA, 98504-7990	(360) 236	-4205
Is a school distri		required under RCW 28A.305.135?	☐ Yes	⊠ No
Name: Address Phone: Fax: TTY: Email: Other:	:	district fiscal impact statement by contacting:		
	analysis required under RC			
Name: A Address Phone: 3 Fax: No TTY: 71	Alexandra Montano : PO Box 47811 Olympia WA 98504-7811 360-236-4205 ne	s may be obtained by contacting:		
Other: N				

Regulatory	Fairness Act Cost Considerations for	a Small Busine	ess Economic Impact Statement:
	oposal, or portions of the proposal, may b 85 RCW). Please check the box for any a		requirements of the Regulatory Fairness Act (see otion(s):
adopted sol regulation tl adopted. Citation and ☐ This rul	lely to conform and/or comply with federal his rule is being adopted to conform or cod description:	statute or regul mply with, and d exempt because	CW 19.85.061 because this rule making is being ations. Please cite the specific federal statute or lescribe the consequences to the state if the rule is not at the agency has completed the pilot rule process ale.
☐ This rul	_		ne provisions of RCW 15.65.570(2) because it was
☐ This rul	e proposal, or portions of the proposal, is	exempt under R	CW 19.85.025(3). Check all that apply:
	RCW 34.05.310 (4)(b)		RCW 34.05.310 (4)(e)
	(Internal government operations)		(Dictated by statute)
	RCW 34.05.310 (4)(c)		RCW 34.05.310 (4)(f)
	(Incorporation by reference)		(Set or adjust fees)
	RCW 34.05.310 (4)(d)		RCW 34.05.310 (4)(g)
	(Correct or clarify language)		((i) Relating to agency hearings; or (ii) process
			requirements for applying to an agency for a license or permit)
☐ This rul	e proposal, or portions of the proposal, is	exempt under R	CW.
Explanation	of exemptions, if necessary:		
	COMPLETE THIS SEC	TION ONLY IF	NO EXEMPTION APPLIES
If the propo	sed rule is not exempt , does it impose m	ore-than-minor	costs (as defined by RCW 19.85.020(2)) on businesses?
☐ No	Briefly summarize the agency's analysis	showing how c	osts were calculated.
econom The purpose protecting a	ic impact statement is required. Insert state e of chapter 246-101 WAC, Notifiable Condition and improving public health through prevention	tement here: ons, is to provide on and control of i	e-than-minor cost to businesses, and a small business critical information to public health authorities to aid them in infectious and noninfectious conditions as required under the information gathered under this chapter to take
10443 43.20.	000, 70.104.000, and 40.70.040. Public fiedici	i autilorities use i	ine information gathered under this chapter to take

The purpose of chapter 246-101 WAC, Notifiable Conditions, is to provide critical information to public health authorities to aid them in protecting and improving public health through prevention and control of infectious and noninfectious conditions as required under RCWs 43.20.050, 70.104.055, and 43.70.545. Public health authorities use the information gathered under this chapter to take appropriate action, including, but not limited to, treating ill people; providing preventive therapies for individuals who came into contact with infectious agents; investigating and halting outbreaks; removing harmful health exposures from the environment; assessing broader health-related patterns, including historical trends, geographic clustering, and risk factors; and redirecting program activities and developing policies based on broader health-related patterns. The chapter establishes notification requirements and standards for conditions that pose a threat to public health consistent with this purpose and the authorizing statutes it is adopted under.

The current rules require health care providers, health care facilities, laboratories, veterinarians, food service establishments, child care facilities, and schools to notify public health authorities of cases of notifiable conditions identified in chapter 246-101-WAC, cooperate with public health authorities when conducting case investigations, and follow infection control measures when necessary to control the spread of disease.

The rules were last revised in 2011. Since then, there have been a number of advances and developments which can only be addressed in rule. The board and department, through joint rule making, have proposed changes to Chapter 246-101 WAC, Notifiable Conditions, to better protect public health by improving our understanding of emerging conditions, allowing more thorough case investigations, and improving the public health response to infectious and noninfectious conditions. The public health goals for these changes are to reduce the risk of transmission of disease and prevent serious complications and fatalities.

If adopted, the proposed rules would significantly amend notification requirements applicable to health care providers, health care facilities, laboratories, and veterinarians; create notification requirements for the Washington State Department of Agriculture; and clarify requirements for food service establishments, schools, child care facilities, and the general public. Proposed changes to the rules include:

- Adding or revising notification and specimen submission requirements for 74 new or existing conditions;
- Adding race and ethnicity to the list of data components that must be reported;

- Eliminating three categories of conditions (other rare diseases of public health significance, emerging conditions with outbreak potential, and disease of suspected bioterrorism origin);
- Eliminating notification requirements for veterinarians and clarifying requirements for veterinarians to cooperate with public health authorities during case investigations;
- Establishing notification requirements for the Washington State Department of Agriculture;
- Updating Local Health Jurisdiction duties to reflect current technology used for notifying the department, clarifying existing and establishing new notification timelines, and clarifying notification, case report, and outbreak report content requirements;
- Updating reference to the Security and Confidentiality Guidelines developed by the Centers for Disease Control and Prevention;
- Updating statutory references throughout the chapter; and
- Improving overall clarity and usability of the chapter by merging health care provider and facility rules, repealing unnecessary rules, clarifying requirements for suspected cases of notifiable conditions, and revising language consistent with clear rule writing standards.

The board held a public hearing on April 8, 2020. As a result of the hearing the board determined it would file a supplemental proposal to CR-102 filed on March 18, 2020 as WSR 20-07-108. The supplemental proposal:

- Continues the board's consideration of the original proposal until its August 12, 2020 meeting in recognition of interested parties' limited ability to comment on the proposed changes as a result of the coronavirus disease (COVID-19) pandemic; and
- Proposes further amendments to the rule, including:
 - O Adding Silicosis as a notifiable condition for healthcare providers and healthcare facilities. This analysis, includes assumed probable costs for health care providers and facilities to prepare and submit cases.
 - Adding race and ethnicity to the list of data components that must be included in reports as required in WAC 246-101-105, 246-101-115, 246-101-205, 246-101-215, and 246-101-225. The department assumes that even with adding these additional data components the proposed changes will not add any new costs for health care providers and facilities.
 - Other administrative changes and clarifications. No new costs are associated with these amendments.

The following businesses are required to comply with the proposed rule. The North American Industry Classification System (NAICS) codes were used and the minor cost thresholds are identified.

Table A:

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	# of businesses in WA	Minor Cost Threshold = 1% of Average Annual Payroll	Minor Cost Threshold = .3% of Average Annual Receipts
621111	Offices of Physicians (except Mental Health Specialists)	2576	\$19,450.07	\$5,891.42
621112	Offices of Physicians; Mental Health Specialists	130	\$2,243.26	\$727.85
621330	Offices of Mental Health Practitioners (except Physicians)	235	\$2,665.03	\$351.33
621399	Offices of All Other Miscellaneous Health Practitioners	1042	\$1,482.68	\$528.32
621410	Family Planning Centers	53	\$6,906.27	\$2,106.01
621420	Outpatient Mental Health and Substance Abuse Centers	329	\$14,653.15	\$1,830.45
621491	HMO Medical Centers	71	Redacted	\$51,522.51
621492	Kidney Dialysis Centers	105	\$21,245.21	\$59,055.28

621493	Freestanding Ambulatory Surgical and Emergency Centers	58	Redacted	\$12,617.37
621498	All Other Outpatient Care Centers	110	\$33,260.62	\$2,370.09
621511	Medical Laboratories	192	\$15,104.13	\$17,874.80
621910	Ambulance Services	52	\$24,603.63	\$7,390.03
621991	Blood and Organ Banks	37	\$35,058.86	\$3,564.01
621999	All Other Miscellaneous Ambulatory Health Care Services	59	Redacted	\$4,185.45
622110	General Medical and Surgical Hospitals	147	\$622,801.12	\$156,044.36
622210	Psychiatric and Substance Abuse Hospitals	28	\$41,280.23	\$10,762.16
622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	6	\$303,145.51	\$15,972.98
623110	Nursing Care Facilities (Skilled Nursing Facilities)	258	\$33,681.92	\$7,099.53

Probable cost of compliance including: cost of equipment, supplies, labor, professional services and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue.

WAC 246-101-101, Notifiable Conditions – Health Care Providers and Facilities; and WAC 246-101-201, Notifiable Conditions – Laboratories

The proposed rules require health care providers, health care facilities, and laboratories to submit case reports and specimens to public health authorities for specified conditions, within specified timeframes, with specified information, and using a specified format. The rules do not require health care providers, health care facilities, or laboratories to provide service or conduct laboratory tests that they do not include as a part of their business practices. Table 1 outlines the probable costs by condition (per case) along with the total annual costs by condition. Table 2 outlines the additional probable one-time costs for providers, facilities, and laboratories for training and for updating Standard Operating Procedures, Laboratory Information Management Systems (LIMS), and Electronic Laboratory Reporting (ELR) systems.

Table 1: Probable Annual Costs (WAC 246-101-101, -105, -115, -201, -205, -215, -225)

Condition	Providers / Facilities: Added Cost per Case Report ¹	Laboratories: Added Cost per Case Report ²	Laboratories: Added Cost per Specimen Submission ³	Assumed Number of Cases per Year ⁴	Total Annual Cost per Condition
Amoebic meningitis	\$0 - \$82.50	\$0 - \$30.00	\$0 - \$15.00	0 - 1	\$0 – \$127.50
Anaplasmosis	\$0 - 412.50	\$0 - 100.00	\$0 - \$75.00	0 - 5	\$0 - \$587.50

¹ Costs are for staff time to prepare the case report.

² Costs are for staff time to prepare the case report.

³ Costs are for staff time to prepare documentation to accompany specimens and packaging materials.

⁴ For rare conditions, such as anthrax, that have not occurred in Washington State, the Department assumed a single case per year to provide a cost estimate in the event a case of the condition ever occurs.

Babesiosis	\$0 - \$247.50	\$0 - \$60.00	\$0 - \$45.00	0-3	\$0 – \$352.50
Bacillus cereus (biovar anthracis only	\$0 - \$82.50	\$0 - \$30.00	\$0	0-1	\$0 - \$112.50
Baylisascariasis	\$0 - \$82.50	\$30.00	\$15.00	1	\$0 - \$127.50
Blood lead level (adult between 5 μg/dl and 10μg/dl)	N/A	\$8,000 - \$10,000	N/A	400 – 500	\$8,000 - \$10,000
Bordetella pertussis	N/A	\$0	\$0	Fewer notifications	\$0
Borrelia burgdorferi or mayonii	N/A	\$0 - \$20.00	\$0 - \$15.00	0-1	\$0 - \$35.00
Brucella species	N/A	\$0 - \$20.00	\$0 - \$15.00	0-1	\$0 - \$35.00
Burkholderia mallei	N/A	\$0	\$0	Fewer notifications	\$0
Burkholderia pseudomallei	N/A	\$0	\$0	Fewer notifications	\$0
California serogroup viruses	N/A	\$0 - \$20.00	\$0 - \$15	0-1	\$0 - \$35.00
Campylobacteriosis	\$05	\$0	\$0	Fewer test results	\$0
Candida auris	\$1,402.50	\$510.00	\$255.00	17	\$2,167.50
Carbapenem-resistant Enterobacteriaceae: Klebsiella species, E. coli, Enterobacter species	\$24,750.00	\$6,000.00	\$4,500.00	300	\$35,250.00
Chagas disease (Trypanosoma cruzi)	\$825.00- \$1,650.00	\$200 - \$400	\$150 - \$300	10-20	\$1,175 - \$3,525
Chikungunya virus	N/A	\$0 - \$100	\$0 - \$75	0 - 5	\$0 - \$175.00
Chlamydia trachomatis	N/A	\$10,000	\$0	500	\$10,000
Chlamydia trachomatis (De-identified negative results)	N/A	\$162,240	\$0	5,408	\$167,648
Coccidioidomycosis (Coccidioides)	\$4,125.00 - \$6,600.00	\$1,000.00 - \$1,600.00	\$750.00 – 1,200.00	-50-80	\$5,875 - \$9,400
Coronavirus: MERS-associated	\$82.50	\$60.00	\$50.00	2	\$192.50

 $^{^{5}}$ New condition for health care facilities only.

Coronavirus: Novel coronavirus (COVID-19)	\$8,250.00 - \$82,500.00	\$3,000.00 - \$30,000.00	\$2,5000.00 - \$25,000.00	100 – 1000 (estimate based on very limited data)	\$13,750.00 - \$137,500.00
Cryptococcus gattii	\$82.50 - \$825.00	\$20.00 - \$200.00	\$0	1-10	\$102.50 - \$1,025.00
Cysticercosis	\$0 - \$165.00	N/A	N/A	0 - 2	\$0 - \$165.00
Dengue viruses	N/A	\$0 - \$60.00	\$0 - \$45.00	0-3	\$0 - \$125.00
Diphtheria (Corynebacterium Diphtheria)	N/A	\$0	\$0	Fewer notifications	\$0
Eastern and western equine encephalitis virus	N/A	\$0 - \$20.00	\$0 - \$15.00	0-1	\$0 - \$35.00
Echinococcosis (Echinococcus granulosus or multilocularis)	\$0 - \$82.50	\$0.00 - \$20.00	\$0.00 - \$15.00	0-1	\$0 - \$117.50
Ehrlichiosis (Ehrlichia species)	\$0 -165.00	\$0 - \$40.00	\$0 - \$30.00	0 – 2	\$0 - \$235.00
Gonorrhea (Neisseria gonorrhoeae)	\$0	\$1,400.00	\$0	70	\$1,400.00
Gonorrhea (Neisseria gonorrhoeae) (De-identified negative results)	N/A	\$106,380	\$0	3,546	\$106,380.00
Haemophilus influenzae (children <5 years of age)	N/A	\$0	\$0	Fewer notification	\$0
Hantaviral infections	\$0	\$0	\$0 - \$75.00	0-5	\$0 – \$75
Hepatitis A virus	N/A	\$60.00 - \$120.00	\$30.00 - \$60.00	2 - 4	\$90.00 - \$180.00
Hepatitis B (chronic)	\$0	N/A	N/A	1,521	\$0
Hepatitis B virus	N/A	\$30,680	N/A	1,547	\$30,680.00
Hepatitis C (acute), (chronic), and (perinatal)	\$0	N/A	N/A	N/A	\$0
Hepatitis C virus	N/A	\$330,848	\$0	7,712 positives and 15,000 nonpositive results for nucleic acid detection tests	\$330,848

Hepatitis C virus (De-identified negative results)	N/A	\$478,590	\$0	145,953	\$478,590.00
Hepatitis D	\$0	\$140	\$0	14	\$140
Histoplasmosis (Histoplasma capsulatum)	\$82.50	\$0.00 - \$20.00	\$0 - \$25.00	0-1	\$82.50 - \$127.50.00
HIV	N/A	\$61,708	\$0	13,752	\$61,708.00
HIV (De-identified negative results)	N/A	\$419,940	\$0	13,998	\$419,940.00
Human prion disease	N/A	\$400.00	\$500.00	20	\$900.00
Hypersensitivity Pneumonitis, Occupational	\$1567.50 - \$2392.50	N/A	N/A	19 – 29	\$1567.50 - \$2392.50
Japanese encephalitis virus	N/A	\$0 - \$20.00	\$0 - \$15.00	0-1	\$0 - \$35.00
La Crosse encephalitis virus	NA	\$0 - \$20.00	\$0 - \$15.00	0-1	\$0 - \$35.00
Listeriosis (Listeria monocytogenes)	N/A	\$0	\$0	Fewer notifications	\$0
Malaria (Plasmodium species)	N/A	\$0	\$0	Fewer notifications	\$0
Mumps virus	N/A	\$0	\$0	No change in number of notifications	\$0
Powassan virus	N/A	\$0.00 - \$20.00	\$0 - \$15.00	0-1	\$0 - \$35.00
Psittacosis (Chlamydia psittaci)	N/A	\$0	\$0	Fewer notifications	\$0
Relapsing fever (Borrelia hermsii, miyamotoi, or recurrentis)	\$0	\$0 - \$20.00	\$0 - \$15.00	0 - 1	\$0 - \$35.00
Rickettsia infection (Rickettsia species)	\$0 - \$412.50	\$100.00	\$75.00	0-5	\$0 - \$587.50
Rubella	N/A	\$0 - \$60.00	\$0 - \$30.00	0-2	\$0 - \$90.00
Rubeola (Measles virus)	N/A	\$0	\$0	No change in number of notifications	\$0
Silicosis	\$82.50 - \$660	N/A	N/A	1-8	\$82.50 to \$660

		4	4- 4		4- 4
Smallpox (Variola virus)	N/A	\$0.00 - \$150.00	\$0 - \$75.00	0 - 5	\$0 - \$225.00
St. Louis encephalitis virus	N/A	\$0.00 - \$20.00	\$0 - \$15.00	0 - 1	\$0 - \$35.00
Syphilis (Treponema pallidum)	N/A	\$120.00	\$0	6	\$120.00
Syphilis (Treponema pallidum) (De-identified negatives)	N/A	\$42,980	\$0	14,766	\$42,980.00
Taenia solium	See Cysticercosis and Taeniasis	\$400.00	\$300.00	20	\$700.00
Taeniasis	\$0 - \$412.50	N/A	N/A	0 - 5	\$0 - \$412.50
Tick paralysis	\$0 - \$165.00	N/A	N/A	0 – 2	\$0 - \$165.00
Trichinellosis (Trichinella species)	N/A	\$0	\$0	Fewer notifications	\$0
Tuberculosis (Mycobacterium tuberculosis complex)	\$0	\$0	\$0	Fewer notifications	\$0
Typhus	\$82.50	N/A	N/A	1	\$82.50
Vaccinia (vaccine- acquired smallpox)	N/A	\$0 - \$150.00	\$0 - \$125.00	0-5	\$0 - \$275.00
West Nile virus	N/A	\$0	\$0	Fewer notifications	\$0
Yellow fever virus	N/A	\$0	\$0	Fewer notifications	\$0
Zika virus	N/A	\$0 - \$1,380.00	\$0 - \$1,035.00	0 – 69	\$0 - \$2,415.00
RANGE OF TOTAL PROBABLE COSTS FOR ALL REGULATED ENTITIES IN THE STATE COMBINED				\$1,720	,451.50 - \$1,860,721.5

Table 2: Probable One-time Costs (WAC 246-101-101, -105, -115, -201, -205, -215, -225)

Cost Description	Providers / Facilities	Laboratories:
Update Standard Operating Procedures	N/A	74 conditions X \$12 = \$888
Update Laboratory Information Management Systems	N/A	74 conditions X \$60 = \$4,440
Update Electronic Laboratory Reporting	N/A	74 conditions X \$60 = \$4,440
Create de-identified annual summary report in LIMS	N/A	5 conditions X \$800 = \$40,000

Total Cost Per Regulated Entity	\$0	\$49,768

WAC 246-101-105. Duties: Health Care Providers and Facilities

WAC 246-101-115, Content of Case Reports: Health care providers and health care facilities

WAC 246-101-205, Duties: Laboratory Directors

The proposed rules amend multiple sections in order to establish consistent content of health care provider, facility, and laboratory case reports and specimen submission forms. The only exception to this proposed standard is WAC 246-101-118, Content of case reports for occupational traumatic injury hospitalizations: Health care facilities. The costs of these changes are included in Table 1: Probable Annual Costs (WAC 246-101-101, -105, -115, -201, -205, -215, -225), and Table 2: Probable One-time Costs (WAC 246-101-101, 246-101-105, 246-101-115, 246-101-201, 246-101-205, 246-101-215, 246-101-225) above.

WAC 246-101-110, Means of notification: Health care providers and health care facilities

The proposed rule requires all case reports be type written. This change would eliminate hand-written case reports. The department assumes that by providing electronic forms on its website, the proposed change is cost neutral for health care providers and facilities.

WAC 246-101-205, Duties: Laboratory directors

The proposed rule requires laboratories to submit presumptive and final test results to the department for a patient residing outside and visiting Washington State. The department assumes the probable cost for a laboratory to prepare and submit case reports for patients visiting Washington State are included in costs identified in Table 1 and Table 2 for updating laboratory LIMS and ELR systems, updating standard operating procedures for each notifiable condition, and confirming receipt for case reports for conditions notifiable immediately or within 24 hours.

WAC 246-101-220, Means of notification: Laboratory directors

The proposed rule requires all presumptive and final test results be submitted via secure electronic data transmission. This change would eliminate hand-written presumptive and final test results, and non-electronic mail submission (e.g. USPS, FedEx, UPS, etc.). The department assumes that by providing electronic forms on its website, the proposed change to eliminate hand-written test results is cost neutral for health care providers and facilities. The department also assumes the proposed requirement to use secure electronic data submission of test results is the standard for laboratories to share sensitive data and the probable cost for this change is negligible.

WAC 246-101-405, Duties: Veterinarians and the state department of agriculture

The proposed rule eliminates the requirement for veterinarians to notify the department of suspected human cases of specifically named zoonotic diseases that poses a high risk of transmission to humans. The department has historically received no case reports from veterinarians under this requirement and assumes there will be no increased or decreased cost for this proposed change.

Probable Benefit and Cost Conclusion

The department and board evaluated the qualitative and qualitative costs and benefits of the proposed rules, taking into account the general goals and specific objectives of the statute being implemented.

Benefit Summary

The proposed rules implement the general goals and specific objectives of RCW 43.20.050, RCW 43.70.545, and RCW 70.104.055 by establishing a surveillance system that includes notification, investigation, and collection and distribution of data related to infectious and noninfectious conditions. This data is critical to Local Health Jurisdictions, the department, and other public health authorities tasked with preventing and controlling the spread of disease. Public health authorities also use the data to assess broader patterns, including historical trends and geographic clustering of disease. Based on these assessments, officials are able to take appropriate actions such as conducting outbreak investigations, redirecting program activities, and developing new policies to prevent and control infectious and noninfectious conditions.

Public health surveillance plays an essential role in disease control by providing public health authorities with information and data necessary to take public health action. Surveillance provides data and information to assess the burden and distribution of adverse health events, prioritize public health actions, implement disease control measures to reduce the number and severity of cases, monitor the impact of control measures, identify reservoirs or vectors of disease, identify emerging health conditions that may have a significant impact upon population health, and contribute to surveillance activities at the national and international level to implement more effective control measures on a broader scale.⁶

Public health surveillance plays a key role in identifying, controlling, and preventing the spread of zoonotic disease and can also play a role in promoting equity. Many of the new conditions in the proposed rules disproportionality impact subpopulations who are already experiencing health disparities as documented in this analysis.

The proposed rules establish notification requirements for new conditions and revised notification and specimen submission requirements for some current conditions. These changes are help to avoid the costs associated with the burden on an individual with a case of a condition, the public health system, and the population as a whole.

⁶ Groseclose SL, Buckeridge DL. Public health surveillance systems: recent advances in their use and evaluation. Annual Rev Public Health. 2017; 38:57–79.

Cost Summary

The proposed rules impose new costs for health care providers, health care facilities, and laboratories for new requirements related to case reports and specimens submitted under the proposed rules. Below is a summary of the costs described in the preceding section-by-section analysis.

The probable one-time cost per entity is \$0 for providers/facilities and \$49,768 for non-CLIA waived laboratories (Table 2). The estimate for each laboratory is likely inflated due to the fact that some laboratories do not test for many of the conditions and will not include the one-time costs of updating their systems. In addition, some one-time costs are specific to laboratories using ELR (not exclusively, but primarily large labs). The department assumes that some laboratories will incur zero one-time costs associated with the proposed amendments, with any one lab incurring no more than \$\$49,768 in one-time costs.

In addition to these one-time costs, the probable annual costs for all regulated entities in Washington State combined (Table 1) range from \$1,720,451.50 - \$1,860,721.50. No one entity will absorb all of these costs. As noted above, the department assumes some regulated entities (e.g. laboratories who do not test for notifiable conditions, or health care providers who do not diagnose notifiable conditions) will incur zero costs. The annual costs of the rules statewide will be distributed among the remaining businesses, with larger entities likely to incur the largest costs due to higher testing volumes. Three healthcare providers/facilities provided annual cost estimates in the cost questionnaires. These estimates were \$72.80, \$100 (respondent did not indicate number of employees), and \$574 annually. One laboratory (>5000 employees) estimated that the proposed changes would cost them \$12,000 - \$15,000 in one-time costs and \$2,500 - \$5,000 in annual costs.

Analysis of whether the proposed rule may impose more than minor costs on businesses in the industry.

Based on the minor cost thresholds and the summary of costs identified above, the department and board assume that the proposed rules will impose more than minor costs on the businesses in the industry.

Determination of whether the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Based on the minor cost thresholds and the summary of costs identified above, the department and board assume that the proposed rules will have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest required to comply with the proposed rules.

The following steps were taken to reduce the costs of the rule on small businesses. If the costs could not be reduced, an explanation of why was provided.

Electronic Laboratory Reporting (ELR)

Alternative 1: Mandatory Electronic Laboratory Reporting using HL7 Messaging with Mitigating Measures for Small Laboratories
The board and department considered mandating laboratory submission of test results using HL7 messaging, and including mitigating measures for small laboratories that allow those businesses to submit results using a less costly method. The benefit of this approach is that it would move a majority of the reporting to HL7 messaging, which would improve timelines of reporting and reduce the burden on Local Health Jurisdictions and the department, freeing up limited public health resources to promote public health. This approach would simultaneously mitigate the costs for small laboratories that do not have capacity to acquire and maintain a costly HL7 system.

However, there are a number of barriers to using this approach. This alternative would require the board and department to define a small laboratory based on income or number of employees. This is not necessarily a proxy for the number of notifiable conditions a laboratory reports each year, so this approach could require a laboratory to invest in an expensive ELR system even if they only submit a small number of notifiable conditions each year. In addition, some laboratories are part of hospitals which have a large number of employees, but the board and department heard from the TAC that this does not mean that the laboratory itself has a large staff or operating budget. Using the number of notifiable conditions reported each year as a way to define small laboratories versus large laboratories would be an inaccurate measure of a laboratory's budget and their ability to absorb the costs of mandatory HL7 as a small lab could report a large number of cases each year. Using number of case reports to define laboratory size is not only inaccurate and unenforceable (because the decentralized reporting system in Washington State makes it challenging to track how many cases are submitted by any one laboratory to determine if they meet the definition of a large business), but also creates a potential incentive for labs to underreport in order to stay below the large laboratory threshold. The fact that health care providers and others conducting Rapid Screening Tests (RST) are also laboratories under the rule further complicates this alternative.

Alternative 2: Mandatory Electronic Laboratory Reporting with Three Reporting Options

In order to maintain the benefits outlined above while addressing the challenges, the board and department considered allowing all laboratories to choose reporting methods from the following options:

- Option A: HL7 according to the most recent HL7 national guidelines, or
- Option B: Department created and maintained web-submitter that would convert the data into HL7, or
- Option C (for blood lead RST results only): A Excel spreadsheet or similar electronic format allowing RST results to be submitted via secure electronic data transmission.

While this alternative would provide a less costly option for small laboratories or laboratories who report a small number of cases each year, there was no way to guarantee that the web-submitter would be operational by the time the rule went into effect. Without the web-submitter, this alternative would not have provided adequate mitigation for small businesses.

Alterative 3: Maintain the Status Quo

The status quo allows laboratories to submit case reports using HL7 or using other formats (e.g. postal service). While this would be the least burdensome alternative for laboratories, this option would not allow the public health benefits outlined above (e.g. increased timeless and accuracy of reporting) and would continue to allow hand-written case reports, which create issues with legibility and increased risk of data entry errors. This alternative does not provided the needed public health benefits.

Alternative 4: Remove Secure Facsimile, Postal Mail, and Handwritten Case Report as Options for Submitting Case Reports, but Do Not Mandate Electronic Lab Reporting Using HL7 Messaging

This option has potential to improve timeliness of notification and data accuracy for laboratory reports, particularly for those submitting RST results, (e.g., fewer legibility issues and manual data entry errors; more complete information; more usable and consistent information due to the use of department standardized tools) and to reduce the burden on Local Health Jurisdictions and the department of processing paper reports thereby freeing up limited public health resources to promote public health.

However, we learned that many laboratories who have not already moved to ELR through HL7, including the State Public Health Laboratories and those reporting using RST (such as ECEAP programs which submit large volumes of lead tests) still rely heavily on facsimile to submit case reports. The Lead Program at the department has had great success in helping Laboratories move away from facsimile toward other electronic methods of submission (e.g. secure email using a standardized spreadsheet format provided by the department) through relationship-building and technical assistance. There are opportunities to work with laboratories to help them voluntarily move away from facsimile, and to continue to pursue a web-submitter resource, before removing this frequently used reporting method through rule. The board and department determined that removing the postal mail and handwritten case reports as options at this time, but allowing the continued use of secure facsimile, was the least burdensome alternative that still created the benefits of increased timeliness and accuracy of reporting.

Description of how small businesses were involved in the development of the proposed rule.

The department and board requested participation from small business on the TAC that provided professional expertise and recommendations for revision of the Notifiable Conditions rules, Chapter 246-101 WAC. In addition, the Association of Community and Migrant Health Centers and the Commission on Hispanic Affairs participated in the TAC.

The department and board also requested comments and cost estimates on the draft rules from licensed health care providers, health care facilities, and laboratories. In addition, staff contacted small laboratories and facilitates via email and phone in an effort to receive feedback on the rules, both content and cost.

Estimated number of jobs that will be created or lost as the result of compliance with the proposed rule.

The department and board estimate no jobs will be created or lost as the result of compliance with the proposed rules.

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

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Address: PO Box 47811 Olympia WA 98504-7811

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Other:

Date: 06/15/2020

Name: Michelle A. Davis and Jessica Todorovich for John

Wiesman, DrPH, MPH

Title: State Board of Health Executive Director and Chief of

Staff for Secretary of Health

Signature:

Mishelle A Lavis

PART I: GENERAL PROVISIONS

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

- WAC 246-101-005 Purpose ((of notifiable conditions reporting)) and scope. (1) The purpose of ((notifiable conditions reporting))
 this chapter is to provide ((the information necessary for public health officials to protect the public's health by tracking communicable diseases and other conditions. These data are critical to local health departments and the departments of health and labor and industries in their efforts to prevent and control the spread of diseases and other conditions. Public health officials take steps to protect the public, based on these notifications. Treating persons already ill, providing preventive therapies for individuals who came into contact with infectious agents, investigating and halting outbreaks, and removing harmful health exposures are key ways public health officials protect the public. Public health workers also use these data to assess broader patterns, including historical trends and geographic clustering. By analyzing the broader picture, officials are able to take appropriate actions, including outbreak investigation, redirection of program activities, or policy development)) critical information to public health authorities to aid them in protecting and improving the public's health through prevention and control of infectious and noninfectious conditions. Public health authorities use the information gathered under this chapter to take appropriate action including, but not limited to:
 - (a) Treating ill persons;
- (b) Providing preventive therapies for individuals who came into contact with infectious agents;
 - (c) Investigating and halting outbreaks;
 - (d) Removing harmful health exposures from the environment;
- (e) Assessing broader health-related patterns, including historical trends, geographic clustering, and risk factors; and
- (f) Redirecting program activities and developing policies based on broader health-related patterns.
- (2) This chapter establishes notification requirements and standards for conditions that pose a threat to public health consistent with the purpose as established in this section.

AMENDATORY SECTION (Amending WSR 14-11-009, filed 5/8/14, effective 6/8/14)

WAC 246-101-010 Definitions ((within the notifiable conditions regulations)), abbreviations, and acronyms. The ((following)) definitions, abbreviations, and acronyms in this section apply ((in the in-

[1] OTS-1363.6

terpretation and enforcement of)) throughout this chapter unless the context clearly requires otherwise:

- (1) "Animal case" means an animal, alive or dead, with a diagnosis or suspected diagnosis of a notifiable condition in Table Agriculture-1 of WAC 246-101-805 made by a veterinarian licensed under chapter 18.92 RCW, veterinary medical facility licensed under chapter 18.92 RCW, or veterinary laboratory as defined under chapter 16.70 RCW based on clinical criteria, or laboratory criteria, or both.
- (2) "Associated death" means a death resulting directly or indirectly from ((the confirmed condition of influenza or varicella. There should be)) a confirmed case of the specified condition, with no period of complete recovery between the ((illness)) onset of the condition and death.
- $((\frac{(2)}{(2)}))$ "Blood lead level" means a measurement of lead content in whole blood.
- $((\frac{3}{(3)}))$ <u>(4)</u> "Board" means the Washington state board of health. $((\frac{4}{(4)}))$ <u>(5)</u> "Business day" means any day that the department is open for business.
- (6) "Carrier" means a person harboring a specific infectious agent without developing symptoms and serving as a potential source of infection to others.
- $((\frac{(5)}{(5)}))$ <u>(7)</u> "Case" means a person, alive or dead, $((\frac{\text{diagnosed}}{(5)}))$ with a ((particular disease or)) diagnosis or suspected diagnosis of a condition <u>made</u> by a health care provider ((with diagnosis)), health care facility, or laboratory based on clinical criteria, or laboratory criteria, or both, such as the Centers for Disease Control and Prevention, National Notifiable Diseases Surveillance System, Council of State and Territorial Epidemiologists case definitions.
- (((6) "Child day care facility" means an agency regularly providing care for a group of children for less than twenty-four hours a day and subject to licensing under chapter 74.15 RCW.
- (7) "Condition notifiable within three business days" means a notifiable condition that must be reported to the local health officer or the department within three business days following date of diagnosis. For example, if a condition notifiable within three business days is diagnosed on a Friday afternoon, the report must be submitted by the following Wednesday.))
- "Communicable disease" means ((a)) an infectious disease ((caused by an infectious agent)) that can be transmitted from ((one)) <u>a</u> person, animal, or object to ((another)) <u>a</u> person by direct or indirect means including, but not limited to, transmission through an intermediate host or vector, food, water, or air.
- (9) (("Contact" means a person exposed to an infected person, animal, or contaminated environment that may lead to infection.
- (10))) "Condition" means an infectious or noninfectious condition as these terms are defined in this chapter.
- (10) "Department" or "DOH" means the Washington state department of health.
- (11) (("Disease of suspected bioterrorism origin" means a disease caused by viruses, bacteria, fungi, or toxins from living organisms that are used to produce death or disease in humans, animals, or plants. Many of these diseases may have nonspecific presenting symptoms. The following situations could represent a possible bioterrorism event and should be reported immediately to the local health department:

[2] OTS-1363.6

- (a) A single diagnosed or strongly suspected case of disease caused by an uncommon agent or a potential agent of bioterrorism occurring in a patient with no known risk factors;
- (b) A cluster of patients presenting with a similar syndrome that includes unusual disease characteristics or unusually high morbidity or mortality without obvious etiology; or
- (c) Unexplained increase in a common syndrome above seasonally expected levels.
- (12) "Elevated blood lead level" means blood lead levels equal to or greater than 10 micrograms per deciliter for persons aged fifteen years or older, or equal to or greater than 5 micrograms per deciliter in children less than fifteen years of age.
- (13) "Emerging condition with outbreak potential" means a newly identified condition with potential for person-to-person transmission.
- (14) "Food service establishment" means a place, location, operation, site, or facility where food is manufactured, prepared, processed, packaged, dispensed, distributed, sold, served, or offered to the consumer regardless of whether or not compensation for food occurs.
- (15)) "Health care-associated infection" means an infection acquired <u>from contaminated products</u>, <u>devices</u>, <u>or food products</u> in a health care facility.
 - $((\frac{(16)}{(16)}))$ <u>(12)</u> "Health care facility" means:
- (a) Any assisted living facility licensed under chapter 18.20 RCW; birthing center licensed under chapter 18.46 RCW; nursing home licensed under chapter 18.51 RCW; hospital licensed under chapter 70.41 RCW; adult family home licensed under chapter 70.128 RCW; ambulatory surgical facility licensed under chapter 70.230 RCW; or private establishment licensed under chapter 71.12 RCW;
- (c) In reference to a sexually transmitted ($(\frac{\text{disease}}{\text{other settings}})$ infection, other settings as defined in chapter 70.24 RCW.
- (((17))) (13) "Health care provider" means any person having direct or supervisory responsibility for the delivery of health care whose scope of practice allows for diagnosis and treatment of notifiable conditions and who is:
 - (a) Licensed or certified in this state under Title 18 RCW; or
- (b) Military personnel providing health care within the state regardless of licensure.
- ((18) "Health care services to the patient" means treatment, consultation, or intervention for patient care.
- (19) "Health carrier" means a disability insurer regulated under chapter 48.20 or 48.21 RCW, a health care service contractor as defined in RCW 48.44.010, or a health maintenance organization as defined in RCW 48.46.020.
- (20) "HIV testing" means conducting a laboratory test or sequence of tests to detect the human immunodeficiency virus (HIV) or antibodies to HIV performed in accordance with requirements to WAC 246-100-207. To assure that the protection, including, but not limited to, pre- and post-test counseling, consent, and confidentiality afforded to HIV testing as described in chapter 246-100 WAC also applies to the enumeration of CD4 + (T4) lymphocyte counts (CD4 + counts) and CD4 + (T4) percents of total lymphocytes (CD4 + percents) when used to diagnose HIV infection, CD4 + counts and CD4 + percents will be presumed HIV testing except when shown by clear and convincing evidence to be for use in the following circumstances:

[3] OTS-1363.6

- (a) Monitoring previously diagnosed infection with HIV;
- (b) Monitoring organ or bone marrow transplants;
- (c) Monitoring chemotherapy;
- (d) Medical research; or
- (e) Diagnosis or monitoring of congenital immunodeficiency states or autoimmune states not related to HIV.

The burden of proving the existence of one or more of the circumstances identified in (a) through (e) of this subsection shall be on the person asserting the existence.

- (21))) (14) "Immediately ((notifiable condition))" means ((a notifiable condition of urgent public health importance, a case or suspected case of which must be reported to the local health officer or the department)) without delay, twenty-four hours a day, seven days a week.
- (a) For health care providers and health care facilities, immediately means at the time ((of diagnosis or suspected diagnosis, twenty-four hours a day, seven days a week)) a case is identified;
- (b) For laboratories, immediately means upon receiving a presumptive or final test result; or
- (c) For state agencies and local health jurisdictions, immediately means upon receiving notification of a case.
- (((22))) (15) "Infection control measures" means the management of <u>an</u> infected person((s)), or of a person suspected to be infected, and others in a manner to prevent transmission of the infectious agent. Infection control measures include, but are not limited to, isolation and quarantine.
- (16) "Infectious condition" means a disease caused by a pathogenic organism such as bacteria, virus, fungus, or parasite, and includes communicable disease and zoonotic disease.
- (17) "Influenza, novel" or "influenza virus, novel" means a human infection with an influenza A virus subtype that is different from currently circulating human influenza subtypes. Novel subtypes include, but are not limited to, H2, H5, H7, and H9 subtypes.
- ((23)) (18) "Institutional review board" ((means any board, committee, or other group formally designated by an institution, or authorized under federal or state law, to review, approve the initiation of, or conduct periodic review of research programs to assure the protection of the rights and welfare of human research subjects)) <u>has the same meaning</u> as defined in RCW 70.02.010.
- ((\(\frac{(24)}{)}\)) (19) "Isolation" means the separation ((\(\frac{\text{or}}{\text{restriction}}\)) of infected individuals, or of persons suspected to be infected, from other persons to prevent transmission of the infectious agent)) of infected or contaminated persons or animals from others to prevent or limit the transmission of the infectious agent or contaminant from those infected or contaminated to those who are susceptible to disease or who may spread the infectious agent or contaminant to others.
- $((\frac{(25)}{)}))$ (20) "Laboratory" means any facility licensed as a <u>test site or</u> medical test site under chapter 70.42 RCW and chapter 246-338 WAC, including any laboratory that is granted a Clinical Laboratory Improvement Amendment (CLIA)-Waiver.
- $((\frac{(26)}{)})$ $\underline{(21)}$ "Laboratory director" means the $(\frac{director\ or\ man-ager,}{ager,})$) person, or person's designee, by whatever title known, having the administrative responsibility $(\frac{(in\ any\ licensed\ medical\ test\ site}))$ for a laboratory.
- (((27))) <u>(22)</u> "Local health ((department" means the city, town, county, or district agency providing public health services to persons

[4] OTS-1363.6

within the area, established under chapters 70.05, 70.08, and 70.46 RCW)) jurisdiction" or "LHJ" means a county health department under chapter 70.05 RCW, city-county health department under chapter 70.08 RCW, or health district under chapter 70.46 RCW.

- $((\frac{(28)}{)}))$ $\underline{(23)}$ "Local health officer" means the $((\frac{individual\ hav-ing\ been\ appointed\ under\ chapter\ 70.05\ RCW\ as\ the\ health\ officer\ for\ the\ local\ health\ department,\ or\ having\ been\ appointed\ under\ chapter\ 70.08\ RCW\ as\ the\ director\ of\ public\ health\ of\ a\ combined\ city-county\ health\ department.$
- (29) "Member of the general public" means any person present within the boundary of the state of Washington.
- (30) "Monthly notifiable condition" means a notifiable condition which must be reported to the local health officer or the department within one month of diagnosis.
- (31)) legally qualified physician who has been appointed as the health officer for the local health jurisdiction under chapter 70.05 RCW, or their designee.
 - (24) "MERS" means Middle East respiratory syndrome.
- (25) "Noninfectious condition" means a disease or health concern caused by nonpathogenic factors.

 (26) "Notifiable condition" means a ((disease or)) condition ((of))
- (26) "Notifiable condition" means a ((disease or)) condition ((of public health importance)) identified in Table HC-1 of WAC 246-101-101, Table Lab-1 of WAC 246-101-201, and Table Agriculture-1 of WAC 246-101-805, or designated by the local health officer as notifiable under chapter 70.05 RCW, a case of which((, and for certain diseases, a suspected case of which, must be brought to the attention of the local health officer or the state health officer.
- (32) "Other rare diseases of public health significance" means a disease or condition, of general or international public health concern, which is occasionally or not ordinarily seen in the state of Washington including, but not limited to, spotted fever rickettsiosis, babesiosis, tick paralysis, anaplasmosis, and other tick borne diseases. This also includes public health events of international concern and communicable diseases that would be of general public concern if detected in Washington.
- (33))) requires notification to public health authorities under this chapter; or a condition designated by the local health officer as notifiable under chapter 70.05 RCW. Notifiable condition does not include provisional conditions as defined under WAC 246-101-015.
- (27) "Outbreak" means the occurrence ((of cases or suspected cases)) of a ((disease or)) condition in ((any)) an area over a given period of time in excess of the expected number of ((cases)) occurrences including, but not limited to, foodborne disease, waterborne disease, and health care-associated infection.
 - ((34) "Patient" means a case, suspected case, or contact.
- $\overline{(35)}$)) $\underline{(28)}$ "Pesticide poisoning" means the disturbance of function, damage to structure, or illness in humans resulting from the inhalation, absorption, ingestion of, or contact with any pesticide.
- (((36))) (29) "Presumptive" means a preliminary test result that has not yet been confirmed as a definitive result.
- (30) "Principal health care provider" means the attending health care provider recognized as primarily responsible for diagnosis or treatment of a patient, or in the absence of such, the health care provider initiating diagnostic testing or treatment for the patient.
- (((37))) (31) "Provisional condition" means a condition the department has requested be reported under WAC 246-101-105.

[5] OTS-1363.6

- (32) "Public health authorities" ((means)) includes local health ((departments)) jurisdictions, the ((state health)) department, ((and)) the department of labor and industries ((personnel charged with administering provisions of this chapter.
- (38))), the department of agriculture, sovereign tribal nations, and tribal epidemiology centers.
- (33) "Quarantine" means the ((separation or restriction on activities of an individual having been exposed to or infected with an infectious agent, to prevent disease transmission.
- (39)) limitation of freedom of movement of persons or domestic animals that have been exposed to, or are suspected to have been exposed to, an infectious agent:
- (a) For a period of time not longer than the longest usual incubation period of the infectious agent; and
 - (b) In a way to prevent effective contact with those not exposed.
- (34) "Rapid screening test" or "RST" means a U.S. Food and Drug Administration-approved test that provides same day results and is suitable for obtaining presumptive test results. RST includes point-of-care testing.
- (35) "Reference laboratory" means a laboratory licensed inside or outside of Washington state that receives a specimen from another licensed laboratory and performs one or more tests on that specimen.
- $\underline{\text{(36)}}$ "School" ((means a facility for programs of education as defined)) has the same meaning as in RCW 28A.210.070 (($\frac{\text{(preschool and kindergarten through grade twelve)}})).$
 - (((40))) <u>(37) "SARS" means severe acute respiratory syndrome.</u>
- (38) "Secretary" means the secretary of the Washington state department of health.
- (39) "Secure electronic data transmission" means electronic communication and accounts developed and maintained to prevent unauthorized access, loss, or compromise of sensitive information including, but not limited to, secure file transfer, secure email, secure facsimile, a health information exchange authorized under RCW 41.05.039, and secure electronic disease surveillance system.
- (40) "Secure electronic disease surveillance system" means the secure electronic data transmission system maintained by the department and used by local health jurisdictions to submit notifications, case reports, and outbreak reports under this chapter.
- (41) "Sexually transmitted disease (((STD)))" or "sexually transmitted infection" means a bacterial, viral, fungal, or parasitic disease or condition which is usually transmitted through sexual contact, including:
 - (a) Acute pelvic inflammatory disease;
 - (b) Chancroid;
 - (c) Chlamydia trachomatis infection;
 - (d) Genital and neonatal Herpes simplex;
 - (e) Genital human papilloma virus infection;
 - (f) Gonorrhea;
 - (q) Granuloma inquinale;
 - (h) Hepatitis B infection;
- (i) Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS);
 - (j) Lymphogranuloma venereum;
 - (k) Nongonococcal urethritis (NGU); and
 - (1) Syphilis.
- ((41))) <u>(42) "Specimen" means material associated or suspected</u> to be associated with a notifiable condition including, but not limi-

[6] OTS-1363.6

- ted to, isolates, blood, serum, stool, urine, tissue, respiratory secretions, swab, other body fluid, or an environmental sample.
- (43) "State health officer" means the person ((designated)) appointed by the secretary ((of the department)) under RCW 43.70.020 to serve as statewide health officer((, or, in the absence of this designation, the person having primary responsibility for public health matters in the state.
- (42) "Suspected case" means a person whose diagnosis is thought likely to be a particular disease or condition with suspected diagnosis based on signs and symptoms, laboratory evidence, or both.
- (43) "Third-party payor" means an insurer regulated under Title 48 RCW authorized to transact business in this state or other jurisdiction including a health care service contractor and health maintenance organization, an employee welfare benefit plan, or a state or federal health benefit program as defined in RCW 70.02.010.
- (44) "Unexplained critical illness or death" means cases of illness or death with infectious hallmarks but no known etiology, in previously healthy persons one to forty-nine years of age excluding those with chronic medical conditions (e.g., malignancy, diabetes, AIDS, cirrhosis))).
- $((\frac{45}{}))$ <u>(44)</u> "Veterinarian" means an individual licensed and practicing under provisions of chapter 18.92 RCW(($\frac{1}{}$ Veterinary medicine, surgery, and dentistry)).
- (45) "Zoonotic disease" means an infectious condition of animals that can cause disease when transmitted to humans.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-015 Provisional ((condition)) notification and submission of specimen. ((This section describes how conditions can become notifiable; what period of time conditions are provisionally notifiable; what analyses must be accomplished during provisional notification status; the transition from provisionally notifiable condition to permanently notifiable condition or deletion of notification requirements. The department's goal for provisionally notifiable conditions is to collect enough information to determine whether requiring notification improves public health.

- (1) The state health officer may:
- (a) Request reporting of cases and suspected cases of disease and conditions in addition to those required in Tables HC-1 of WAC 246-101-101, Lab-1 of WAC 246-101-201, and HF-1 of WAC 246-101-301 on a provisional basis for a period of time less than forty-eight months when:
- (i) The disease or condition is newly recognized or recently acknowledged as a public health concern;
- (ii) Epidemiological investigation based on notification of cases may contribute to understanding of the disease or condition;
- (iii) There is reason to expect that the information acquired through notification will assist the state and/or local health department to design or implement intervention strategies that will result in an improvement in public health; and
- (iv) Written notification is provided to all local health officers regarding:

[7] OTS-1363.6

- (A) Additional reporting requirements; and
- (B) Rationale or justification for specifying the disease or condition as notifiable.
- (b) Request laboratories to submit specimens indicative of infections in addition to those required in Table Lab-1 of WAC 246-101-201 on a provisional basis for a period of time less than forty-eight months, if:
 - (i) The infection is of public health concern;
- (ii) The department has a plan for using data gathered from the specimens; and
- (iii) Written notification is provided to all local health officers and all laboratory directors explaining:
 - (A) Actions required; and
 - (B) Reason for the addition.
- (2) Within forty months of the state health officer's designation of a condition as provisionally notifiable in subsection (1)(a) of this section, or requests for laboratories to submit specimens indicative of infections in subsection (1)(b) of this section, the department will conduct an evaluation for the notification requirement that:
- (a) Estimates the societal cost resulting from the provisionally notifiable condition;
- (i) Determine the prevalence of the provisional notifiable condition; and
- (ii) Identify the quantifiable costs resulting from the provisionally notifiable condition; and
- (iii) Discuss the qualitative costs resulting from the provisionally notifiable condition.
- (b) Describes how the information was used and how it will continue to be used to design and implement intervention strategies aimed at combating the provisionally notifiable condition;
- (c) Verifies the effectiveness of previous intervention strategies at reducing the incidence, morbidity, or mortality of the provisional notifiable condition;
- (d) Identifies the quantitative and qualitative costs of the provisional notification requirement;
- (e) Compares the costs of the provisional notification requirement with the estimated cost savings resulting from the intervention based on the information provided through the provisional notification requirement;
- (f) Describes the effectiveness and utility of using the notifiable conditions process as a mechanism to collect these data; and
- (g) Describes that a less burdensome data collection system (example: Biennial surveys) would not provide the information needed to effectively establish and maintain the intervention strategies.
- (3) Based upon the evaluation in subsection (2) of this section, the board will assess results of the evaluation after the particular condition is notifiable or the requirement for laboratories to submit specimens indicative of infections has been in place for no longer than forty months. The board will determine based upon the results of the evaluation whether the provisionally notifiable condition or the requirement for laboratories to submit specimens indicative of infections should be:
- (a) Permanently notifiable in the same manner as the provisional notification requirement;
- (b) Permanently notifiable in a manner that would use the evaluation results to redesign the notification requirements; or
 - (c) Deleted from the notifiable conditions system.

[8] OTS-1363.6

- (4) The department shall have the authority to declare an emergency and institute notification requirements under the provisions of RCW 34.05.350.)) (1) The state health officer may request additional notification, submission of laboratory test results, or submission of specimens for notifiable conditions.
- (2) The state health officer may request notification, submission of laboratory test results, and submission of specimens for a condition they determine should be provisionally reported.
- (3) The state health officer may request information under subsection (1) of this section when they:
- (a) Determine additional information in case reports or additional submission of specimens for a notifiable condition is needed in order to properly prevent and control the condition; and
- (b) Determine that provisional notification or submission of laboratory test results or specimens for a condition other than a notifiable condition is likely to contribute to understanding the condition, provide information necessary to prevent and control the condition, and improve public health.
- (4) The state health officer shall notify the board, local health officers, health care providers, laboratory directors, health care facilities, and the department of agriculture of the request, as applicable. The notification must include the:
- (a) Determination required under subsection (3) of this section including documentation supporting the determination; and
 - (b) As applicable, the requested:
 - (i) Test results;
 - (ii) Timeline for notification;
 - (iii) Public health authority to be notified;
 - (iv) Content of notification;
 - (v) Means of notification;
 - (vi) Specimen submission;
 - (vii) Timeline for specimen submission; and
 - (viii) Specimen submittal documentation for the condition.
- (5) Within forty months of the state health officer's designation of a provisional condition or additional information for a notifiable condition, the state health officer shall:
- (a) Discontinue notification, submission of laboratory test results, or submission of specimens for the condition; or
- (b) Request that the board consider revising this chapter to require notification, submission of laboratory tests, and submission of specimens for the condition and provide an estimate of the probable benefits and probable costs.
- (6) If the state health officer chooses to discontinue notification, submission of laboratory test results, or submission of specimens for the condition, the state health officer shall notify the board, local health officers, health care providers, laboratory directors, health care facilities, and the department of agriculture that the applicable provisional condition or requested changes to the notifiable condition has been discontinued.
- (7) If the board directs the state health officer to discontinue notification, submission of laboratory test results, or submission of specimens for the condition, the state health officer shall notify local health officers, health care providers, laboratory directors, health care facilities, and the department of agriculture that the applicable provisional condition or requested changes to the notifiable condition has been discontinued.

[9] OTS-1363.6

PART II: NOTIFIABLE CONDITIONS—HEALTH CARE PROVIDERS AND HEALTH CARE FACILITIES

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-101 Notifiable conditions ((and the))—Health care providers and health care facilities. ((This section describes the conditions that Washington's health care providers must notify public health authorities of on a statewide basis. The board finds that the conditions in Table HC-1 of this section are notifiable for the prevention and control of communicable and noninfectious diseases and conditions in Washington.

(1) Principal health care providers shall notify public health authorities of the conditions identified in Table HC-1 of this section as individual case reports following the requirements in WAC 246-101-105, 246-101-110, 246-101-115, and 246-101-120.

(2) Other health care providers in attendance, other than the principal health care provider, shall notify public health authorities of the conditions identified in Table HC-1 of this section unless the condition notification has already been made.

(3) Local health officers may require additional conditions to be notifiable within the local health officer's jurisdiction.

Table HC-1 (Conditions Notifiable by Health Care Providers)

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to State Department of Health
Acquired Immunodeficiency Syndrome (AIDS)	Within 3 business days	4	
Animal Bites (when human exposure to rabies is suspected)	Immediately	4	
Anthrax	Immediately	√	
Arboviral Disease (acute disease only including, but not limited to, West Nile virus, eastern and western equine encephalitis, dengue, St. Louis encephalitis, La Crosse encephalitis, Japanese encephalitis, and Powassan)	Within 3 business days	4	
Asthma, occupational	Monthly		√
Birth Defects - Autism Spectrum Disorders	Monthly		→
Birth Defects - Cerebral Palsy	Monthly		→
Birth Defects - Alcohol Related Birth Defects	Monthly		√
Botulism (foodborne, infant, and wound)	Immediately	√	
Brucellosis (Brucella species)	Within 24 hours	√	
Burkholderia mallei (Glanders) and pseudomallei (Melioidosis)	Immediately	4	
Campylobacteriosis	Within 3 business days	\	

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to State Department of Health
Chancroid	Within 3 business days	4	
Chlamydia trachomatis infection	Within 3 business days	4	
Cholera	Immediately	√	
Cryptosporidiosis	Within 3 business days	4	
Cyclosporiasis	Within 3 business days	4	
Diphtheria	Immediately	√	
Disease of suspected bioterrorism origin	Immediately	√	
Domoic acid poisoning	Immediately	4	
E. coli - Refer to "Shiga toxin-producing E. coli"	Immediately	√	
Emerging condition with outbreak potential	Immediately	√	
Giardiasis	Within 3 business days	4	
Gonorrhea	Within 3 business days	4	
Granuloma inguinale	Within 3 business days	4	
Haemophilus influenzae (invasive disease, ehildren under age 5)	Immediately	4	
Hantavirus pulmonary syndrome	Within 24 hours	√	
Hepatitis A (acute infection)	Within 24 hours	√	
Hepatitis B (acute infection)	Within 24 hours	4	
Hepatitis B surface antigen + pregnant women	Within 3 business days	4	
Hepatitis B (chronic infection) - Initial diagnosis, and previously unreported prevalent cases	Monthly	4	
Hepatitis C (acute infection)	Within 3 business days	4	
Hepatitis C (chronic infection)	Monthly	√	
Hepatitis D (acute and chronic infection)	Within 3 business days	4	
Hepatitis E (acute infection)	Within 24 hours	√	
Herpes simplex, neonatal and genital (initial infection only)	Within 3 business days	4	
Human immunodeficiency virus (HIV) infection	Within 3 business days	4	
Influenza, novel or unsubtypable strain	Immediately	4	
Influenza-associated death (lab confirmed)	Within 3 business days	4	
Legionellosis	Within 24 hours	4	
Leptospirosis	Within 24 hours	→	
Listeriosis	Within 24 hours	₹	
Lyme Disease	Within 3 business days	4	
Lymphogranuloma venereum	Within 3 business days	4	

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to State Department of Health
Malaria	Within 3 business days	4	
Measles (rubeola) - Acute disease only	Immediately	4	
Meningococcal disease (invasive)	Immediately	√	
Monkeypox	Immediately	√	
Mumps (acute disease only)	Within 24 hours	→	
Outbreaks of suspected foodborne origin	Immediately	√	
Outbreaks of suspected waterborne origin	Immediately	√	
Paralytic shellfish poisoning	Immediately	₹	
Pertussis	Within 24 hours	√	
Pesticide poisoning (hospitalized, fatal, or cluster)	Immediately		√
Pesticide poisoning (all other)	Within 3 business days		4
Plague	Immediately	√	
Poliomyelitis	Immediately	₹	
Prion disease	Within 3 business days	4	
Psittacosis	Within 24 hours	¥	
Q Fever	Within 24 hours	→	
Rabies (Confirmed Human or Animal)	Immediately	√	
Rabies, suspected human exposure (suspected human rabies exposures due to a bite from or other exposure to an animal that is suspected of being infected with rabies)	Immediately	4	
Relapsing fever (borreliosis)	Within 24 hours	→	
Rubella (including congenital rubella syndrome) (acute disease only)	Immediately	4	
Salmonellosis	Within 24 hours	√	
SARS	Immediately	√	
Serious adverse reactions to immunizations	Within 3 business days	4	
Shiga toxin-producing <i>E. coli</i> infections (enterohemorrhagie <i>E. coli</i> including, but not limited to, <i>E. coli</i> O157:H7)	Immediately	4	
Shigellosis	Within 24 hours	√	
Smallpox	Immediately	4	
Syphilis	Within 3 business days	4	
Tetanus	Within 3 business days	4	
Trichinosis	Within 3 business days	4	
Tuberculosis	Immediately	→	
Tularemia	Immediately	4	
Vaccinia transmission	Immediately	₹	
Vancomycin-resistant Staphylococcus aureus (not to include vancomycin-intermediate)	Within 24 hours	4	
Varicella-associated death	Within 3 business days	4	

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to State Department of Health
Vibriosis	Within 24 hours	√	
Viral hemorrhagic fever	Immediately	√	
Yellow fever	Immediately	√	
Yersiniosis	Within 24 hours	√	
Other rare diseases of public health significance	Within 24 hours	√	
Unexplained critical illness or death	Within 24 hours	√	

($\sqrt{\ }$) Indicates which agency should receive case and suspected case reports.))

- (1) For the purposes of this section:
- (a) "Local health jurisdiction" means where the patient resides, or, in the event the patient residence cannot be determined, the local health jurisdiction in which the patient received treatment.
- (b) "Unexplained critical illness or death" means a severe illness or death with infectious hallmarks, but no known etiology, in a previously healthy person one to forty-nine years of age excluding those with chronic medical conditions such as malignancy, diabetes, AIDS, or cirrhosis.
- (2) The conditions identified in Table HC-1 are notifiable to public health authorities under this table and this chapter.

<u>Table HC-1 (Conditions Notifiable by Health Care Providers and Health Care Facilities)</u>

Notifiable Condition (Agent)	Laboratory Confirmation Required Before Submitting Case Report	Time Frame for Notification from Identification of a Case	Who Must Be Notified	Who Must Report: Health Care Providers (Providers) or Health Care Facilities (Facilities)
Acquired immunodeficiency syndrome (AIDS)		Within 3 business days	DOH (for facilities) and LHJ (for providers)	<u>Both</u>
Amoebic meningitis		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
<u>Anaplasmosis</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Anthrax (Bacillus anthracis and confirmed Bacillus cereus biovar anthracis only - Do not report all Bacillus cereus)	Yes	<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Arboviral disease (acute disease only) including, but not limited to: Chikungunya Dengue Eastern and western equine encephalitis Japanese encephalitis La Crosse encephalitis Powassan virus infection St. Louis encephalitis West Nile virus infection Zika virus infection See also "Yellow fever"		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Asthma, occupational		Within 30 days	Washington state department of labor and industries (L&I)	<u>Both</u>

Notifiable Condition (Agent)	Laboratory Confirmation Required Before Submitting Case Report	Time Frame for Notification from Identification of a Case	Who Must Be Notified	Who Must Report: Health Care Providers (Providers) or Health Care Facilities (Facilities)
Babesiosis		Within 3 business days	<u>LHJ</u>	<u>Both</u>
<u>Baylisascariasis</u>		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Birth defects - Abdominal wall defects (inclusive of gastroschisis and omphalocele)		Within 30 days	<u>LHJ</u>	<u>Facilities</u>
Birth defects - Autism spectrum disorders		Within 30 days	<u>DOH</u>	<u>Both</u>
Birth defects - Cerebral palsy		Within 30 days	<u>DOH</u>	<u>Both</u>
Birth defects - Down syndrome		Within 30 days	<u>DOH</u>	<u>Facilities</u>
Birth defects - Alcohol related birth defects		Within 30 days	<u>DOH</u>	<u>Both</u>
Birth defects - Hypospadias		Within 30 days	<u>DOH</u>	<u>Facilities</u>
Birth defects - Limb reductions		Within 30 days	<u>DOH</u>	<u>Facilities</u>
Birth defects - Neural tube defects (inclusive of anencephaly and spina bifida)		Within 30 days	<u>DOH</u>	<u>Facilities</u>
Birth defects - Oral clefts (inclusive of cleft lip with/without cleft palate)		Within 30 days	<u>DOH</u>	<u>Facilities</u>
Blood lead level			ties performing blood l	
RST results (See WAC 246-101-200)		report as a laboratory	y and comply with the r 01-201 through 246-10	1-230.
Botulism, foodborne, infant, and wound		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Brucellosis		Within 24 hours	<u>LHJ</u>	<u>Both</u>
<u>Campylobacteriosis</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Cancer (See chapter 246-102 WAC)				
<u>Candida auris</u> infection or <u>colonization</u>		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Carbapenem-resistant Enterobacteriaceae infections limited to: Klebsiella species E. coli Enterobacter species	Yes	Within 3 business days	<u>LHJ</u>	<u>Both</u>
Chagas disease		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Chancroid		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Chlamydia trachomatis infection	Yes	Within 3 business days	<u>LHJ</u>	Both
Cholera (Vibrio cholerae O1 or O139)	Yes	Immediately	<u>LHJ</u>	<u>Both</u>
Coccidioidomycosis		Within 3 business days	<u>LHJ</u>	<u>Both</u>

	Laboratory Confirmation Required Before Submitting	Time Frame for Notification from Identification of a	Who Must Be	Who Must Report: Health Care Providers (Providers) or Health Care Facilities
Notifiable Condition (Agent)	Case Report	Case	Notified	(Facilities)
Coronavirus infection (severe communicable) SARS-associated coronavirus MERS-associated coronavirus Novel coronavirus (COVID-19)	Yes	<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Cryptococcus gattii or undifferentiated Cryptococcus species (i.e., Cryptococcus not identified as C. neoformans)	Yes	Within 3 business days	<u>LHJ</u>	<u>Both</u>
Cryptosporidiosis		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Cyclosporiasis		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Cysticercosis		Within 3 business days	<u>LHJ</u>	<u>Both</u>
<u>Diphtheria</u>		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Domoic acid poisoning		Immediately	<u>LHJ</u>	<u>Both</u>
E. coli (See "Shiga toxin-producing E. coli")				
Echinococcosis		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Ehrlichiosis		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Giardiasis		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Glanders (Burkholderia mallei)	<u>Yes</u>	Immediately	<u>LHJ</u>	<u>Both</u>
Gonorrhea		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Granuloma inguinale		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Gunshot wounds (nonfatal)		Within 30 days	<u>DOH</u>	<u>Facilities</u>
Haemophilus influenzae (invasive disease, children under 5 years of age)	Yes	<u>Immediately</u>	<u>LHJ</u>	Both
Hantaviral infection		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Hepatitis A (acute infection)	<u>Yes</u>	Within 24 hours	<u>LHJ</u>	<u>Both</u>
Hepatitis B (acute infection)	<u>Yes</u>	Within 24 hours	<u>LHJ</u>	<u>Both</u>
Hepatitis B, report pregnancy in hepatitis B virus infected patients (including carriers)	Yes	Within 3 business days	<u>LHJ</u>	Both
Hepatitis B (chronic infection) - Initial diagnosis, and previously unreported prevalent cases	Yes	Within 3 business days	<u>LHJ</u>	Both
Hepatitis B (perinatal) - Initial diagnosis, and previously unreported cases	Yes	Within 3 business days	<u>LHJ</u>	Both
Hepatitis C (acute infection)	<u>Yes</u>	Within 24 hours	<u>LHJ</u>	<u>Both</u>
Hepatitis C (acute infection) RTS results (See WAC 246-101-200)		RST shall report	ies performing hepatiti rt as a laboratory and c VAC 246-101-201 thro	omply with the

Notifiable Condition (Agent)	Laboratory Confirmation Required Before Submitting Case Report	Time Frame for Notification from Identification of a Case	Who Must Be Notified	Who Must Report: Health Care Providers (Providers) or Health Care Facilities (Facilities)
Hepatitis C (chronic infection)	Yes	Within 3 business days	<u>LHJ</u>	<u>Both</u>
Hepatitis C (perinatal) - Initial diagnosis, and previously unreported cases	Yes	Within 24 hours	<u>LHJ</u>	<u>Both</u>
Hepatitis C (chronic infection) RST results (See WAC 246-101-200)		RST shall repo	es performing hepatitis ort as a laboratory and c VAC 246-101-201 thro	comply with the
Hepatitis D (acute and chronic infection)	Yes	Within 24 hours	<u>LHJ</u>	<u>Both</u>
Hepatitis E (acute infection)	Yes	Within 24 hours	<u>LHJ</u>	<u>Both</u>
Herpes simplex, neonatal and genital (initial infection only)		Within 3 business days	<u>LHJ</u>	<u>Providers</u>
<u>Histoplasmosis</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Human immunodeficiency virus (HIV) infection		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Human immunodeficiency virus (HIV) infection RST results (See WAC 246-101-200)		report as a laboratory	lities performing HIV i 7 and comply with the r 01-201 through 246-10	requirements of WAC
Human prion disease		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Hypersensitivity pneumonitis, occupational		Within 30 days	<u>L&I</u>	<u>Both</u>
Influenza, novel or unsubtypable strain		<u>Immediately</u>	LHJ	Both
Influenza-associated death (laboratory confirmed)		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Legionellosis		Within 24 hours	<u>LHJ</u>	<u>Both</u>
<u>Leptospirosis</u>		Within 24 hours	<u>LHJ</u>	<u>Both</u>
<u>Listeriosis</u>		Within 24 hours	<u>LHJ</u>	<u>Both</u>
<u>Lyme disease</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Lymphogranuloma venereum		Within 3 business days	<u>LHJ</u>	<u>Both</u>
<u>Malaria</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Measles (rubeola) - Acute disease only		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Melioidosis (Burkholderia pseudomallei)	Yes	Immediately	<u>LHJ</u>	Both
Meningococcal disease, invasive		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Monkeypox		Immediately	<u>LHJ</u>	<u>Both</u>
Mumps, acute disease only		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Outbreaks and suspected outbreaks		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Paralytic shellfish poisoning		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Pertussis		Within 24 hours	<u>LHJ</u>	<u>Both</u>

Notifiable Condition (Agent)	Laboratory Confirmation Required Before Submitting Case Report	Time Frame for Notification from Identification of a Case	Who Must Be Notified	Who Must Report: Health Care Providers (Providers) or Health Care Facilities (Facilities)
Pesticide poisoning (hospitalized, fatal, or cluster)		<u>Immediately</u>	<u>DOH</u>	<u>Both</u>
Pesticide poisoning (all other)		Within 3 business days	<u>DOH</u>	<u>Both</u>
Plague		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Poliomyelitis		Immediately	<u>LHJ</u>	<u>Both</u>
Pregnancy in patient with hepatitis B virus		See "Hepatitis B, repatitis B,	port pregnancy in hepa tients (including carrier	titis B virus infected
<u>Psittacosis</u>		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Q fever		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Rabies (confirmed human or animal)		<u>Immediately</u>	<u>LHJ</u>	Both
Rabies, suspected human exposure (suspected human rabies exposures due to a bite from or other exposure to an animal that is suspected of being infected with rabies)		Immediately	<u>LHJ</u>	<u>Both</u>
Relapsing fever (borreliosis)		Within 3 business days	<u>LHJ</u>	<u>Both</u>
<u>Rickettsia</u> infection		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Rubella, acute disease only (including congenital rubella syndrome)		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Salmonellosis		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Serious adverse reactions to immunizations		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Shiga toxin-producing <i>E. coli</i> (STEC) infections/ enterohemorrhagic <i>E. coli</i> infections	Yes	<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Shigellosis		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Silicosis		Within 30 days	<u>L&I</u>	<u>Both</u>
<u>Smallpox</u>		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Syphilis		Within 3 business days	<u>LHJ</u>	<u>Both</u>
<u>Taeniasis</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
<u>Tetanus</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
<u>Tick paralysis</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
<u>Trichinosis</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Tuberculosis disease (confirmed or highly suspicious, i.e., initiation of empiric treatment)		Within 24 hours	LHJ	Both
<u>Tularemia</u>		Immediately	<u>LHJ</u>	<u>Both</u>
<u>Typhus</u>		Within 3 business days	<u>LHJ</u>	<u>Both</u>

Notifiable Condition (Agent)	Laboratory Confirmation Required Before Submitting Case Report	Time Frame for Notification from Identification of a Case	Who Must Be Notified	Who Must Report: Health Care Providers (Providers) or Health Care Facilities (Facilities)
<u>Vaccinia transmission</u>		<u>Immediately</u>	<u>LHJ</u>	<u>Both</u>
Vancomycin-resistant Staphylococcus aureus (not to include vancomycin-intermediate)	Yes	Within 24 hours	<u>LHJ</u>	<u>Both</u>
Varicella-associated death		Within 3 business days	<u>LHJ</u>	<u>Both</u>
Vibriosis (Vibrio species not including Vibrio cholerae O1 or O139) See Cholera (Vibrio cholerae O1 or O139)	Yes	Within 24 hours	<u>LHJ</u>	<u>Both</u>
Viral hemorrhagic fever		Immediately	<u>LHJ</u>	<u>Both</u>
Yellow fever		Immediately	<u>LHJ</u>	<u>Both</u>
<u>Yersiniosis</u>		Within 24 hours	<u>LHJ</u>	<u>Both</u>
Unexplained critical illness or death		Within 24 hours	<u>LHJ</u>	<u>Both</u>

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-105 Duties ((of the))—Health care providers and health care facilities. ((Health care providers shall:

- (1) Notify the local health department where the patient resides, or, in the event that patient residence cannot be determined, the local health department in which the health care providers practice, regarding:
- (a) Cases or suspected cases of notifiable conditions specified as notifiable to local health departments in Table HC-1 of WAC 246-101-101;
- (b) Cases of conditions designated as notifiable by the local health officer within that health officer's jurisdiction;
- (c) Outbreaks or suspected outbreaks of disease including, but not limited to, suspected or confirmed outbreaks of varicella, influenza, viral meningitis, health care-associated infection suspected due to contaminated food products or devices, or environmentally related disease;
- (d) Known barriers which might impede or prevent compliance with orders for infection control or quarantine; and
- (e) Name, address, and other pertinent information for any case, suspected case or carrier refusing to comply with prescribed infection control measures.
- (2) Notify the department of conditions designated as notifiable to the local health department when:
- (a) A local health department is closed or representatives of the local health department are unavailable at the time a case or suspected case of an immediately notifiable condition occurs;

- (b) A local health department is closed or representatives of the local health department are unavailable at the time an outbreak or suspected outbreak of communicable disease occurs.
- (3) Notify the department of pesticide poisoning that is fatal, causes hospitalization or occurs in a cluster.
- (4) Notify the department regarding cases of notifiable conditions specified as notifiable to the department in Table HC-1 of WAC 246-101-101.
- (5) Assure that positive preliminary test results and positive final test results for notifiable conditions of specimens referred to laboratories outside of Washington for testing are correctly notified to the local health department of the patient's residence or the department as specified in Table Lab-1 of WAC 246-101-201. This requirement can be satisfied by:
- (a) Arranging for the referral laboratory to notify either the local health department, the department, or both; or
- (b) Forwarding the notification of)) (1) Unless a health care facility has assumed the notification duties of the principal health care provider under subsection (4) of this section, the principal health care provider shall submit individual case reports:
- (a) To the required public health authority under Table HC-1 of 246-101-101 and the requirements of WAC 246-101-110 and 246-101-115, and this section;
- (b) To the local health jurisdiction as required by the local health officer within that health officer's jurisdiction.

 (2) A health care facility shall submit individual case reports:
- (a) To the required public health authority under Table HC-1 of <u>WAC 246-101-101 and the requirements of WAC 246-101-110 and</u> 246-101-115, and this section that occur or are treated in their fa-<u>cilities.</u>
- (b) To the local health jurisdiction as required by the local
- health officer within that health officer's jurisdiction.

 (3) This section does not require a health care provider or a health care facility to confirm the absence of cases of conditions listed in Table HC-1 of WAC 246-101-101.
- (4) A health care facility may assume the notification requirements established in this chapter for a health care provider practicing within the health care facility.
- (5) A health care facility shall not assume the notification requirements established in this chapter for a laboratory that is a component of the health care facility.
 - (6) Health care providers and health care facilities shall:
- (a) Provide the laboratory with the following information for each test ordered for a notifiable condition:
 - (i) Patient's first and last name;
 - (ii) Patient's physical address including zip code;
 - (iii) Patient's date of birth;
 - (iv) Patient's sex;
 - (v) Patient's race;
 - (vi) Patient's ethnicity;
- (vii) For hepatitis B tests only, pregnancy status (pregnant/not pregnant/unknown) of patients twelve to fifty years of age only;
 - (viii) Patient's best contact telephone number;
- (ix) Patient's medicaid status, for blood lead level tests for patients less than seventy-two months of age only;
 - (x) Requesting health care provider's name;
 - (xi) Requesting health care provider's phone number;

- (xii) Address where patient received care;
- (xiii) Specimen type;
- (xiv) Specimen collection date; and
- (xv) Condition being tested for.
- (b) For specimens associated with a notifiable condition sent to a laboratory outside of Washington state, provide the laboratory with the information under (a) of this subsection, Table Lab-1 of WAC 246-101-201, and WAC 246-101-220 and 246-101-225.
- (c) If the presumptive or final test results are consistent with Table Lab-1 of WAC 246-101-201, the health care provider or health care facility shall either:
- (i) Confirm the laboratory submitted the case report consistent with WAC 246-101-220 and 246-101-225; or
- $\underline{\text{(ii) Submit}}$ the ((test result)) presumptive and final test results from the ((referral)) out-of-state laboratory ((to the local health department, the department, or both.
- (6))) with the case report according to the requirements of this chapter.
- (d) Cooperate with public health authorities during investigation of:
- $((\frac{a)}{a})$ Circumstances of a case or suspected)) $\underline{(i)}$ A case of a notifiable condition $(\frac{a}{a})$ and
 - $((\frac{b}{b}))$ <u>(ii)</u> An outbreak or suspected outbreak (($\frac{b}{b}$)).
- $((\frac{7}{}))$ (e) Maintain an infection control program as described in WAC 246-320-176 for hospitals and WAC 246-330-176 for ambulatory surgical facilities;
- $\underline{(f)}$ Provide adequate and understandable instruction in disease control measures to each patient who has been diagnosed with a case of a communicable disease, and to contacts who may have been exposed to the disease (($\frac{\cdot}{\cdot}$
- (8) Maintain responsibility for deciding date of discharge for hospitalized tuberculosis patients.
- (9) Notify the local health officer of intended discharge of tuberculosis patients in order to assure appropriate outpatient arrangements are arranged.
- (10) By July 1, 2011, when ordering a laboratory test for a notifiable condition as identified in Table HC-1 of WAC 246-101-101, providers must provide the laboratory with the following information for each test order:
 - (a) Patient name;
 - (b) Patient address including zip code;
 - (c) Patient date of birth;
 - (d) Patient sex;
 - (e) Name of the principal health care provider;
 - (f) Telephone number of the principal health care provider;
 - (g) Type of test requested;
 - (h) Type of specimen;
 - (i) Date of ordering specimen collection.)); and
 - (g) Notify the local health jurisdiction of:
- (i) Known barriers that might impede or prevent compliance with infection control measures; and
- (ii) Name, address, and other pertinent information for any case or carrier refusing to comply with infection control measures.
- (7) Health care providers and health care facilities may provide health information, demographic information, or infectious or noninfectious condition information in addition to the information required under this chapter when the provider or facility determines that the

additional information will aid the public health authority in protecting and improving the public's health through prevention and control of infectious and noninfectious conditions.

(8) When a health care provider or health care facility submits information under subsection (7) of this section, they shall submit the information under the requirements of WAC 246-101-110.

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-110 Means of notification—Health care providers and health care facilities. Health care providers ((shall adhere to the following timelines and procedures:

- (1) Conditions designated as immediately notifiable must be reported to the local health officer or the department, as specified in Table HC-1 of WAC 246-101-101, immediately as the time of diagnosis or suspected diagnosis. This applies twenty-four hours a day, seven days a week. Each local health jurisdiction, as well as the department, maintains after-hours emergency phone contacts for this purpose. A party sending a report by secure facsimile copy or secure electronic transmission during normal business hours must confirm immediate receipt by a live person.
- (2) Conditions designated as notifiable within twenty-four hours must be reported to the local health officer or the department, as specified in Table HC-1 of WAC 246-101-101, within twenty-four hours of diagnosis or suspected diagnosis, seven days a week. Reports during normal public health business hours may be sent by secure electronic transmission, telephone, or secure facsimile copy of a case report. A party sending a report outside of normal public health business hours must use the after-hours emergency phone contact for the appropriate jurisdiction.
- (3) Conditions designated as notifiable within three business days must be reported to the local health officer or department, as specified in Table HC-1 of WAC 246-101-101, within three business days. Notification may be sent by written case report, secure electronic transmission, telephone, or secure facsimile copy of a case report; and
- (4) Conditions designated as notifiable on a monthly basis must be reported to the local health officer or the department, as specified in Table HC-1 of WAC 246-101-101, on a monthly basis. Notification may be sent by written case report, secure electronic transmission, telephone, or secure facsimile copy of a case report)) and health care facilities shall:
- (1) Submit a case report for each case under Table HC-1 of WAC 246-101-101, 246-101-115, and this section by secure electronic data transmission;
- (2) Submit a case report to the department instead of the local health jurisdiction when:
- (a) The local health jurisdiction is closed or representatives of the local health jurisdiction are unavailable:
 - (i) For immediately notifiable conditions; or
- (ii) At the time an outbreak or suspected outbreak of a communicable disease occurs.

[21] OTS-1363.6

- (b) The patient who is the subject of the case report resides outside Washington state and is a visitor to Washington state;
- (3) Call the public health authority designated for the condition in Table HC-1 of WAC 246-101-101 immediately and confirm receipt of a case report for conditions designated as:
 - (a) Immediately notifiable; or
- (b) Notifiable within twenty-four hours if the case report is submitted outside of the local health jurisdiction's normal business hours.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-115 Content of ((notifications)) case reports—Health care providers and health care facilities. (1) ((For each condition listed in Table HC-1 of WAC 246-101-101,)) Health care providers and health care facilities shall provide the following information ((for)) in each case ((or suspected case)) report for a notifiable condition, excluding occupational traumatic injury hospitalizations:

- (a) Patient's first and last name;
- (b) Patient's physical address including zip code;
- (c) ((Patient telephone number;
- (d))) Patient's date of birth;
- (((e))) <u>(d)</u> Patient<u>'s</u> sex;
- (e) Patient's race;
- (f) Patient's ethnicity;
- (g) For hepatitis B acute or chronic infection case reports, pregnancy status (pregnant/not pregnant/unknown) of patients twelve to fifty years of age;
 - (h) Patient's best contact telephone number;
 - (i) Name of the principal health care provider;
 - (j) Telephone number of the principal health care provider;
 - (k) Address where patient received care;
 - (1) Name of the person providing the report;
 - (m) Telephone number of the person providing the report;
- $\underline{\text{(n)}}$ Diagnosis or suspected diagnosis of (($\frac{\text{disease or}}{\text{and}}$)) $\underline{\text{the}}$ condition; $\underline{\text{and}}$
- $((\frac{g}{g}))$ <u>(o)</u> Pertinent laboratory $(\frac{data}{g})$ <u>results</u>, if available $(\frac{data}{g})$
 - (h) Name of the principal health care provider;
 - (i) Telephone number of the principal health care provider;
 - (i) Address of the principal health care provider;
- (k) Name and telephone number of the person providing the report; and
- (1) Other information as the department may require on forms generated by the department)).
- (2) The local health officer $((\frac{or}{or}))$ and the state health officer may $((\frac{require\ other}{other}))$ request additional information of epidemiological or public health value when conducting a case investigation or to otherwise prevent and control a specific notifiable condition.

- WAC 246-101-120 Handling ((of case reports and medical)) confidential information—Health care providers and health care facilities.
- (1) All records and specimens ((containing)) related to a case that contain or are accompanied by patient identifying information are confidential. Patient identifying information includes information that can directly or indirectly identify a patient.
- (2) Health care providers, health care facilities, and health care facility personnel shall maintain the confidentiality of patient health care information consistent with chapter 70.02 RCW and any other applicable confidentiality laws.
 - (3) Health care providers and health care facilities shall:
- (((2) Health care providers who know of a person with a notifiable condition, other than a sexually transmitted disease, shall release identifying information only to other individuals responsible for protecting the health and well-being of the public through control of disease, including the local health department.
- (3) Health care providers with knowledge of a person with sexually transmitted disease, and following the basic principles of health care providers, which respect the human dignity and confidentiality of patients:
- (a) May disclose the identity of a person or release identifying information only as specified in RCW 70.24.105; and
- (b) Shall under RCW 70.24.105(6), use only the following customary methods for exchange of medical information:
- (i) Health care providers may exchange medical information related to HIV testing, HIV test results, and confirmed HIV or confirmed STD diagnosis and treatment in order to provide health care services to the patient. This means that information shared impacts the care or treatment decisions concerning the patient; and the health care provider requires the information for the patient's benefit.
- (ii) Health care providers responsible for office management are authorized to permit access to a patient's medical information and medical record by medical staff or office staff to carry out duties required for care and treatment of a patient and the management of medical information and the patient's medical record.
- (c) Health care providers)) (b) When conducting a clinical HIV research project ((shall)), report the identity of an individual participating in the project unless:
- (i) The project has been approved by an institutional review board; and
- (ii) The project has a system in place to remind referring health care providers of ((their reporting obligations)) notification requirements under this chapter.
- ((4) Health care providers shall establish and implement policies and procedures to maintain confidentiality related to a patient's medical information.))

PART III: NOTIFIABLE CONDITIONS-LABORATORIES AND LABORATORY DIRECTORS

NEW SECTION

WAC 246-101-200 Rapid screening testing. An individual or entity including, but not limited to, health care providers and health care facilities, that conduct an RST for any of the following conditions, meets the definition of a laboratory under this chapter, and shall comply with WAC 246-101-201 through 246-101-230:

- (1) Blood lead level testing;
- (2) Hepatitis C (acute infection);
- (3) Hepatitis C (chronic infection); or
- (4) HIV infection.

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-201 Notifiable conditions ((and))—Laboratories. ((This section describes the conditions about which Washington's laboratories must notify public health authorities of on a statewide basis. The board finds that the conditions in Table Lab-1 of this section are notifiable for the prevention and control of communicable and noninfectious diseases and conditions in Washington. The board also finds that submission of specimens for many of these conditions will further prevent the spread of disease.

(1) Laboratory directors shall notify public health authorities of positive preliminary test results and positive final test results of the conditions identified in Table Lab-1 of this section as individual case reports and provide specimen submissions following the requirements in WAC 246-101-205, 246-101-210, 246-101-215, 246-101-220, 246-101-225, and 246-101-230.

(2) Local health officers may require additional conditions to be notifiable within the local health officer's jurisdiction.

Table Lab-1 (Conditions Notifiable by Laboratory Directors)

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to Department of Health	Specimen Submission to Department of Health (Type & Timing)
Arboviruses (West Nile virus, eastern and western equine encephalitis, dengue, St. Louis encephalitis, La Crosse encephalitis, Japanese encephalitis, Powassan, California serogroup, Chikungunya)	2 business days	₹		On request

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to Department of Health	Specimen Submission to Department of Health (Type & Timing)
Acute: IgM positivity PCR positivity Viral isolation				
Bacillus anthracis (Anthrax)	Immediately	4		Culture (2 business days)
Blood Lead Level	Elevated Levels - 2 business days Nonelevated Levels - Monthly		4	
Bordetella pertussis (Pertussis)	Within 24 hours	4		Culture, when available (2 business days)
Borrelia burgdorferi (Lyme disease)	2 business days	4		On request
Borrelia hermsii or recurrentis (Relapsing fever, tick- or louseborne)	Within 24 hours	4		On request
Brucella species (Brucellosis)	Within 24 hours	4		Cultures (2 business days)
<i>Burkholderia mallei</i> and <i>pseudomallei</i>	Immediately	4		Culture (2 business days); additional specimens when available
Campylobacter species (Campylobacteriosis)	2 business days	4		On request
CD4 + (T4) lymphocyte counts and/or CD4 + (T4) (patients aged thirteen or older)	Monthly	Only when the local health department is designated by the Department of Health	√(Except King County)	
Chlamydophila psittaci (Psittacosis)	Within 24 hours	₹		On request
Chlamydia trachomatis	2 business days	√		
Clostridium botulinum (Botulism)	Immediately	4		Serum and/or stool; any other specimens available (i.e., foods submitted for suspected foodborne ease; debrided tissue submitted for suspected wound botulism) (2 business days)
Corynebacterium diphtheriae (Diphtheria)	Immediately	4		Culture (2 business days)
Coxiella burnetii (Q fever)	Within 24 hours	4		Culture (2 business days)
Cryptococcus non v. neoformans	N/A	N/A		Culture (2 business days) or other specimens upon request
Cryptosporidium (Cryptosporidiosis)	2 business days	4		On request

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to Department of Health	Specimen Submission to Department of Health (Type & Timing)
Cyclospora cayetanensis (Cyclosporiasis)	2 business days	4		Specimen (2 business days)
E. coli - Refer to "Shiga toxin- producing E. coli"	Immediately	4		
Francisella tularensis (Tularemia)	Immediately	4		Culture or other appropriate clinical material (2 business days)
Giardia lamblia (Giardiasis)	2 business days	→		On request
Haemophilus influenzae (children < 5 years of age)	Immediately	4		Culture, from sterile sites only, when type is unknown (2 business days)
Hantavirus	Within 24 hours	₹		On request
Hepatitis A virus (acute) by IgM positivity (Hepatocellular enzyme levels to accompany report)	Within 24 hours	4		On request
Hepatitis B virus (acute) by IgM positivity	Within 24 hours	4		On request
Hepatitis B virus - HBsAg (Surface antigen) - HBeAg (E antigen) - HBV DNA	Monthly	√		
Hepatitis C virus	Monthly	√		
Hepatitis D virus	2 business days	√		On request
Hepatitis E virus	Within 24 hours	₩		On request
Human immunodeficiency virus (HIV) infection (for example, positive Western Blot assays, P24 antigen or viral culture tests)	2 business days	Only when the local health department is designated by the Department of Health	√(Except King County)	•
Human immunodeficiency virus (HIV) infection (Il viral load detection test results - detectable and undetectable)	Monthly	Only when the local health department is designated by the Department of Health	√(Except King County)	
Influenza virus, novel or unsubtypable strain	Immediately	4		Isolate or clinical specimen (2 business days)
Legionella species (Legionellosis)	Within 24 hours	4		Culture (2 business days)
Leptospira species (Leptospirosis)	Within 24 hours	4		On request
Listeria monocytogenes (Listeriosis)	Within 24 hours	4		Culture (2 business days)
Measles virus (rubeola) Acute: IgM positivity PCR positivity	Immediately	4		Isolate or clinical specimen associated with positive result (2 business days)

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to Department of Health	Specimen Submission to Department of Health (Type & Timing)
Mumps virus Acute: IgM positivity PCR positivity	Within 24 hours	4		Isolate or clinical specimen associated with positive result (2 business days)
Mycobacterium tuberculosis (Tuberculosis)	2 business days		→	Culture (2 business days)
Mycobacterium tuberculosis (Tuberculosis) (Antibiotic sensitivity for first isolates)	2 business days		4	
Neisseria gonorrhoeae (Gonorrhea)	2 business days	4		
Neisseria meningitidis (Meningococeal disease)	Immediately	4		Culture (from sterile sites only) (2 business days)
Plasmodium species (Malaria)	2 business days	√		On request
Poliovirus Acute: IgM positivity PCR positivity	Immediately	4		Isolate or clinical specimen associated with positive result (2 business days)
Rabies virus (human or animal)	Immediately	√ (Pathology Report Only)		Clinical specimen associated with positive result (2 business days)
Salmonella species (Salmonellosis)	Within 24 hours	4		Culture (2 business days)
SARS-associated coronavirus	Immediately	4		Isolate or clinical specimen associated with positive result (2 business days)
Shiga toxin-producing <i>E. coli</i> (enterohemorrhagie <i>E. coli</i> including, but not limited to, <i>E. coli</i> O157:H7)	Immediately	4		Culture (2 business days) or specimen if no culture is available
Shigella species (Shigellosis)	Within 24 hours	4		Culture (2 business days)
Treponema pallidum (Syphilis)	2 business days	4		Serum (2 business days)
Trichinella species	2 business days	√		On request
Vancomyein-resistant Staphylococcus aureus	Within 24 hours	4		Culture (2 business days)
Variola virus (smallpox)	Immediately	4		Isolate or clinical specimen associated with positive result (2 business days)
Vibrio cholerae O1 or O139 (Cholera)	Immediately	4		Culture (2 business days)
Vibrio species (Vibriosis)	Within 24 hours	4		Culture (2 business days)
Viral hemorrhagic fever: Arenaviruses Bunyaviruses Filoviruses Flaviviruses	Immediately	4		Isolate or clinical specimen associated with positive result (2 business days)

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department	Notifiable to Department of Health	Specimen Submission to Department of Health (Type & Timing)
Yellow fever virus	Immediately	→		Serum (2 business days)
Yersinia enterocolitica or pseudotuberculosis	Within 24 hours	↓		On request
Yersinia pestis (Plague)	Immediately	4		Culture or other appropriate clinical material (2 business days)

(\forall) Indicates which agency should receive case and suspected case reports.

- (3) The local health department may request laboratory reporting of additional test results pertinent to an investigation of a notifiable condition (e.g., hepatocellular enzyme levels for hepatitis or negative stool test results on salmonellosis rescreening).
- (4) Laboratory directors may notify the local health department, the department, or both of other laboratory results.)) (1) For the purposes of Table Lab-1:
- (a) "At least annually" means deidentified negative screening results may be submitted in a single report no less than once per year, but may be submitted more frequently as a single report or as individual screening results.
- (b) "Deidentified negative screening result" means an initial test result that indicates the absence of disease, and that has personally identifiable information removed from it using the Health Insurance Portability and Accountability Act of 1996 Safe Harbor method defined in 45 C.F.R. 164.514. A deidentified negative screening result does not include a negative test result associated with a previous positive test result, such as a negative nucleic acid or viral load test that is performed after a positive antibody or antigen test.
- (c) "LHJ" means where the patient resides, or, in the event that patient residence cannot be determined, the local health jurisdiction in which the ordering health care provider practices, or the local health jurisdiction in which the laboratory operates.
- (d) "Within two business days" means specimens must be in transit to the Washington state public health laboratories within two business days of:
- (i) Completing a test and the specimen being ready for packaging; or
- (ii) Receiving a request from a local health jurisdiction or the department, provided the specimen is still available at the time of the request.
 - (2) This chapter does not require a laboratory to:
- (a) Test for agents (conditions) or speciate if the laboratory does not perform the test as part of its normal work. A laboratory director shall only report a case of a condition if it is identified as part of their normal testing protocols; or
- (b) Retain specimens indefinitely in anticipation of a request from a local health jurisdiction or the department.
- (3) The agents (conditions) in Table Lab-1 are notifiable by a laboratory director as indicated in Table Lab-1 and this chapter.

Table Lab-1 (Conditions Notifiable by Laboratory Directors)

	<u>Notification</u>	n of Results	Specimen Submission State Public Hea	on to the Washington olth Laboratories
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit
Amoebic meningitis	Positive result by any method	Immediately to LHJ	Specimen associated with positive result, if available	Within 2 business days
Anaplasma species (Anaplasmosis)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result, if available	Within 2 business days of request by LHJ or DOH
Babesia species (Babesiosis)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result, if available	Within 2 business days of request by LHJ or DOH
Bacillus anthracis (Anthrax)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days
<u>Bacillus cereus,</u> <u>biovar anthracis</u> only	Confirmed positive result by any method	Immediately to LHJ	Do not ship specimen	Do not ship specimen
Baylisascaris (Baylisascariasis)	Positive result by any method	Within 24 hours to LHJ	Specimen associated with positive result, if available	Within 2 business days
Blood lead level	Elevated results equal to or greater than 5 micrograms per deciliter for: RST Venous	Within 2 business days to DOH	N/A	N/A
	Nonelevated results less than 5 micrograms per deciliter for: RST Venous	Within 30 days to DOH		
Bordetella pertussis (Pertussis)	Positive results by: Culture	Within 24 hours to LHJ	<u>Isolate</u>	Within 2 business days
	Nucleic acid detection ((nucleic acid testing (NAT)) or (nucleic acid amplification testing (NAAT))		If no isolate available, specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Borrelia burgdorferi or Borrelia mayonii (Lyme disease)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Borrelia hermsii, parkeri, turicatae, miyamotoi, or recurrentis (Relapsing fever, tick- or louse-borne)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Brucella species (Brucellosis)	Positive result by any method excluding Immunoglobulin G (IgG)	Within 24 hours to LHJ	Isolate, excluding confirmed positive B. melitensis, B. abortus, or B. suis	Within 2 business days

	Notification	n of Results	Specimen Submission State Public Hea	on to the Washington olth Laboratories
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit
			If no isolate available, specimen associated with positive result	
Burkholderia mallei (Glanders)	Positive result by any method excluding IgG	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive	Within 2 business days
Burkholderia pseudomallei (Melioidosis)	Positive result by any method excluding IgG	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days
California serogroup viruses, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Campylobacter species (Campylobacteriosis)	Positive result by: Culture Nucleic acid detection (NAT or NAAT) Antigen detection	Within 2 business days to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Candida auris	Positive result by any method	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days

	Notification	n of Results		on to the Washington alth Laboratories
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit
Carbapenem-resistant Enterobacteriaceae: Klebsiella species E. coli Enterobacter species	Positive for known carbapenemase resistance gene (including, but not limited to, KPC, NDM, VIM, IMP, OXA-48) demonstrated by nucleic acid detection (NAT or NAAT), or whole genome sequencing Positive on a phenotypic test for carbapenemase production including, but not limited to, Metallo-B-lactamase test, modified Hodge test (MHT) (for E. coli and Klebsiella species only), CarbaNP, Carbapenem Inactivation Method (CIM) or modified CIM (mCIM) Resistant to any carbapenem including, but not limited to, doripenem, ertapenem, imipenem or meropenem	Within 2 business days to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days
CD4 + counts ¹ , or CD4 + percents ² , or both (patients aged thirteen or older)	All results	Within 30 days to DOH except in King County where this is notifiable to the LHJ	N/A	N/A
Chikungunya virus, acute (Arbovirus)	Positive result by any method excluding Immunoglobulin G (IgG)	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Chlamydia psittaci (Psittacosis)	Positive result by any method excluding IgG	Within 24 hours to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
<u>Chlamydia</u> <u>trachomatis</u>	Positive and indeterminate result by any method	Within 2 business days to LHJ	N/A	N/A
<u>Chlamydia</u> <u>trachomatis</u>	Deidentified negative screening result	At least annually to DOH	<u>N/A</u>	N/A
<u>Clostridium</u> <u>botulinum (Botulism)</u>	Positive result by any method	Immediately to LHJ	Presumptive positive isolate	Within 2 business days

	<u>Notification</u>	n of Results	Specimen Submission State Public Hea	on to the Washington olth Laboratories
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit
			If no isolate available, specimen associated with presumptive positive result	
<u>Coccidioides</u> (Coccidioidomycosis)	Positive result by any method	Within 2 business days to LHJ	<u>Isolate</u>	Within 2 business days
			If no isolate available, specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Coronavirus SARS-associated coronavirus MERS-associated coronavirus Novel coronavirus (SARS-CoV-2)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate, if no isolate available, specimen associated with presumptive positive result	Within 2 business days of request by LHJ or DOH
Corynebacterium diphtheriae	Positive result by: Culture	Immediately to LHJ	<u>Isolate</u>	Within 2 business days
(Ďiphtheria)	Nucleic acid detection (NAT or NAAT)		If no isolate available, specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Coxiella burnetii (Q fever)	Positive result by any method	Within 24 hours LHJ	Specimen associated with presumptive positive result	Within 2 business days
Crimean-Congo hemorrhagic fever virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days
Cryptococcus gattii or undifferentiated Cryptococcus species (i.e., Cryptococcus not identified as C. neoformans)	Positive results by any method excluding cryptococcal antigen	Within 2 business days to LHJ	Isolate If no isolate available, specimen associated with positive result (excluding serum)	Within 2 business days
			<u>Serum</u>	Within 2 business days of request by LHJ or DOH
Cryptosporidium (Cryptosporidiosis)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Cyclospora cayetanensis (Cyclosporiasis)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Dengue virus, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
E. coli - Refer to "Shiga toxin- producing E. coli"				

	<u>Notification</u>	n of Results	Specimen Submission State Public Hea	on to the Washington alth Laboratories
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit
Eastern and western equine encephalitis virus, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result excluding specimens from viral culture	Within 2 business days of request by LHJ or DOH
Ebola virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive specimen	Within 2 business days
Echinococcus granulosus or E. multilocularis (Echinococcosis)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Ehrlichia species (Ehrlichiosis)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Francisella tularensis (Tularemia)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days
Giardia duodenalis, G. lamblia, G. intestinalis (Giardiasis)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Guanarito virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days
Haemophilus influenzae (children < 5 years of age)	Positive result for specimen from a normally sterile site by: Culture Nucleic acid detection (NAT or NAAT)	Immediately to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days
Hantavirus including, but not limited to: Andes virus Bayou virus Black Creek Canal virus Dobrava-Belgrade virus Hantaan virus Seoul virus Sin nombre virus	Positive result by any method	Within 24 hours to LHJ	Specimen associated with positive result	Within 2 business days

	<u>Notification</u>	n of Results	Specimen Submission State Public Hea	on to the Washington alth Laboratories
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit
Hepatitis A virus	Positive results for: IgM Nucleic acid detection (NAT or NAAT) Hepatocellular enzyme levels to accompany report, if available, for positive IgM results	Within 24 hours to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Hepatitis B virus	Positive results for: IgM anti-HBc HBsAg HBeAg HBV Nucleic acid detection (NAT or NAAT) either qualitative or quantitative, for example PCR or genotyping If associated with a positive result listed above, and available: Hepatocellular enzyme levels Pregnancy status Negative IgM anti- HBc result	Within 24 hours to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Hepatitis C virus	Positive result by any method Positive and nonpositive results for: HCV nucleic acid detection (NAT or NAAT) for qualitative, quantitative, and genotype tests If associated with a positive result and available: Hepatocellular enzyme levels Pregnancy status Negative result for IgM anti-HAV Negative result for IgM anti-HBc	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Hepatitis C virus	Deidentified negative screening result	At least annually to DOH	N/A	N/A

	Notification of Results			on to the Washington alth Laboratories
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit
Hepatitis D virus	Positive result by any method If associated with a positive result and available: Hepatocellular enzyme levels	Within 24 hours to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Hepatitis E virus	Positive result by any method If associated with a positive result and available: Hepatocellular enzyme levels	Within 24 hours to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Histoplasma capsulatum	Positive result by any method	Within 2 business days to LHJ	<u>Isolate</u>	Within 2 business days
(histoplasmosis)			Serum	Within 2 business days of request by LHJ or DOH
Human immunodeficiency virus (HIV)	Positive and indeterminate results and subsequent negative results associated with those positive or indeterminate results for the tests below: Antibody detection tests (including RST) Antigen detection tests (including RST) Viral culture	Within 2 business days to DOH except in King County where this is notifiable to the LHJ	N/A	N/A
	All HIV nucleic acid detection (NAT or NAAT) tests: Qualitative and quantitative Detectable and undetectable HIV antiviral resistance testing genetic sequences			
Human immunodeficiency virus (HIV)	Deidentified negative screening result	At least annually to DOH	N/A	N/A
Human prion disease	Positive result by any method excluding Tau protein	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH
Influenza virus, novel or unsubtypable strain	Positive novel and unsubtypable result	Immediately to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days

	Notification of Results		Specimen Submission to the Washington State Public Health Laboratories		
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit	
Japanese encephalitis virus, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH	
Junin virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result		
La Crosse encephalitis virus, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH	
Lassa virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days	
Legionella species (Legionellosis)	Positive result by any method	Within 24 hours to LHJ	Isolate If no isolate available but respiratory specimen available and associated with a positive test (as in the case of a PCR positive), respiratory specimen associated with positive result	Within 2 business days	
<u>Leptospira species</u> (<u>Leptospirosis</u>)	Positive result by any method	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days of request by LHJ or DOH	
Listeria monocytogenes (Listeriosis)	Positive result for specimen from a normally sterile site by: Culture Nucleic acid detection (NAT or NAAT)	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days	
Lujo virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days	
Machupo virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days	

	Notification of Results		Specimen Submission to the Washington State Public Health Laboratories			
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit		
Marburg virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days		
Measles virus - See "Rubeola (measles virus)"						
Mumps virus	Positive result for: Culture Nucleic acid detection (NAT or NAAT)	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days		
	IgM		Specimen associated with positive IgM	Within 2 business days of request by LHJ or DOH		
Mycobacterium tuberculosis complex (Tuberculosis)	Positive result for: Culture Nucleic acid detection (NAT or NAAT) Drug susceptibilities (molecular and culture based)	Within 2 business days to DOH	Mycobacterium tuberculosis complex positive isolate (earliest available isolate for the patient)	Within 2 business days		
Neisseria gonorrhoeae (Gonorrhea)	Positive and indeterminate result by any method	Within 2 business days to LHJ	<u>N/A</u>	N/A		
Neisseria gonorrhoeae (Gonorrhea)	Deidentified negative screening result	At least annually to DOH	<u>N/A</u>	<u>N/A</u>		
Neisseria meningitidis (Meningococcal disease)	Positive result for specimen from a normally sterile site by any method	Immediately to LHJ	Isolate from a normally sterile site If no isolate available, specimen associated with positive result	Within 2 business days Within 2 business days of request by LHJ or DOH		
Plasmodium species (Malaria)	Positive results for: Nucleic acid detection (NAT or NAAT) Malaria-specific antigens by rapid diagnostic test PCR Microscopy (thick or thin smear)	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH		
Poliovirus (Poliomyelitis)	IgM positivity; PCR positivity	Immediately to LHJ	Isolate If no isolate available, specimen associated with positive result Within 2 busines days			
Powassan virus, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH		

	Notification of Results		Specimen Submission to the Washington State Public Health Laboratories		
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit	
Rabies virus	Positive result by any method	Immediately to LHJ	Specimen associated with positive result	Within 2 business days	
Rickettsia species including, but not limited to: Rickettsia rickettsii Rickettsia africae Rickettsia conorii Rickettsia typhi Rickettsia parkeri Rickettsia philipii	Positive results by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH	
Rubella Positive result by: Culture IgM Nucleic acid detection (NAT or		Isolate If no isolate available, specimen associated with positive result Within 2 busine days			
	NAAT)		Other specimen	Within 2 business days of request by LHJ or DOH	
Rubeola (measles virus)	Positive result by: Culture IgM Nucleic acid detection (NAT or NAAT)	Immediately to LHJ	Isolate and specimen associated with positive culture	Within 2 business days	
			Isolate and specimen association with positive NAT or NAAT result		
			Specimen associated with positive IgM Other specimen	Within 2 business days of request by LHJ or DOH	
Sabia virus (Viral hemorrhagic fever)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days	
Salmonella species (Salmonellosis, typhoid fever)	Positive result by any method	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result Within 2 business days		
Shiga toxin- producing E. coli/ enterohemorrhagic E. coli (STEC)	Positive result by any method	Immediately to LHJ	Isolate If no isolate available, specimen associated with positive result		
Shigella species (Shigellosis)	Positive result by any method	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result Within 2 business days		
St. Louis encephalitis virus, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH	

	Notification of Results		Specimen Submission to the Washington State Public Health Laboratories		
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit	
Taenia solium (Taeniasis or Cysticercosis)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH	
Treponema pallidum (Syphilis)	Positive and indeterminate result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days	
Treponema pallidum (Syphilis)	Deidentified negative screening result	At least annually to DOH	N/A	N/A	
Trichinella species (Trichinellosis)	Positive serologic test for <i>Trichinella</i>	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH	
<u>Trypanosoma cruzi</u> (Chagas disease)	Positive result by any method	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days	
Vaccinia (vaccine- acquired smallpox)	Any request for testing associated with a suspect case	Immediately to LHJ	Any specimen collected from a suspect case	Immediately	
Vancomycin-resistant Staphylococcus aureus	Resistance to vancomycin	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days	
Variola virus (smallpox)	Any request for testing associated with a suspect case	Immediately to LHJ	Specimen collected from a suspect case	Immediately	
Vibrio cholerae O1 or O139 (Cholera)	Positive result by any method	Immediately to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days	
Vibrio species (Vibriosis) not including Vibrio cholerae O1 or O139 (Cholera) See "Vibrio cholerae O1 or O139 (Cholera)"	Positive result by any method	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days	
West Nile virus, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result Within 2 business days of request by LHJ or DOH		
Yellow fever virus (Arbovirus)	Positive result by any method excluding IgG	Immediately to LHJ	Specimen associated with positive result Within 2 business days		
Yersinia enterocolitica, Y. pseudotuberculosis, Y. intermedia, Y. fredericksenii, or Y. kristensenii (Yersiniosis)	Positive result by any method	Within 24 hours to LHJ	Isolate If no isolate available, specimen associated with positive result	Within 2 business days of request by LHJ or DOH	

	Notification of Results		Specimen Submission to the Washington State Public Health Laboratories		
Agent (Condition)	What to Submit in a Case Report	When and Whom to Notify Upon Receiving Presumptive or Final Test Result	What to Submit	When to Submit	
Yersinia pestis (Plague)	Positive result by any method	Immediately to LHJ	Presumptive positive isolate If no isolate available, specimen associated with presumptive positive result	Within 2 business days	
Zika virus, acute (Arbovirus)	Positive result by any method excluding IgG	Within 2 business days to LHJ	Specimen associated with positive result	Within 2 business days of request by LHJ or DOH	

^{1 &}quot;CD4 + counts" means CD4 + (T4) lymphocyte counts.

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-205 ((Responsibilities and)) Duties ((of the))—

- <u>Laboratory directors</u>. (1) <u>A laboratory director((s)) shall:

 (a) ((Notify the local health department where the patient re-</u> sides, or, in the event that patient residence cannot be determined, the local health department in which the ordering health care provider practices, or the local health department in which the laboratory operates, regarding:
- (i) Positive preliminary test results and positive final test results of notifiable conditions specified as notifiable to the local health department in Table Lab-1.
- (ii) Positive preliminary test results and positive final test results of conditions specified as notifiable by the local health officer within that health officer's jurisdiction.)) Submit case reports:
- (i) To the local health jurisdiction or the department as required in Table Lab-1 of WAC 246-101-201, and under the requirements of WAC 246-101-220, 246-101-225, and this section; and
- (ii) To the local health jurisdiction as required by the local health officer within that health officer's jurisdiction.
- (b) Notify the department of conditions designated as notifiable to the local health ((department)) jurisdiction when:
- (i) A local health ((department)) jurisdiction is closed or representatives of the local health ((department)) jurisdiction are unavailable at the time a ((positive preliminary test result or positive)) presumptive or final test result of an immediately notifiable condition occurs; or
- (ii) ((A local health department is closed or representatives of the local health department are unavailable at the time an outbreak or suspected outbreak of communicable disease occurs.
- (c) Notify the department of positive preliminary test results or positive final test results for conditions designated notifiable to the department in Table Lab-1.

² "CD4 + percents" means CD4 + (T4) percents of total lymphocytes.

- (d) Notify the department of nonelevated blood lead levels on a monthly basis.
- (e) Submit specimens for conditions noted in Table Lab-1 to the Washington state public health laboratories or other laboratory designated by the state health officer for diagnosis, confirmation, storage, or further testing.
- (f) Ensure that positive preliminary test results and positive final test results for notifiable conditions of specimens referred to other laboratories for testing are correctly notified to the correct local health department or the department. This requirement can be satisfied by:
- (i) Arranging for the referral laboratory to notify either the local health department, the department, or both; or
- (ii) Forwarding the notification of the test result from the referral laboratory to the local health department, the department, or both.
- (g))) The notifiable test result pertains to a patient who resides outside of and is visiting Washington state as indicated by information provided by the requesting health care provider or health care facility.
- (c) Submit specimens required in Table Lab-1 of WAC 246-101-201 under the requirements of WAC 246-101-210 and 246-101-215, and this section;
- (d) Cooperate with public health authorities during investigation of:
- (i) The circumstances of a case (($\frac{\text{or suspected case}}{\text{cand}}$)) of a notifiable condition (($\frac{\text{or other communicable disease}}{\text{cand}}$); (($\frac{\text{and}}{\text{cand}}$))
 - (ii) An outbreak or suspected outbreak of disease.
- (2) A laboratory director((s)) may designate responsibility for working and cooperating with public health authorities to certain employees as long as designated employees are:
 - (a) Readily available; and
 - (b) Able to provide requested information in a timely manner.
- (3) ((By July 1, 2011, when referring)) A laboratory director may refer a specimen of a notifiable condition to a reference laboratory for testing.
- (4) When a laboratory director refers a specimen ((to another)) of a notifiable condition to a reference laboratory for ((a test for a notifiable condition)) testing, the laboratory director((s)) shall:
- (a) Provide the <u>reference</u> laboratory with <u>Table Lab-1 of WAC 246-101-201</u>, and WAC 246-101-220 and 246-101-225; and the following information for each ((test referral)) <u>specimen</u>:
 - (((a) Patient name;
- (b) Full address of patient, or patient zip code at a minimum, when available in laboratory database;
- (c) Date of birth or age of patient, when available in laboratory database;
 - (d) Sex of patient, when available in laboratory database;
 - (e) Name of the principal health care provider;
 - (f) Telephone number of the principal health care provider;
- (g) Address of the principal health care provider, when available;
 - (h) Type of test requested;
 - (i) Type of specimen; and
 - (j) Date of specimen collection.

- (4) By January 1, 2013, laboratory databases must have the ability to receive, store, and retrieve all of the data elements specified in subsection (3)(a) through (j) of this section.))
 - (i) Patient's first and last name;
 - (ii) Patient's physical address including zip code;
 - (iii) Patient's date of birth;
 - (iv) Patient's sex;
 - (v) Patient's race;
 - (vi) Patient's ethnicity;
- (vii) For hepatitis B virus case reports, pregnancy status (pregnant, not pregnant, or unknown) of patients twelve to fifty years of age;
 - (viii) Patient's best contact telephone number;
- (ix) Patient's medicaid status, for blood lead level tests for patients less than seventy-two months of age only;
 - (x) Requesting health care provider's name;
 - (xi) Requesting health care provider's phone number;
 - (xii) Address where patient received care;
 - (xiii) Name of submitting laboratory;
 - (xiv) Telephone number of submitting laboratory;
 - (xv) Specimen type;
 - (xvi) Specimen collection date;
 - (xvii) Date laboratory received specimen; and
 - (xviii) Test method requested.
 - (b) Ensure the case report is submitted appropriately either by:
- (i) Arranging for the reference laboratory to submit the case report under Table Lab-1 of WAC 246-101-201, and WAC 246-101-220 and 246-101-225; or
- (ii) Submitting the case report under Table Lab-1 of WAC 246-101-201, and WAC 246-101-220 and 246-101-225.
- (5) A laboratory director may provide health information, demographic information, or infectious or noninfectious condition information in addition to the information required under this chapter when the provider or facility determines that the additional information will aid the appropriate public health authority in protecting and improving the public's health through prevention and control of infectious and noninfectious conditions.
- (6) When a laboratory director submits information under subsection (4) of this section, they shall submit the information under the requirements of WAC 246-101-220.

 $\underline{\text{AMENDATORY SECTION}}$ (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-210 Means of specimen submission—<u>Laboratory directors and laboratories</u>. (1) ((When submitting specimens as indicated in Table Lab-1 of WAC 246-101-201, laboratories shall adhere to the following timelines and procedures:
- (a) Specimens designated for submission within two business days must be in transit within two business days from the time the specimen is ready for packaging;
- (b) Specimens designated for submission on request may be request ted by the local health departments or the department. The laboratory

shall ship a requested specimen within two business days of receiving the request, provided the specimen is still available at the time of the request. This is not intended to require laboratories to save specimens indefinitely in anticipation of a request.

- (2) Local health jurisdictions may temporarily waive specimen submission for circumstances at their discretion by communication with individual laboratories.)) A laboratory director shall submit specimens under Table Lab-1 of WAC 246-101-201 and this chapter.
- (2) For test results notifiable to local health jurisdictions, the local health officer may temporarily waive specimen submission requirements and notify laboratories, including the Washington state public health laboratories, of the basis for the waiver, which requirements are being waived and how long the waiver will be in effect.
- (3) ((Laboratories)) <u>A laboratory</u> shall forward ((all)) required specimens ((submissions)) to:

Washington State Public Health Laboratories Washington State Department of Health 1610 N.E. 150th Street Shoreline, WA 98155

(4) The state health officer may designate additional laboratories as public health ((referral)) reference laboratories.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-215 Content of documentation accompanying specimen submission—Laboratory directors. ((For each condition listed in Table Lab-1 of WAC 246-101-201,)) \underline{A} laboratory director((s)) shall provide the following information with each specimen ((submission:

- (1) Type of specimen tested;
- (2) Name of reporting laboratory;
- (3) Telephone number of reporting laboratory;
- (4) Date of specimen collection;
- (5) Requesting health care provider's name;
- (6) Requesting health care provider's phone number;
- (7) Requesting health care provider's address, when available;
- (8) Test result;
- (9) Name of patient;
- (10) Sex of patient, when available in laboratory database;
- (11) Date of birth or age of patient, when available in laboratory database;
- (12) Full address of patient, or patient zip code at a minimum, when available in laboratory database;
- (13) Telephone number of patient, when available in laboratory database;
- (14) Other information of epidemiological value, when available)) submitted under this chapter to the Washington state public health laboratories:
 - (1) Patient's first and last name;
 - (2) Patient's physical address including zip code;
 - (3) Patient's date of birth;
 - (4) Patient's sex;

- (5) Patient's race;
- (6) Patient's ethnicity;
- (7) For hepatitis B virus, pregnancy status (pregnant, not pregnant, or unknown) of patients twelve to fifty years of age;
 - (8) Patient's best contact telephone number;
 - (9) Requesting health care provider's name;
 - (10) Requesting health care provider's phone number;
 - (11) Address where patient received care;
 - (12) Name of submitting laboratory;
 - (13) Telephone number of submitting laboratory;
 - (14) Specimen type;
 - (15) Specimen collection date;
 - (16) Date laboratory received specimen;
 - (17) Test method used; and
 - (18) Test result.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-220 Means of notification ((for positive preliminary test results and positive final test results))—Laboratory directors. A laboratory director((s)) shall ((adhere to the following timelines and procedures:

- (1) Conditions designated as immediately notifiable must be reported to the local health officer or the department, as specified in Table Lab-1 of WAC 246-101-201, immediately at the time of positive preliminary test result or positive final test result. This applies twenty-four hours a day, seven days a week. Each local health jurisdiction, as well as the department, maintains after-hours emergency telephone contacts for this purpose. A party sending notification by secure facsimile copy or secure electronic transmission during normal business hours must confirm immediate receipt by a live person.
- (2) Conditions designated as notifiable within twenty-four hours must be reported to the local health officer or the department, as specified in Table Lab-1 of WAC 246-101-201, within twenty-four hours of positive preliminary test result or positive final test result, seven days a week. Reports during normal public health business hours may be sent by secure electronic transmission, telephone, or secure facsimile copy of a case report. A party sending a report outside of normal public health business hours must use the after-hours emergency phone contact for the appropriate jurisdiction.
- (3) Conditions designated as notifiable within two business days must be reported to the local health officer or the department, as specified in Table Lab-1 of WAC 246-101-201, within two business days. Notification may be sent by secure electronic transmission, telephone, or secure facsimile copy of a case report; and
- (4) Conditions designated as notifiable on a monthly basis must be reported to the local health officer or the department, as specified in Table Lab-1 of WAC 246-101-201, on a monthly basis. Notification may be sent by written case report, secure electronic transmission, telephone, or secure facsimile copy of a case report)):
- (1) Submit case reports as required under this chapter by secure electronic data transmission.

- (2) Call the local health jurisdiction in which the case occurred immediately and confirm receipt of a presumptive or final test result for a condition designated as:
 - (a) Immediately notifiable; or
- (b) Notifiable within twenty-four hours when submitting the test result outside the local health jurisdiction's normal business hours.

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-225 Content of ((notifications for positive preliminary test results and positive final test results)) case reports—Laboratory directors. (1) ((For each condition listed in Table Lab-1 of WAC 246-101-201,)) A laboratory director((s must)) shall provide the following information ((for)) in each ((positive culture or suggestive test result)) case report required under this chapter:

- (((a) Type of specimen tested;
- (b) Name of reporting laboratory;
- (c) Telephone number of reporting laboratory;
- (d) Date of specimen collection;
- (e) Date specimen received by reporting laboratory;
- (f) Requesting health care provider's name;
- (g) Requesting health care provider's phone number;
- (h) Requesting health care provider's address, when available;
- (i) Test result;
- (j) Name of patient;
- (k) Sex of patient, when available in laboratory database;
- (1) Date of birth or age of patient, when available in laboratory database; and
- (m) Full address of patient, or patient zip code at a minimum, when available in laboratory database.)) (a) Patient's first and last name;
 - (b) Patient's physical address including zip code;
 - (c) Patient's date of birth;
 - (d) Patient's sex;
 - (e) Patient's race;
 - (f) Patient's ethnicity;
- (g) For hepatitis B virus, pregnancy status (pregnant, not pregnant, or unknown) of patients twelve to fifty years of age;
 - (h) Patient's best contact telephone number;
- (i) Patient's medicaid status, for blood lead tests for patients less than seventy-two months of age only;
 - (j) Requesting health care provider's name;
 - (k) Requesting health care provider's phone number;
 - (1) Address where patient received care;
 - (m) Name of submitting laboratory;
 - (n) Telephone number of submitting laboratory;
 - (o) Specimen type;
 - (p) Specimen collection date;
 - (g) Date laboratory received specimen;
 - (r) Test method used; and
 - (s) Test result.

(2) The local health ((officers and)) officer or the state health officer may ((require laboratory directors to report other)) request additional information of epidemiological or public health value when conducting a case investigation or otherwise for prevention and control of a specific notifiable condition.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-230 Handling ((of case reports and medical)) confidential information—Laboratory directors. (1) All records and specimens ((containing)) related to a case that contain or are accompanied by patient identifying information are confidential. ((The Washington state public health laboratories, other laboratories approved as public health referral laboratories, and any persons, institutions, or facilities submitting specimens or records containing patient—identifying information)) Patient identifying information includes information that can directly or indirectly identify a patient.
- (2) A laboratory shall maintain the confidentiality of ((identifying information accompanying submitted laboratory specimens)) health information consistent with chapter 70.02 RCW and any other applicable confidentiality laws.
- $((\frac{(2)}{(2)}))$ <u>(3) A laboratory director((s))</u> shall establish and implement policies and procedures to maintain confidentiality related to $((\frac{a \text{ patient's medical}}))$ <u>health</u> information.
- (((3) Laboratory directors and personnel working in laboratories who know of a person with a notifiable condition, other than a sexually transmitted disease, shall release identifying information only to other individuals responsible for protecting the health and well-being of the public through control of disease.
- (4) Laboratory directors and personnel working in laboratories with knowledge of a person with sexually transmitted disease, and following the basic principles of health care providers, which respect the human dignity and confidentiality of patients:
- (a) May disclose identity of a person or release identifying information only as specified in RCW 70.24.105; and
- (b) Shall under RCW 70.24.105(6), use only the following customary methods for exchange of medical information:
- (i) Laboratory directors and personnel working in laboratories may exchange medical information related to HIV testing, HIV test results, and confirmed HIV or confirmed STD diagnosis and treatment in order to provide health care services to the patient. This means that information shared impacts the care or treatment decisions concerning the patient; and the laboratory director or personnel working in the laboratory require the information for the patient's benefit.
- (ii) Laboratory directors are authorized to permit access to a patient's medical information and medical record by laboratory staff or office staff to carry out duties required for care and treatment of a patient, the management of medical information, and the management of the patient's medical record.))

PART IV: NOTIFIABLE CONDITIONS-DUTIES OF OTHERS

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-405 ((Responsibilities of)) Duties—Veterinarians.

(1) A veterinarian((s)) shall((÷

(a) Notify the local health officer of the jurisdiction in which the human resides of any suspected human case or suspected human outbreak based on the human's exposure to a confirmed animal case of any disease listed in Table V-1 of this section:

$T \rightarrow h \downarrow h$	(Conditions	Motifiahlo	htz	Motorinariane)
Table V I	(COHAICIONS	Nociliable	Dy	vecerinarians,

Notifiable Condition	Time Frame for Notification	Notifiable to Local Health Department
Anthrax	Immediately	√
Arboviral Disease	Within 24 hours	√
Brucellosis (Brucella species)	Within 24 hours	√
Burkholderia mallei (Glanders)	Immediately	√
Disease of suspected bioterrorism origin (including but not limited to anthrax)	Immediately	4
E. coli - Refer to "Shiga toxin-producing E. coli"	Immediately	√
Emerging condition with outbreak potential	Immediately	√
Influenza virus, novel or unsubtypable strain	Immediately	√
Leptospirosis	Within 24 hours	√
Plague	Immediately	√
Psittacosis	Within 24 hours	√
Q Fever	Within 24 hours	√
Rabies (suspected human or animal)	Immediately	√
Shiga toxin-producing <i>E. coli</i> infections (enterohemorrhagie <i>E. coli</i> including, but not limited to, <i>E. coli</i> O157:H7)	Immediately	7
Tularemia	Immediately	→

^{(\(\}frac{1}{2}\)) Indicates that the condition is notifiable to the local health department.

- (b))) cooperate with public health authorities in ((the)) their:
- <u>(a) Investigation of human and animal</u> cases, (($\frac{\text{suspected cases}_r$)) outbreaks, (($\frac{\text{and}}{\text{o}}$)) suspected outbreaks, and clusters of zoonotic disease(($\frac{\text{cond}}{\text{cond}}$)
- (c) Cooperate with public health authorities in the implementation of infection control measures including isolation and quarantine.
- (d) Comply with requirements in chapter 16-70 WAC for submitting positive specimens and isolates for specific diseases, and provide information requested by the department or local health jurisdiction.
 - (2) The department of health shall:
- (a) Coordinate with the state veterinarian at the department of agriculture to develop, maintain, and implement a procedure for noti-

fying the department of animal cases of the conditions listed in Table V-1 of this section.

- (b) Notify the local health jurisdiction of reported animal cases of the conditions in Table V-1 of this section)); and
 - (b) Implementation of infection control measures.
- (2) Cooperation with public health authorities includes, but is not limited to:
- (a) Providing information requested by the department or local health jurisdiction; and
 - (b) Following infection control measures for:
 - (i) Humans under chapter 246-100 WAC;
 - (ii) Dogs, cats, ferrets, and hybrids under WAC 246-100-197; and (iii) Other animals under chapter 16.36 RCW.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-410 ((Responsibilities of food service)) <u>Duties</u>— Food establishments. The person in charge of a food ((service)) establishment shall:
- (1) For the purposes of this section "food establishment" has the same meaning as defined and referenced under WAC 246-215-01115.
- $\underline{(2)}$ Notify the local health (($\frac{\text{department}}{\text{department}}$)) $\underline{\text{jurisdiction}}$ of potential foodborne disease as required in WAC (($\frac{246-215-260}{246-215-02215}$.
- $((\frac{(2)}{)})$ (3) Cooperate with public health authorities in $((\frac{the}{)})$ their investigation and control of cases, $((\frac{suspected cases}{case}))$ outbreaks, and suspected outbreaks $((\frac{of foodborne or waterborne disease}{case}))$. This includes, but is not limited to, the release of the name and other pertinent information about food handlers diagnosed with a notifiable condition or other communicable disease $((\frac{as it relates to a foodborne or waterborne disease investigation}))$.
- $((\frac{3}{3}))$ Mot release information about food handlers with a notifiable condition or other communicable disease to other employees or the general public.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-415 ((Responsibilities of child day)) Duties—Child care facilities. (1) For the purposes of this section "child care facility" means an agency that regularly provides early childhood education and early learning services for a group of children for less than twenty-four hours a day and is subject to licensing under chapter 74.15 or 43.216 RCW, or both.
 - (2) A child ((day)) care ((facilities)) facility shall:
- ((\frac{(1)}{)}) (a) Notify the local health ((\frac{department}{})) jurisdiction of cases, ((\frac{suspected cases,}{})) outbreaks, and suspected outbreaks of notifiable conditions in Table HC-1 of WAC 246-101-101 that may be associated with the child ((\frac{day}{})) care facility.

- $((\frac{(2)}{)})$ (b) Consult with a health care provider or the local health $((\frac{department}{)})$ jurisdiction for information about the control and prevention of infectious $((\frac{cr}{communicable}))$ conditions, as necessary.
- $((\frac{(3)}{)})$ <u>(c)</u> Cooperate with public health authorities in $((\frac{\text{the}}{}))$ their investigation and control of cases, $((\frac{\text{suspected cases}_{r}}{}))$ outbreaks, and suspected outbreaks $((\frac{\text{of disease}}{}))$ that may be associated with the child $((\frac{\text{day}}{}))$ care facility.
- $((\frac{4}{}))$ <u>(d)</u> Establish and implement policies and procedures to maintain confidentiality related to $(\frac{medical}{})$ <u>health</u> information in their possession.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-420 ((Responsibilities of)) <u>Duties—Schools</u>. A school((s)) shall:
- (1) Notify the local health ((department)) jurisdiction of cases, ((suspected cases,)) outbreaks, and suspected outbreaks of ((disease)) notifiable conditions in Table HC-1 of WAC 246-101-101 that may be associated with the school.
- (2) Cooperate with the local health ((department)) jurisdiction in monitoring influenza.
- (3) Consult with a health care provider or the local health (($\frac{de-partment}{partment}$)) jurisdiction for information about the control and prevention of infectious (($\frac{de-de-partment}{de-de-partment}$)) conditions, as necessary.
- (4) Cooperate with public health authorities in ((the)) their investigation and control of cases, $((suspected\ cases,))$ outbreaks, and suspected outbreaks $((of\ disease))$ that may be associated with the school.
- (5) Release identifying information only to other individuals responsible for protecting the health and well-being of the public through control of disease consistent with applicable confidentially laws.
- (6) ((Schools shall)) Establish and implement policies and procedures to maintain confidentiality related to ((medical)) health information in their possession.

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-425 ((Responsibilities of)) <u>Duties—The general public</u>. (1) Members of the general public shall <u>cooperate with</u>:
- (a) ((Cooperate with)) Public health authorities in ((the)) their investigation and control of cases, ((suspected cases,)) outbreaks, and suspected outbreaks ((of notifiable conditions or other communicable diseases)); and
- (b) ((Cooperate with the)) <u>Implementation</u> of infection control measures((, including isolation and quarantine)).

(2) Members of the general public may notify the local health ((department)) jurisdiction of any case, ((suspected case,)) outbreak, or ((potential)) suspected outbreak ((of communicable disease)).

PART V: NOTIFIABLE CONDITIONS ((AND))—LOCAL HEALTH JURISDICTIONS ((AND THE DEPARTMENT))

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-505 Duties ((of the))—Local health officer or the local health ((department)) jurisdiction. (1) A local health officer((s)) or ((the)) local health ((department)) jurisdiction shall:
 - (a) Review and determine appropriate action for:
- (i) Each ((reported)) case ((or suspected case)) of a notifiable condition submitted to the local health jurisdiction;
- (ii) Any ((disease or)) condition considered a threat to public health; and
- (iii) Each ((reported)) outbreak or suspected outbreak of disease ((requesting)) submitted to the local health jurisdiction, and request assistance from the department in carrying out any of these investigations when necessary.
- (b) Establish a system at the local health (($\frac{\text{department}}{\text{diction}}$) jurisdiction for maintaining confidentiality of (($\frac{\text{written}}{\text{written}}$)) records (($\frac{\text{and}}{\text{written}}$)) under WAC 246-101-515;
- (c) Notify health care providers, laboratories, and health care facilities within the ((jurisdiction of the)) <u>local</u> health ((depart-ment)) <u>jurisdiction</u> of requirements in this chapter;
- (d) Notify the department of cases of ((any)) conditions notifiable to the local health $((department\ (except\ animal\ bites)\ upon\ completion\ of\ the\ case\ investigation))$ jurisdiction under WAC 246-101-510 and 246-101-513;
- (e) ((Distribute appropriate notification forms to persons responsible for reporting;
- (f)) Notify the principal health care provider <u>named in the case</u> <u>report</u>, if possible, prior to initiating a case investigation ((by the local health department));
- (($\frac{g}{Carry}$ out the HIV partner notification requirements of WAC $\frac{246-100-072}{}$;
- $\frac{(h)}{(f)}$ Allow laboratories to contact the health care provider ordering the diagnostic test before initiating patient contact if requested and the delay is unlikely to jeopardize public health; and
- $((\frac{1}{2}))$ (g) Conduct investigations and institute <u>infection</u> control measures in accordance with chapter 246-100 WAC.
 - (2) The local health ((department)) jurisdiction may:

- (a) Adopt alternate arrangements for meeting the ((reporting)) requirements under this chapter through cooperative agreement between the local health ((department)) jurisdiction and any health care provider, laboratory, or health care facility((\div)). The alternative must provide the same level of public health protection as the reporting requirement for which an alternative is sought;
- (b) Receive health information, demographic information, and infectious or noninfectious condition information in addition to that required under this chapter from health care providers, health care facilities, laboratories, the department of agriculture, and the department of labor and industries when the entity submitting the information determines that the additional information will aid the public health authority in protecting and improving the public's health through prevention and control of infectious and noninfectious conditions.
- (3) When the local health jurisdiction receives information under subsection (2) (b) of this section, the local health jurisdiction shall handle the information under the requirements of WAC 246-101-515.
- $\underline{\text{(4)}}$ Each local health officer has the authority $\underline{\text{under chapter}}$ $\underline{\text{70.05 RCW}}$ to:
- (a) Carry out additional steps ((determined to be)) necessary to verify a diagnosis reported by a health care provider;
- (b) Require any person suspected of having a notifiable condition to submit to examinations ((required)) necessary to determine the presence or absence of the condition;
- (c) Investigate any case ((or suspected case)) of a ((reportable disease or)) notifiable condition or other ((illness, communicable or otherwise)) infectious or noninfectious condition, if deemed necessary; and
- (d) Require the notification of additional conditions of public health importance occurring within the jurisdiction of the local health officer.

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-510 Means of notification—Local health officer or local health jurisdiction. (1) A local health ((departments)) jurisdiction shall:

- (a) Maintain a twenty-four-hour telephone number to receive confirmation calls of case reports submitted under this chapter for:
 - (i) Immediately notifiable conditions; and
- (ii) Conditions designated as notifiable within twenty-four hours.
- (b) Notify the department immediately ((by telephone or secure electronic data transmission of any case or suspected case of:
 - (a) Botulism;
 - (b) Cholera;
 - (c) Diphtheria;
- (d) Disease of suspected bioterrorism origin (including, but not limited to, anthrax);
 - (e) Emerging condition with outbreak potential;
 - (f) Influenza, novel strain;

OTS-1363.6

- (g) Measles;
- (h) Paralytic shellfish poisoning;
- (i) Plaque;
- (j) Poliomyelitis;
- (k) Rabies, human;
- (1) SARS;
- (m) Smallpox;
- (n) Tularemia;
- (o) Viral hemorrhagic fever; and
- (p) Yellow fever.
- (2) Immediate notifications of cases and suspected cases shall include:
 - (a) Patient name;
 - (b) Patient's notifiable condition; and
 - (c) Condition onset date.
- (3) For each case of any condition notifiable to the local health department, submit to the department case report either on a form provided by the department or in a format approved by the department. Case reports must be sent by secure electronic transmission or telephone within seven days of completing the case investigation. If the case investigation is not complete within twenty-one days of notification, pertinent information collected from the case investigation must be sent to the department and shall include:
 - (a) Patient name;
 - (b) Patient's notifiable condition or suspected condition;
 - (c) Source or suspected source; and
 - (d) Condition onset date.
- (4) Local health officials will report asymptomatic HIV infection cases to the department according to a standard code developed by the department.
- (5) When notified of an outbreak or suspected outbreak of illness due to an infectious agent or toxin, the local health department shall:
- (a) Notify the department immediately by telephone or secure electronic data transmission.
 - (b) Include in the initial notification:
 - (i) Organism or suspected organism;
 - (ii) Source or suspected source; and
 - (iii) Number of persons affected.
- (c) Within seven days of completing the outbreak investigation, submit)) using either telephone or secure electronic data transmission:
- (i) Upon receiving a case report for a condition that is immediately notifiable to the local health jurisdiction under this chapter, excluding Meningococcal disease, invasive (Neisseria meningitides); Shiga toxin-producing E. coli (STEC)/enterohemorrhagic E. coli; and Vaccinia (vaccine-acquired smallpox); and
- (ii) Of an outbreak or suspected outbreak within their jurisdiction;
- (c) Notify the department using a secure electronic disease surveillance system within three business days of receiving a case report for a condition that is not immediately notifiable to the local health jurisdiction under this chapter;
- (d) If after submitting a notification to the department, the local health officer determines no further investigation is necessary, indicate in the secure electronic disease surveillance system that no

<u>further investigation is warranted within three business days of the</u> determination.

- (e) Immediately reassign cases to the department upon determining the patient who is the subject of the case:
 - (i) Is a resident of another local health jurisdiction; or
 - (ii) Resides outside Washington state.
- (f) Submit a case report to the department using a secure electronic disease surveillance system for each case report received by the local health jurisdiction for which the local health officer determined an investigation was necessary:
- (i) Within seven days of completing the investigation for any condition notifiable to the local health jurisdiction; or
- (ii) Within twenty-one days of receiving the case report if the investigation is not complete.
- (g) Submit an outbreak report to the department ((a report on forms provided by the department or in a format approved by the department)) using secure electronic data transmission within seven days of completing an outbreak investigation. The department may waive this requirement if ((telephone or secure electronic data transmission)) notification under (b)(ii) of this subsection provided ((pertinent)) sufficient information.
- (2) The local health officer shall confirm that each case is based on clinical criteria, or laboratory criteria, or both prior to submitting the case report to the department. This criteria includes, but is not limited to, the Centers for Disease Control and Prevention, National Notifiable Diseases Surveillance System, Council of State and Territorial Epidemiologists case definitions.

NEW SECTION

WAC 246-101-513 Content of notifications, case reports, and outbreak reports—Local health officer. A local health officer shall provide the following information for each notification, case report, and outbreak report submitted under WAC 246-101-510:

- (1) Notifications must include:
- (a) Patient's first and last name;
- (b) Patient's notifiable condition;
- (c) Date local health jurisdiction was notified;
- (d) Condition symptom onset date (preferred), or alternatively, diagnosis date;
 - (e) Patient's date of birth; and
 - (f) Patient's sex.
 - (2) Case reports must include:
 - (a) Patient's first and last name;
 - (b) Patient's date of birth;
 - (c) Patient's race;
 - (d) Patient's ethnicity;
- (e) For hepatitis B acute or chronic infection case reports, pregnancy status (pregnant, not pregnant, or unknown) of patients twelve to fifty years of age;
 - (f) Investigation start date;
 - (g) Investigation completion date;
 - (h) Initial notification source;

- (i) Hospitalization status of patient;
- (j) Whether the patient died during this illness;
- (k) Probable geographic region of exposure (i.e., county, state, or country other than the United States of America);
 - (1) Travel out of the country (as applicable);
- (m) Whether the case is associated with an ongoing outbreak investigation; and
- (n) The data used to verify the case meets clinical criteria, or laboratory criteria, or both. This includes, but is not limited to, the Centers for Disease Control and Prevention, National Notifiable Diseases Surveillance System, Council of State and Territorial Epidemiologists case definitions.
 - (3) Outbreak reports must include:
 - (a) Organism or suspected organism;
 - (b) Source or suspected source; and
 - (c) Number of persons infected and potentially exposed.

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-515 Handling ((of case reports and medical)) confidential information—Local health officers and local health jurisdictions. (1) All records and specimens related to a case, that contain or are accompanied by patient identifying information are confidential. Patient identifying information includes information that can directly or indirectly identify a patient.
- (2) Local health officers and local health jurisdiction employees shall maintain the confidentiality of health information consistent with chapter 70.02 RCW and RCW 42.56.360(2).
- (3) Local health officers or local health ((departments)) jurisdictions shall establish and ((maintain)) implement confidentiality policies and procedures related to employee handling of ((all reports of cases and suspected cases, prohibiting disclosure of report information identifying an individual case or suspected cases except:
- (a) To employees of the local health department, another local health department, or other official agencies needing to know for the purpose of administering public health laws and these regulations;
- (b) To health care providers, designees of health care facilities, laboratory directors, and others for the purpose of collecting additional information about a case or suspected case as required for disease prevention and control;
- (2))) health information under this chapter and chapters 70.02 and 70.24 RCW and RCW 42.56.360(2).
- (4) Local health officers shall ((require and maintain signed confidentiality agreements with)):
- (a) Require all local health ((department)) jurisdiction employees with access to ((identifying)) health information ((related to a case or suspected case of a person diagnosed with a notifiable condition. The agreements will be renewed)) to sign confidentiality agreements;
 - (b) Retain current signed confidentiality agreements;
- (c) Reference in confidentiality agreements the penalties for violation of chapter 70.24 RCW and administrative actions that may be

taken by the local health jurisdiction if the confidentiality agreement is violated; and

- (d) Renew confidentiality agreements at least annually ((and will include reference to criminal and civil penalties for violation of chapters 70.02 and 70.24 RCW and other administrative actions that may be taken by the local health department.
- (3) Local health departments may release statistical summaries and epidemiological studies based on individual case reports if no individual is identified or identifiable)).

AMENDATORY SECTION (Amending WSR 06-16-117, filed 8/1/06, effective 9/1/06)

- WAC 246-101-520 Special conditions—AIDS and \mathtt{HIV} —Local health officers and local health jurisdictions. (1) The local health officer and local health ((department)) jurisdiction personnel shall maintain individual case reports for AIDS and HIV as confidential records consistent with the requirements of this section.
- (2) The local health officer and local health ((department)) jurisdiction personnel ((must)) shall:
- (a) Use identifying information $((\Theta n))$ of HIV-infected individuals only:
- (i) ((For purposes of contacting)) To contact the HIV-positive individual to provide test results and post-test counseling or referring the individual to social and health services; or
- (ii) To contact persons who have experienced substantial exposure, including sex and injection equipment-sharing partners, and spouses; or
- (iii) To link with other name-based public health disease registries when doing so will improve ability to provide needed care services and counseling and disease prevention, provided that the identity or identifying information of the HIV-infected person is not disclosed outside of the local health jurisdiction; or
 - (iv) As specified in WAC 246-100-072; or
- (v) To provide case reports to the ((state health)) department; or
 - (vi) To conduct investigations under RCW 70.24.022 or 70.24.024.
- (b) Destroy case report identifying information on asymptomatic HIV-infected individuals received as a result of this chapter within ((three months)) ninety days of receiving a complete case report, or maintain HIV case reports in secure systems ((that meet the following standards and are)) consistent with the ((2006)) 2011 Data Security and Confidentiality Guidelines ((developed)) for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action published by the Centers for Disease Control and Prevention.
 - (3) The local health officer shall:
- $((\frac{1}{(i)}))$ <u>(a) Describe the secure systems ((must be described)</u>) in written policies ((that are reviewed)) and review the policies annually ((by the local health officer));
- $((\frac{1}{(1)}))$ <u>(b) Limit access to case report information ((must be limited)</u>) to <u>local</u> health ((<u>department</u>)) <u>jurisdiction</u> staff who need (($\frac{1}{(1)}$)) the information to perform their job duties (($\frac{1}{(1)}$);

- (c) Maintain a current list of ((these)) local health jurisdiction staff ((must be maintained by the local health officer)) with access to case report information;
- (((iii) All)) <u>(d) Enclose</u> physical locations containing electronic or paper copies of surveillance data ((must be enclosed)) in a locked, secured area with limited access and not accessible by window;
- (((iv))) <u>(e) Store paper copies or electronic media containing surveillance information ((must be housed))</u> inside locked file cabinets that are in the locked, secured area;
- $((\frac{(v)}{(v)}))$ (f) Destroy information by either shredding it with a crosscut shredder ((must be available for destroying information and)) or appropriately sanitizing electronic media ((must be appropriately sanitized)) prior to disposal;
- $((\frac{(vi)}{)})$ $\underline{(g)}$ Store \underline{f} iles or databases containing confidential information $((\frac{must-reside}{)})$ on either stand-alone computers with restricted access or on networked drives with proper access controls, encryption software, and firewall protection;
- $((\frac{(\text{vii})}{}))$ <u>(h) Protect e</u>lectronic communication of confidential information ((must be protected)) by encryption standards ((that are reviewed annually by the local health officer)) and review the standards annually; and
- $((\frac{\text{(viii)}}{\text{)}}))$ (i) Make available locking briefcases ((must be available)) for transporting confidential information(($\frac{\cdot}{\text{(c)}}$)).
- (4) The local health officer and local health jurisdiction staff shall:
- (a) If maintaining identifying information on asymptomatic HIV-infected individuals more than ninety days following receipt of a completed case report, cooperate with the department ($(of\ health)$) in biennial review of system security measures described in <u>subsection</u> (2) (b) of this ((subsection)) section.
- $((\frac{d}{d}))$ (b) Destroy documentation of referral information established in WAC 246-100-072 containing identities and identifying information on HIV-infected individuals and at-risk partners of those individuals immediately after notifying partners or within ((three months)) ninety days, whichever occurs first, unless such documentation is being used in an investigation of conduct endangering the public health or of behaviors presenting an imminent danger to the public health ((pursuant to)) under RCW 70.24.022 or 70.24.024.
- $((\frac{(e)}{(e)}))$ <u>(c)</u> Not disclose identifying information received as a result of this chapter unless:
- (i) Explicitly and specifically required to do so by state or federal law; or
 - (ii) Authorized by written patient consent.
- (((2) Local health department personnel are authorized to use HIV identifying information obtained as a result of this chapter only for the following purposes:
- (a) Notification of persons with substantial exposure, including sexual or syringe-sharing partners;
- (b) Referral of the infected individual to social and health services;
- (c) Linkage to other public health databases, provided that the identity or identifying information on the HIV-infected person is not disclosed outside of the health department; and
 - (d) Investigations pursuant to RCW 70.24.022 or 70.24.024.
- (3) Public health databases do not include health professions licensing records, certifications or registries, teacher certification

lists, other employment rolls or registries, or databases maintained by law enforcement officials.

- (4) Local health officials will report HIV infection cases to the state health department.
- (5) Local health officers must require and maintain signed confidentiality agreements with all health department employees with access to HIV identifying information. These agreements will be renewed at least annually and include reference to criminal and civil penalties for violation of chapter 70.24 RCW and other administrative actions that may be taken by the department.
- (6)) (5) Local health officers ((must)) shall investigate potential breaches of the confidentiality of HIV identifying information by health ((department)) jurisdiction employees. The local health officer shall report all breaches of confidentiality ((must be reported)) to the state health officer ((or their designee)) for review and appropriate action.
- (((7) Local health officers and local health department personnel must assist the state health department to reascertain the identities of previously reported cases of HIV infection.))

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

WAC 246-101-525 Special condition—Influenza—Local health jurisdictions. A local health ((departments)) jurisdiction shall:

- (1) Maintain a surveillance system for influenza during the ((ap-propriate)) influenza season which may include:
 - (a) Monitoring of excess school absenteeism;
- (b) ((Sample check with)) Requesting information from health care providers((, clinics, nursing homes, and hospitals)) and health care facilities regarding influenza-like illnesses; and
 - (c) Monitoring ((of)) workplace absenteeism and other mechanisms.
- (2) ((Encourage)) Request submission of appropriate clinical specimens from a sample of patients with influenza-like illness to the Washington state public health laboratories or other laboratory approved by the state health officer.

PART VI: NOTIFIABLE CONDITIONS—DEPARTMENT OF HEALTH

AMENDATORY SECTION (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

WAC 246-101-605 Duties (($\frac{\text{of the}}{\text{of the}}$))—Department (($\frac{\text{of health}}{\text{of the}}$)). (1) The department shall:

[57] OTS-1363.6

- (a) <u>Upon request</u>, provide consultation and technical assistance to local health ((departments and)) <u>jurisdictions</u>, the department of labor and industries, and the department of agriculture when they are investigating notifiable conditions ((reports upon request)).
- (b) <u>Upon request</u>, <u>provide</u> consultation and technical assistance to health care providers, laboratories, health care facilities, and others required to ((make notifications to public health authorities of notifiable conditions upon request)) <u>comply with this chapter</u>.
- (c) Develop, maintain, and make available for local health ((departments)) <u>jurisdictions</u> guidance on investigation and control measures for notifiable ((communicable disease)) conditions.
- (d) ((Develop and)) Make <u>case report forms</u> available ((forms for the submission of notifiable conditions data)) to local health ((departments)) jurisdictions, health care providers, laboratories, health care facilities, and others required to ((make notifications to public health authorities of notifiable conditions)) comply with this chapter.
- (e) Maintain a twenty-four hour telephone number ((for reporting notifiable conditions)) to receive:
- (i) Confirmation calls for immediately notifiable condition case reports; and
- (ii) Notification of immediately notifiable case reports or outbreaks and suspected outbreaks from local health jurisdictions.
- (f) Develop routine data dissemination mechanisms that describe and analyze notifiable conditions case investigations and data((\cdot These may include annual and monthly reports and other mechanisms for data dissemination as developed by the department)) in accordance with WAC 246-101-615.
- (g) Conduct investigations and institute $\underline{\text{infection}}$ control measures as necessary.
- (h) Document the known environmental, human, and other variables associated with a case ((or suspected case)) of pesticide poisoning.
- (i) Report the results of the pesticide <u>poisoning</u> investigation to the principal health care provider named in the case report ((form)) and to the local health officer in whose jurisdiction the ((exposure has)) <u>case</u> occurred.
 - (2) The department may:
- (a) Negotiate ((alternate arrangements)) alternatives for meeting ((reporting)) requirements under this chapter through cooperative agreement between the department and any health care provider, laboratory, ((er)) health care facility, or state agency. An alternative must provide the same level of public health protection as the reporting requirement for which an alternative is sought.
- (b) ((Consolidate reporting for notifiable conditions from any))

 Under an approved cooperative agreement, relieve a health care provider, laboratory, or health care facility((, and relieve that health care provider, laboratory, or health care facility from reporting directly to each)) of the duty to notify a local health ((department)) jurisdiction, if the department can ((provide the report)) consolidate and submit notifications to the local health ((department)) jurisdiction within the ((same time as the local health department would have otherwise received it)) time frame for notification required under Table HC-1 of WAC 246-101-101 and Table Lab-1 of WAC 246-101-201.
- (c) Receive health information, demographic information, and infectious or noninfectious condition information in addition to that required under this chapter from health care providers, health care facilities, laboratories, and public health authorities.

[58] OTS-1363.6

(3) When the department receives information under subsection (2)(c) of this section, the department shall handle the information under the requirements of WAC 246-101-610.

<u>AMENDATORY SECTION</u> (Amending WSR 11-02-065, filed 1/4/11, effective 2/4/11)

- WAC 246-101-610 Handling of ((case reports and medical)) confidential information and information exempt from public disclosure—
 State health officer and department. (1) All records and specimens related to a case that contain or are accompanied by patient identifying information are confidential. Patient identifying information includes information that can directly or indirectly identify a patient.
- (2) The state health officer and department employees shall maintain the confidentiality of health information in accordance with chapter 70.02 RCW and RCW 42.56.360(2).
- ((maintain)) implement confidentiality policies and procedures related to employee handling of ((all reports of cases and suspected cases, prohibiting disclosure of report information identifying an individual case or suspected cases except:
- (a) To employees of the local health department, other local health departments, or other official agencies needing to know for the purpose of administering public health laws and these regulations.
- (b) To health care providers, specific designees of health care facilities, laboratory directors, and others for the purpose of collecting additional information about a case or suspected case as required for disease prevention and control.
- (c) For research approved by an institutional review board as indicated under chapter 42.48 RCW. The institutional review board applies federal and state privacy laws to research requests for confidential information.
- $\frac{(2)}{(2)}$)) <u>health information under this chapter and in accordance</u> with chapters 70.02 and 70.24 RCW and RCW 42.56.360(2).
 - (4) The state health officer or department shall:
- (a) Require all department employees, contractors, and others with access to ((identifying)) health information ((related to a case or suspected case of a person diagnosed with a notifiable condition shall be required)) to sign ((a)) confidentiality agreements ((\cdot, The));
 - (b) Retain current signed confidentiality agreements;
- (c) Reference in confidentiality agreements the penalties for violation of chapter 70.24 RCW and administrative actions that may be taken by the department if the confidentiality agreement is violated; and
- $\underline{\text{(d)}}$ Renew confidentiality agreements ((shall be renewed)) at least annually ((and shall include reference to criminal and civil penalties for violation of chapters 70.02 and 70.24 RCW and other administrative actions that may be taken by the department)).

WAC 246-101-615 ((Requirements for)) Data dissemination and notification—Department. The department shall:

- (1) Distribute periodic epidemiological summary reports and an annual review of public health issues to local health officers ((and)), local health ((departments)) jurisdictions, and the department of labor and industries.
- (2) ((Upon execution of a data sharing agreement,)) Make available ((any data or other)) case investigation documentation ((in its possession regarding)) for notifiable conditions reported directly to the department to local health officers or ((their designees within two days of a request)) the department of labor and industries within twenty-four hours of receipt by the department.
- (3) Make other data necessary to conduct case investigations or epidemiological summaries available within two business days of a request from a public health authority.
- $((\frac{3}{3}))$ <u>(4)</u> Periodically distribute statistical summaries and epidemiological studies based on individual case reports if no $(\frac{1}{3})$ <u>vidual</u>)) <u>patient</u> is identified or identifiable.

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

WAC 246-101-630 Special condition—Antibiotic resistant disease— Department. The department shall((÷

- (1))) <u>maintain</u> a surveillance system for monitoring antibiotic resistant disease ((that may include)) <u>including</u>, but not limited to:
- $((\frac{a}{a}))$ <u>(1)</u> Development of a sentinel network of laboratories to provide information regarding antibiotic resistant disease; and
- $((\frac{b}{b}))$ (2) Sample checks with health care providers $(\frac{b}{b})$ and health care facilities regarding antibiotic resistant disease.
- $((\frac{(2) \ \, \text{Encourage submission of appropriate clinical}}))$ $\underline{(3) \ \, \text{Request}}$ $\underline{\text{the health care providers and laboratories submit}}$ specimens from a sample of patients with antibiotic resistant disease to the Washington state public health laboratories or other laboratory approved by the state health officer.

AMENDATORY SECTION (Amending WSR 06-16-117, filed 8/1/06, effective 9/1/06)

- WAC 246-101-635 Special conditions—AIDS and HIV—Department. The following provisions apply ((for)) to the use of AIDS and HIV notifiable conditions case reports, related information, and data and is in addition to the requirements established under WAC 246-101-610:
- (1) Department personnel ((must)) shall not disclose identifying information ((received as a result of receiving information regarding

a notifiable conditions report of)) related to a case of AIDS or HIV unless:

- (a) Explicitly and specifically required to do so by state or federal law; or
 - (b) Authorized by written patient consent.
- (2) Department personnel ((are authorized to)) may use HIV identifying information ((received as a result of receiving information regarding a notifiable conditions report of)) related to a case of AIDS or HIV only for the following purposes:
- (a) Notification of persons with substantial exposure, including sexual or syringe-sharing partners;
- (b) Referral of the infected individual to social and health services; and
- (c) Linkage to other public health databases, provided that the identity or identifying information $((\frac{on}{o}))$ of the HIV-infected person is not disclosed outside $((\frac{of}{o}))$ the $((\frac{health}{o}))$ department.
- (3) ((For the purposes of this chapter, public health databases do not include health professions licensing records, certifications or registries, teacher certification lists, other employment rolls or registries, or databases maintained by law enforcement officials.
- $\frac{(4)}{(4)}$) The state health officer ((must)) <u>shall</u> require and maintain signed confidentiality agreements with all department employees with access to HIV identifying information. <u>The state health officer shall ensure these agreements ((will be)) <u>are renewed at least annually and include reference to ((criminal and civil)) penalties for violation of chapter 70.24 RCW and ((other)) administrative actions that may be taken by the department.</u></u>
- $((\frac{5}{}))$ $\underline{(4)}$ The state health officer $(\frac{must}{})$ \underline{shall} investigate potential breaches of the confidentiality of HIV identifying information by department employees. All breaches of confidentiality shall be reported to the state health officer or their authorized representative for review and appropriate action.
- ((+6))) (5) The department ((must)) shall maintain all HIV case reports in a name-based surveillance system solely for the purpose of complying with HIV reporting guidelines from the ((federal)) Centers for Disease Control and Prevention, and ((must)) shall not disclose or otherwise use any information contained in that system for any other purpose, except as expressly permitted by this section.
- (((7) Authorized representatives of the department must review available records to reascertain the identities of previously reported cases of asymptomatic HIV infection and retain those cases in a confidential name-based system.
 - (8))) (6) The department ((must)) shall:
- (a) Maintain HIV case reports in secure systems that meet the following standards and are consistent with the ((2006)) 2011 Data Security and Confidentiality Guidelines ((developed)) for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action published by the Centers for Disease Control and Prevention((÷

(a)));

- (b) Describe secure systems ((must be described)) in written policies ((that are reviewed)) and review the policies annually ((by the overall responsible party));
- $((\frac{b}{b}))$ <u>(c) Limit access to case report information ((must be limited</u>)) to ((health)) department staff who need it to perform their job duties ((and));

- (d) <u>Maintain</u> a current list of ((these)) <u>department</u> staff ((must be maintained by the overall responsible party)) with access to case report information;
- (((c))) <u>(e) Enclose all</u> physical locations containing electronic or paper copies of surveillance data ((must be enclosed)) in a locked, secured area with limited access and not accessible by window;
- ((\frac{(d)}{)}) (f) Store paper copies or electronic media containing surveillance information ((must be housed)) inside locked file cabinets that are in the locked, secured area;
- $((\frac{(e)}{(e)}))$ (g) Destroy information by either shredding it with a crosscut shredder ((must be available for destroying information and)) or appropriately sanitizing electronic media ((must be appropriately sanitized)) prior to disposal;
- $((\frac{f}{f}))$ (h) Store files or databases containing confidential information ((must reside)) on either stand-alone computers with restricted access or on networked drives with proper access controls, encryption software, and firewall protection;
- $((\frac{g}))$ <u>(i) Protect e</u>lectronic communication of confidential information ((must be protected)) by encryption standards ((that are reviewed)) and review the standards annually ((by the overall responsible party));
- $((\frac{h}{h}))$ <u>(j)</u> <u>Use locking briefcases ((must be available</u>)) for transporting confidential information.
- $((\frac{(9)}{)}))$ The state health officer $((\frac{or\ designee\ must}))$ shall conduct a biennial review of <u>local health jurisdictions</u> system security measures described in WAC 246-101-520 $((\frac{(1)}{b}))$ at <u>local health jurisdictions</u>)) that are maintaining records by name.
- (($\frac{(10)}{)}$) (8) When providing technical assistance to a local health (($\frac{department}{)}$) jurisdiction, authorized representatives of the department may temporarily, and subject to the time limitations in WAC 246-101-520, receive the names of reportable cases of HIV infection for the purpose of partner notification, or special studies. Upon completion of the activities by representatives of the (($\frac{department}{)}$) department, named information will be provided to the local health (($\frac{department}{)}$) jurisdiction subject to the provisions of WAC 246-101-520.
- (($\frac{(11)}{\text{By December 2007}}$, the state health officer, in cooperation with local health officers, will report to the board on:
- (a) The ability of the HIV reporting system to meet surveillance performance standards established by the federal Centers for Disease Control and Prevention;
- (b) The cost of the reporting system for state and local health departments;
 - (c) The reporting system's effect on disease control activities;
- (d) The impact of HIV reporting on HIV testing among persons at increased risk of HIV infection; and
 - (e) The availability of anonymous HIV testing in the state.
- $\frac{(12)}{(12)}$)) $\underline{(9)}$ The state health officer ((must)) \underline{shall} provide a report to the state board of health if federal policy no longer requires that HIV surveillance systems be name-based.

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

WAC 246-101-640 Special condition—Birth defects. The department shall enter into a data sharing agreement with the office of the superintendent of public instruction (the superintendent) to access data from databases maintained by the superintendent containing student health information for the purpose of identifying cases of autism or other conditions of public health interest.

PART VII: NOTIFIABLE CONDITIONS-DEPARTMENT OF LABOR AND INDUSTRIES

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

- WAC 246-101-705 Duties ((of the))—Department of labor and industries. (1) The department of labor and industries shall:
- (a) <u>Be responsible for the investigation of cases identified as notifiable to the department of labor and industries under this chapter;</u>
- (b) Provide consultation and technical assistance to local health
 ((departments)) jurisdictions and the department investigating ((notifiable conditions reports)) cases;
- ((\(\frac{(b)}{c}\))) (c) Upon request, provide consultation and technical assistance to health care providers, laboratories, health care facilities, and others required to ((\(\frac{make notifications to public health authorities of notifiable conditions upon request)) notify and cooperate with public health authorities under this chapter;
- (((c))) <u>(d)</u> Provide technical assistance to businesses and labor organizations for understanding the use of notifiable conditions data collected and analyzed by the department of labor and industries; and
- $((\frac{d}{d}))$ <u>(e)</u> Develop routine data dissemination mechanisms that describe and analyze notifiable conditions case investigations and data. These may include annual and monthly reports and other mechanisms for data dissemination as developed by the department of labor and industries.
 - (2) The department of labor and industries may:
- (a) Receive data through ((any)) cooperative ((relationship)) agreement negotiated by the department of labor and industries and ((any)) a health care provider, laboratory, or health care facility;
- (b) Receive health information, demographic information, and infectious or noninfectious condition information in addition to that required under this chapter from health care providers and health care facilities.

(3) When the department of labor and industries receives information under this section, the department of labor and industries shall handle the information under the requirements of WAC 246-101-710.

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

- WAC 246-101-710 Handling of ((case reports and medical information)) confidential information—Department of labor and industries.

 (1) ((The department of labor and industries shall establish and maintain confidentiality procedures related to employee handling of all reports of cases and suspected cases, prohibiting disclosure of report information identifying an individual case or suspected cases except:
- (a) To employees of the local health department, the department, or other official agencies needing to know for the purpose of administering public health laws and these regulations; and
- (b) To health care providers, specific designees of health care facilities, laboratory directors, and others for the purpose of collecting additional information about a case or suspected case as required for occupational condition prevention and control.
- (2)) All records and specimens related to a case that contain or are accompanied by patient identifying information are confidential. Patient identifying information includes information that can directly or indirectly identify a patient.
- $\underline{\mbox{(3)}}$ The <u>director of the</u> department of labor and industries shall ((require and maintain signed confidentiality agreements with)):
- ((identifying)) health information ((related to a case or suspected case of a person diagnosed with a notifiable condition. Such agreements will be renewed at least annually and include reference to criminal and civil penalties for violation of chapter 70.02 RCW, other chapters of pertinent state law, and other administrative actions that may be taken by the department of labor and industries.
- (3) The department of labor and industries may release statistical summaries and epidemiological studies based on individual case reports if no individual is identified or identifiable)), to sign confidentiality agreements;
 - (b) Retain signed confidentiality agreements;
- (c) Reference in confidentiality agreements the administrative actions that may be taken by the department of labor and industries if the confidentiality agreement is violated; and
 - (d) Renew confidentiality agreements at least annually.

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

- WAC 246-101-715 ((Requirements for)) Data dissemination and notification—Department of labor and industries. The department of labor and industries shall:
- (1) Distribute periodic epidemiological summary reports and an annual review of public health issues to local health officers $((and))_{,}$ local health $((departments))_{,}$ jurisdictions, and the department.
- (2) Make available case investigation documentation for notifiable conditions reported directly to the department of labor and industries, data necessary to conduct case investigations, or epidemiological summaries to local health officers or ((their designees upon execution of a data sharing agreement)) the department within two business days of a request.

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

- WAC 246-101-730 Special condition—Hospitalized burns. The department of labor and industries shall maintain a surveillance system for monitoring hospitalized burn((s)) patients that may include:
- (1) Development of a sentinel network of burn treatment centers and hospitals to provide information regarding hospitalized burn ((s)) patients; and
- (2) Sample checks with health care providers ($(\frac{1}{r}, \frac{1}{r})$) and ($(\frac{1}{r}, \frac{1}{r})$) health care facilities regarding hospitalized burn($(\frac{1}{r})$) patients.

PART VIII: NOTIFIABLE CONDITIONS—DEPARTMENT OF AGRICULTURE

NEW SECTION

- WAC 246-101-805 Duties—Department of agriculture. (1) For the purposes of this section, "new, emerging, or unusual animal diseases or disease clusters with potential public health significance" means zoonotic or potentially zoonotic diseases in animals that have never or rarely been observed in Washington state (new or emerging); or appear in a new species or show evidence of higher pathogenicity than expected (unusual); or appear in a higher than expected number of animals clustered in time or space (cluster).
 - (2) The department of agriculture shall:

- (a) Submit an individual case report for each animal case of a condition identified in Table Agriculture-1 to the department immediately upon being notified of the animal case using secure electronic data transmission under this table and this chapter.
- (b) Call the department and confirm receipt immediately after submitting a case report for the following conditions:
- (i) Anthrax (Bacillus anthracis or Bacillus cereus biovar anthracis);
 - (ii) Influenza virus in swine, influenza H5 and H7 (avian);
- (iii) Livestock exposed to toxic substances which may threaten public health;
 - (iv) Plague (Yersinia pestis);
 - (v) Rabies (suspected human or animal);
 - (vi) Transmissible Spongiform Encephalopathy; and
 - (vii) Tularemia (Francisella tularensis).

Table Agriculture-1 (Conditions Notifiable by the Department of Agriculture)

Notifiable Condition (Agent)

Anthrax (Bacillus anthracisor B. cereus biovar anthracis)

Arboviral Diseases

California serogroup

Chikungunya

Dengue

Eastern equine encephalitis

Japanese encephalitis

La Crosse encephalitis

Powassan

St. Louis encephalitis

Western equine encephalitis

West Nile virus

Zika

Brucellosis (Brucella species)

Coccidioidomycosis (Coccidioides species)

Cryptococcus gattii or undifferentiated Cryptococcus species (i.e., Cryptococcus not identified as C. neoformans)

Cysticercosis (Taenia solium)

Echinococcosis (*Echinococcus* species)

Ehrlichiosis (Ehrlichia species)

Glanders (Burkholderia mallei)

Influenza virus in swine, influenza H5 and H7 (avian)

Leptospirosis (Leptospira species)

Livestock exposed to toxic substances which may threaten public health

Psittacosis (Chlamydia psittaci)

Plague (Yersinia pestis)

Q Fever (Coxiella burnettii)

Rabies (suspected human or animal)

Shiga toxin-producing E. coli infections/enterohemorrhagic E. coli infections

Transmissible Spongiform Encephalopathy

Trichinosis (Trichinella spiralis)

Tuberculosis

Tularemia (Francisella tularensis)

Vancomycin-resistant (Staphylococcus aureus)

Zoonotic Viral Hemorrhagic Fever

New, emerging, or unusual animal diseases or disease clusters with potential public health significance.

- (3) The department of agriculture may provide additional health information, demographic information, or infectious or noninfectious condition information than is required under this chapter to the department, local health jurisdiction, or both when it determines that the additional information will aid the public health authority in protecting and improving the public's health through prevention and control of infectious and noninfectious conditions.
- (4) When the department of agriculture submits information under subsection (3) of this section, they shall submit the information using secure electronic data transmission.
 - (5) The department shall:
- (a) Consult with the department of agriculture on all animal cases; and
- (b) Notify the local health jurisdiction of animal cases submitted to the department.

NEW SECTION

WAC 246-101-810 Content of case reports—Department of agriculture. (1) The state department of agriculture shall provide the following information for each animal case required under WAC 246-101-805:

- (a) Animal species;
- (b) Animal county of current residence;
- (c) Diagnosis or suspected diagnosis of the condition;
- (d) Contact name;
- (e) Contact address;
- (f) Contact telephone number;
- (g) Pertinent laboratory data, if available; and
- (h) Other information of public health significance collected under chapter 16-70 WAC.
- (2) The local health officer or state health officer may request additional information of epidemiological or public health value when conducting a case investigation or for control of a notifiable condition.
- (3) The state health officer and local health officer shall handle all information received under this chapter including, but not limited to, information collected under this subsection and WAC 246-101-805 and information collected during case investigations or for investigation or control of a notifiable condition, consistent with WAC 246-101-515, 246-101-610, and RCW 42.56.380.

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 246-101-001	Provisions of general applicability.
WAC 246-101-301	Notifiable conditions and health care facilities.
WAC 246-101-305	Duties of the health care facility.
WAC 246-101-310	Means of notification.
WAC 246-101-315	Content of notifications.
WAC 246-101-320	Handling of case reports and medical information.
WAC 246-101-401	Notifiable conditions and the responsibilities and duties of others.
WAC 246-101-501	Notifiable conditions and local health departments.
WAC 246-101-601	Notifiable conditions and the department of health.
WAC 246-101-620	Requirements for notification to the department of labor and industries.
WAC 246-101-625	Content of notifications to the department of labor and industries.
WAC 246-101-701	Notifiable conditions and the department of labor and industries.
WAC 246-101-720	Requirements for notification to local health departments.
WAC 246-101-725	Requirements for notification to the department of health.