Small Business Economic Impact Statement
Chapter 246-101 WAC, Notifiable Conditions
February 3, 2021

SECTON 1:

Describe the proposed rule, including: a brief history of the issue; an explanation of why the proposed rule is needed; and a brief description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

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 State Board of Health (Board) and Department of Health (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.

On April 17, 2017, the Department and Board filed a Pre-proposal Statement of Inquiry (CR-101) to begin joint rule making to consider adopting notification requirements for seven new conditions and classes of conditions, and notification and specimen submission requirements for three conditions identified in the current rules under the definition of “Other Rare Disease of Public Health Significance”. After further review by Department subject matter experts, the Department and Board withdrew the original CR-101 and filed a new Pre-proposal Statement of Inquiry on May 18, 2018 to clarify and expand the scope of rule making. The new CR-101 expanded the list of new conditions and classes of conditions for consideration to 21, and expanded to four the number of specific conditions identified in the definition of “Other Rare Disease of Public Health Significance” considered for adoption.

Over the course of rule development, the Department and Board consulted with more than 50 subject matter experts at the Department of Health, Department of Labor and Industries, and Washington State Department of Agriculture, and formed a technical advisory committee (TAC) to gather information in 2018. Members of the TAC represented a variety of stakeholders including health care providers, health care facilities, laboratories, local health jurisdictions, professional associations, health equity organizations, and state agencies. The draft rules were broadly distributed in May 2019 to gather informal comments from interested parties. Further comments were sought in June and July 2019 from local health jurisdictions. Members of the regulated community and the TAC were asked to complete a cost questionnaire for the significant changes in the draft rules in November 2019 to complete the proposed rules and required analyses. In addition, Board and Department staff held two information and listening sessions with community and advocacy organizations to help inform newly established reporting categories for patient ethnicity, race, and preferred language data components. The draft rules were broadly distributed again in December 2020 to gather informal comments from interested parties. A supplemental cost questionnaire was distributed to the regulated community in December of 2020 to gather cost information on changes made the draft rules since the 2019 cost questionnaire.

If adopted, the proposed rules would significantly amend notification requirements applicable to health care providers, health care facilities, laboratories, local health jurisdictions, 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;
- 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, investigation 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.

SECTION 2:

Identify which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS) codes and what the minor cost thresholds are.

Table 1:

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	2576	$19,450.07	$5,891.42

	(except Mental Health Specialists)			
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

SECTION 3:

Analyze the probable cost of compliance. Identify the probable costs to comply with the proposed rule, 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, laboratory 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. Tables 2 and 3 outline the probable costs by condition (per case) along with the total annual costs by condition. Table 4 outlines probable annual costs per entity. Table 5 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 2: Probable Annual per Case Costs (WAC 246-101-101, -105, -115, -201, -205, -215, -225)

Condition	**Providers / Facilities: Added Cost per Case Report[1]**	**Laboratories: Added Cost per Laboratory 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
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	$0[5]	$0	$0	Fewer test results	$0

[1] Costs are for staff time to prepare the case report.
[2] Costs are for staff time to prepare the laboratory 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.
[5] New condition for health care facilities only.

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
Coronavirus: Novel coronavirus (COVID-19)	Novel coronavirus (SARS-CoV-2) estimated costs are outlined in Table 3.				
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	N/A	$106,380	$0	3,546	$106,380.00

gonorrhoeae) (De-identified negative results)					
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
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	$0	$0	$0	Fewer notifications	$0

complex)					
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					$1,665,227.50 - $1,805,497.50

Table 3: Probable per Case Costs for Novel Coronavirus (SARS-CoV-2) (WAC 246-101-101, -105, -115, -201, -205, -215, -225)

Condition	**Providers / Facilities: Added Cost per Case Report[6]**	**Laboratories: Added Cost per Laboratory Report[7]**	**Laboratories: Added Cost per Specimen Submission[8]**	**Assumed Number of Cases per Year[9]**	**Total Annual Per-Case Cost**
Coronavirus: Novel coronavirus (SARS-CoV-2)	$6,187,500.00	$2,250,000.00	$187,000	75,000 (estimate based on very limited data)	$8,624,500.00

Table 4: Probable Annual Costs per Entity (costs not captured in Table 2 or Table 3)

Cost Description	Health Care Facilities	Laboratories:
Annual updates to the system used to transmit data from the facility to the laboratory with a specimen (regular updates required with each new version of the laboratory system)	$2,500 - $5,000	N/A

[6] Costs are for staff time to prepare the case report.
[7] Costs are for staff time to prepare the laboratory report.
[8] Costs are for staff time to prepare documentation to accompany specimens and packaging materials.
[9] 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.

Costs associated with contacting the provider or the facility to collect patient information required under WAC 246-101-205, WAC 246-101-215, and WAC 246-101-225.[10]	N/A	$0 - $41,795.80
Total Cost Per Regulated Entity	$2,500 - $5,000	$0 - $41,795.80

Table 5: 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
Lab reporting updates and information system data components to transmit data to laboratories required in WAC 246-101-105	$15,000	N/A
System updates to report data components required in WAC 246-101-115	$75,000	N/A
Vendor updates to report data components required in WAC 246-101-115	$40,000	N/A
Total Cost Per Regulated Entity	$140,000	$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, laboratory reports, and specimen submission forms. Health care facilities. The costs of these changes are included in Table 2: Probable Annual Costs (WAC 246-101-101, -105, -115, -201, -205, -215, -225), Table 3 (Probable per Case Costs for Novel Coronavirus (SARS-CoV-2) (WAC 246-101-101, -105, -115, -201, -205, -215, -225): Table 4: Probable Annual Costs per Entity (costs not captured in Table 2 or Table 3) (WAC 246-101-105, -115, -205, -215, and -225), and Table 5: Probable One-time Costs (WAC 246-101-101, -105, -115, -201, -205, -215, -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.

[10] WAC 246-101-105, if adopted as proposed, will require providers and facilities to include all of these data components with a specimen when they order a lab test for a notifiable condition, but laboratories have expressed concerns that providers/facilities will not consistently provide these data and that the lab will incur the cost of gathering the data.

WAC 246-101-205, Duties: Laboratory directors

The proposed rule requires laboratories to submit presumptive and final test results to the Department of Health for a patient residing outside and visiting Washington State. The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for patients visiting Washington State are included in costs identified in Tables 2 through 5 for updating laboratory LIMS and ELR systems, updating standard operating procedures for each notifiable condition, and confirming receipt for laboratory 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 of Health and State Board of Health 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, address health inequities, 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.[11]

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

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.

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

One-Time Costs Per Entity
The probable one-time cost per entity is $140,000 for providers/facilities and $49,768 for non-CLIA waived laboratories (Table 5). The estimate for each laboratory is likely inflated due to the fact that some facilities and laboratories do not test for many of the conditions and will not incur 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). Similarly, some facilities indicated that they would incur zero one time costs. 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. Similarly, the Department assumes that some facilities will incur zero one-time costs associated with the proposed amendments, with any one facility incurring no more than $140,000 in one-time costs.

Annual Costs Per Entity
The annual costs by entity are also variable and therefore create a large range (Table 4). For health care facilities the re-occurring costs per entity result from the need to make annual updates to the data system used to transmit data from the facility to the laboratory with a specimen. These regular updates are required with each new version of the laboratory system. This probable annual cost ($2,500 - $5,000) will not impact every facility. Some facilities use paper lab requisition forms for specimen submittals. These paper forms will need to be updated one time when the proposed rules go into effect, but paper forms will not require annual updates.

Annual Costs for All Regulated Entities in Washington State Combined
In addition to these costs per entity, the probable annual costs for all regulated entities in Washington State combined (Table 2), for all conditions (excluding COVID-19 reporting discussed below) range from$1,665,227.50 - $1,805,497.50. 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. Another laboratory estimated the rules would cost them at least $41,795.80 annually—but that was based primarily on the assumption the providers/facilities would not provide all of the required information to the laboratory with each specimen, which would then shift the burden of gathering this information onto the laboratory. Sufficient notification,

education, and technical support to ensure providers/facilities come into compliance with the rules should negate that cost.

Annual Costs Associated with Reporting Novel Coronavirus (SARS-CoV-2) for All Regulated Entities in Washington State Combined

In addition to the probable annual costs of reporting all other conditions for all regulated entities in Washington State combined (Table 2), there are additional probable costs associated with reporting COVID-19. If Washington has close to 75,000 COVID-19 cases per year once the rules become effective (an estimate based on very limited data), the estimated annual cost of reporting this condition for all regulated entities in Washington State combined is $8,624,500.00 (Table 3). The cost per case of reporting COVID-19 is presumably accompanied by per-case revenue increases for facilities and laboratories collecting samples and conducting testing. In addition, while the estimated costs of reporting COVID-19 increases as the estimated number of annual cases increases, the public health need and justification for reporting of these cases also increases.

SECTION 4:

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

Based on the minor cost thresholds in Section 2 and the summary of costs in Section 3 of this Small Business Economic Impact Statement, the Department and Board assume that the proposed rules will impose more than minor costs on the businesses in the industry. As shown in Section 2, the minor cost thresholds based on 1% of average annual payroll range from $1,482.68 to $622,801.12 depending on the entity. The minor cost thresholds based on 0.3% of average annual receipts ranges from $351.33 to $156,044.36 depending on the entity (Table 1). The estimated costs of the rules exceed these number for at least some entities (see Section 3). For example, laboratories have a probable one-time cost of up to $49,768 (Table 5), plus $0 - $41,795.80 in annual costs (Table 4), plus costs per case (Tables 2 and 3), which exceeds the $15,104.13 minor cost threshold for laboratories based on average annual payroll (Table 1).

SECTION 5:

Determine 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 in Section 2 and the summary of costs in Section 3 of this Small Business Economic Impact Statement, 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. For example, as described in Section 4, laboratories have a probable one-time cost of up to $49,768 (Table 5), plus $0 - $41,795.80 in annual costs (Table 4), plus costs per case (Tables 2 and 3). While the costs per case reported will likely increase with the size and revenue of the laboratory, the one-time and annual costs are associated with updating data systems and forms, which represent changes that laboratories may need to make despite the size of their business. This suggests that at least some small laboratories may have similar costs in these arenas as large laboratories which will likely create a disproportionate impact on small businesses.

SECTION 6:

If the proposed rule has a disproportionate impact on small businesses, identify the steps taken to reduce the costs of the rule on small businesses. If the costs can not be reduced provide a clear explanation of why.

The Department and Board considered many alternative changes to the method of reporting for laboratories as described below. Ultimately the agencies opted to remove postal mail and handwritten laboratory report as options for submitting laboratory reports, but did not mandate Electronic Lab Reporting Using HL7 messaging or remove secure facsimile as reporting option.

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 laboratory 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 laboratory 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 laboratory 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 Laboratory Report as Options for Submitting Laboratory 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 laboratory 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 laboratory 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.

SECTION 7:

Describe 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.

SECTION 8:

Identify the 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.