Attachment 12. Justification for the Addition of Disease-Specific Data Elements

451 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for 22 conditions: Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE), Carbon Monoxide (CO) Poisoning; Tuberculosis (TB) Disease, Latent TB Infection (TB Infection), Shiga Toxin-Producing Escherichia coli (STEC), Salmonellosis, Shigellosis, Campylobacteriosis, Cryptosporidiosis, Cyclosporiasis, Cholera, Vibriosis, *S*. Typhi Infection, *S*. Paratyphi Infection, Lyme Disease, Invasive Haemophilus influenzae Disease, Meningococcal Disease, Invasive Pneumococcal Disease, Psittacosis, Legionellosis, Tickborne Rickettsial Diseases (TBRD), and Hepatitis. Names, descriptions, value set codes (the answer list for coded data elements from CDC vocabulary server (PHIN VADS) which can be accessed at http://phinvads.cdc.gov), and justification for the addition of these new data elements are below:

CP-CRE: 8 Data Elements

8 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for CP-CRE. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CP-CRE are an emerging public health problem in the United States. Early detection and aggressive implementation of infection prevention and control strategies are necessary to prevent further spread of CP-CRE, especially novel CP-CRE. These data elements will contribute to enhanced public health surveillance efforts on the part of the CDC program which will allow for timely public health action. Data elements included in this request will help report CP-CRE to CDC with all available testing results (positive, negative, intermediate) of phenotypic carbapenemase production tests as well as results (positive and negative) of any tests performed for resistance mechanisms (e.g., KPC PCR).

Value Set Code	Data Element Name	Data Element Description
TBD	Type of case	Type of case (i.e., was case identified based on testing of a clinical specimen or screening specimen)
TBD	State lab isolate id	Lab isolate identifier from public health lab for mechanism testing
TBD	Phenotypic Test Method	Phenotypic Test Name (phenotypic methods for carbapenemase production)
TBD	Phenotypic Test Result	Result of Phenotypic test

TBD	Genotypic Test Name	Test performed to identify carbapenemase (molecular methods for resistance mechanism)
TBD	Genotypic Test Result	Result of test to identify carbapenemase
TBD	County of facility	County of facility where specimen was collected
TBD	State of facility	State of facility where specimen was collected

CO Poisoning: 4 Data Elements

4 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for CO Poisoning. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The data elements will contribute to enhanced surveillance efforts on the part of the CDC program and allow the program to perform additional epidemiological analyses for CO Poisoning.

Value Set Code	**Data Element Name**	**Data Element Description**
TBD	Smoking status	Current smoker (yes, no, unknown)
TBD	Source of data for case ascertainment	• Hospital/emergency department • Poison control center • Laboratory report • Death certificate • Provider/medical examiner report
TBD	Carboxyhemoglobin (COHb) level	Laboratory test result (%)
TBD	Intent	• Intentional • Unintentional

TB Disease: 95 Data Elements

95 data elements including 36 that are highlighted in yellow that were not included in the ICR (OMB No. 0920-0026), Report of Verified Case of Tuberculosis (RVCT), were added for TB Disease. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: Additional data elements are needed to better characterize the evolving epidemiology of TB Disease in the United States, improve surveillance for drug resistant TB Disease as required by the 2015 National Action Plan for Multidrug-Resistant TB Disease, and recommendations of the Council of State and Territorial

Epidemiologists (CSTE). These additional data elements were selected with substantial input from the state and local public health agencies that will be responsible for collecting and submitting the data.

Value Set Code	Data Element Name	Data Element Description
N/A	TB State Case Number	State case number for the case specific to TB investigations (4 digit report year + 2 letter state + 9 digit alphanumeric number)
N/A	City or County Case Number	City or county case number assigned to this case
PHVS_Sex_MFU	Birth Sex	What was the patient's sex at birth?
PHVS_CaseCountStatus_TB	Previously Counted Case	Has this case already been counted by another reporting area?
N/A	Previously Reported State Case Number	If case previously counted, provide the state case number from the other reporting area.
PHVS_BirthCountry_CDC	Country of Verified Case	If the case was previously reported by another country, specify the country.
N/A	Patient Address City	Patient address city
PHVS_YesNoUnknown_CDC	Inside City Limits	Is the patient's residence within city limits?
N/A	Census Tract of Case-Patient Residence	Census tract where the address is located is a unique identifier associated with a small statistical subdivision of a county. Census tract data allows a user to find population and housing statistics about a specific part of an urban area.
PHVS_Race_CDC	Detailed Race	Provide the detailed race information for the patient.
N/A	Date Arrived in US	If country of birth is NOT United States, regardless of citizenship, indicate the date when the patient first arrived in the US.
PHVS_YesNoUnknown_CDC	US Born	Was the patient eligible for US citizenship at birth?
PHVS_BirthCountry_CDC	Primary Guardian(s) Country of Birth	Indicates the birth country of the primary guardian(s) of patient (pediatric [<15 years old] cases only)
PHVS_YesNoUnknown_CDC	Remain in US After Report	If not US reporting area, did patient remain in the United States for >= 90 days after report date?
PHVS_PrimaryReasonForEvaluation_TB	Initial Reason for Evaluation	What was the initial reason the patient was evaluated for TB?
PHVS_LabTestType_TB	Test Type	Epidemiologic interpretation of the type of test(s) performed for this case. Please provide a response for each of the main test types (culture, smear, pathology/cytology, NAA, TST, IGRA, HIV, diabetes) If test was not done please indicate so.
PHVS_LabTestInterpretation_TB	Test Result	Epidemiologic interpretation of the results of the test(s) performed for this case - This is a qualitative test result. (e.g., positive, detected, negative)
N/A	Date/Time of Lab Result	Date result sent from reporting laboratory. Time of result is an optional addition to date.

PHVS_MicroscopicExamCultureSite_TB	Specimen Source Site	This indicates the anatomical source of the specimen tested.
N/A	Specimen Collection Date/Time	Date of collection of laboratory specimen used for diagnosis of health event reported in this case report. Time of collection is an optional addition to date.
N/A	Test Result Quantitative	Quantitative test result value
PHVS_UnitofMeasure_TB	Result Units	Units of measure for the Quantitative Test Result Value
PHVS_TypeofRadiologyStudy_CDC	Type of Chest Study	Indicate the type of chest study performed. Please provide a response for each of the main test types (plain chest radiograph, chest CT Scan) and if test was not done please indicate so.
PHVS_ResultofRadiologyStudy_TB	Result of Chest Study	Result of chest diagnostic testing
PHVS_YesNoUnknown_CDC	Evidence of Cavity	Did test show evidence of cavity?
PHVS_YesNoUnknown_CDC	Evidence of Miliary TB	Did test show evidence of miliary TB?
N/A	Date of Chest Study	Date of the chest diagnostic study
PHVS_EpidemiologicalRiskFactors_TB	Patient Epidemiological Risk Factors	Exposed risk factors for the patient - Please provide a response for all risk factors in the value set with an associated indicator
PHVS_YesNoUnknown_CDC	Patient Epidemiological Risk Factors Indicator	Provide a response for each value in the patient epidemiological risk factors value set
PHVS_CorrectionalFacilityType_NND	Type of Correctional Facility	If patient was a Resident of Correctional Facility at Diagnostic Evaluation, indicate the type of correctional facility.
PHVS_LongTermCareFacilityType_NND	Type of Long-Term Care Facility	If patient was a Resident of Long Term Care Facility at Diagnostic Evaluation, indicate the type of long term care facility.
PHVS_SmokingStatus_CDC	Smoking Status	What is the patient's current tobacco smoking status?
PHVS_YesNoUnknown_CDC	Patient lived outside of US for more than 2 months	Residence or Travel in countries other than the United States, Canada, Australia, New Zealand, or countries in northern or western Europe for >60 consecutive days at any point in the patient's lifetime.
PHVS_YesNoUnknown_CDC	Identified During Contact Investigation	Was the patient identified during the contact investigation around the likely source case?
PHVS_YesNoUnknown_CDC	Evaluation During Contact Investigation	If patient was identified during contact investigation, was the patient evaluated for TB during the contact investigation?
N/A	Linked Case Number	State case numbers for epidemiologically linked cases
N/A	Date Treatment or Therapy Started	Date the initial treatment regimen was started
PHVS_TreatmentAdministrationType_TB	Treatment Administration Type	Choose all treatment administration types that apply to the case, such as DOT, eDOT, or SAT.
N/A	Date Treatment or Therapy Stopped	Date treatment stopped

PHVS_CaseVerification_TB	Case Verification Category	Indicates case verification criteria result based on factors such as culture results, smear results, major and additional sites of the disease, x-ray results, TST, IDR, reason therapy was stopped.
PHVS_GeneralConditionStatus_TB	Status at Diagnosis of TB	Was the patient alive or dead at the time of diagnostic evaluation?
PHVS_AdditionalDiseaseSite_TB	Site of Disease	What was the site of the patient's TB disease?
PHVS_YesNoUnknown_CDC	Contact Investigation	Was a contact investigation conducted around this case?
PHVS_DiagnosisType_TB	Diagnosis Type	Previous TB or LTBI Diagnosis - Provide only 1 response for LTBI, multiple responses for TB are allowed
PHVS_YesNoUnknown_CDC	History of Previous Illness	Did the subject have a history of TB or LTBI?
N/A	Date of Previous Illness	Date of previous diagnosis
N/A	Previous State Case Number	Previous TB or LTBI State Case Number
PHVS_YesNoUnknown_CDC	Completed Treatment for Previous Diagnosis	Completed Treatment for Previous Diagnosis
PHVS_YesNoUnknown_CDC	Initially Treated with RIPE	Was the patient initially treated with the recommended four-drug therapy (RIPE)?
PHVS_ReasonNotTreatedwithRIPE_TB	Reason Not Treated with RIPE	If not initially treated with RIPE, why not?
PHVS_ReasonTherapyStopped_TB	Reason Therapy Stopped	Indicate the primary reason that therapy was stopped or never started; specify this data when the case is closed.
PHVS_TherapyExtendedReason_TB	Reason Therapy Extended	Select the reason the therapy extended beyond 12 months.
PHVS_FinalTreatmentOutcome_TB	Final Disease Outcome	Final TB disease case outcome
PHVS_Medications_TB	Initial Drug Regimen	Initial drug regimen for the patient: Please provide a response for each of the values in the value set using the associated indicator.
PHVS_YesNoUnknown_CDC	Initial Drug Regimen Indicator	Indicator response for the initial drug regimen question
PHVS_YesNoUnknown_CDC	Isolate Submitted for Genotyping	Was an isolate submitted for genotyping?
N/A	Accession Number for Genotyping	If an isolate was submitted for genotyping to a CDC laboratory only, list the accession number for genotyping.
PHVS_YesNoUnknown_CDC	Phenotypic Drug Susceptibility Completed	Was phenotypic/growth-based drug susceptibility testing done?
PHVS_YesNoUnknown_CDC	Molecular Drug Susceptibility Completed	Was genotypic/molecular drug susceptibility testing done?
PHVS_SusceptibilityTestType_TB	Antimicrobial Susceptibility Test Type	Antimicrobial Susceptibility Test Type of TB drugs. For the initial susceptibility testing please send a response for each values in the value set. Changes in susceptibility should be reported for each individual drug when change is identified.

N/A	Antimicrobial Susceptibility Specimen Collection Date	Antimicrobial Susceptibility Specimen Collection Date
N/A	Antimicrobial Susceptibility Result Reported Date	Antimicrobial susceptibility result reported date
PHVS_MicroscopicExamCultureSite_TB	Antimicrobial Susceptibility Specimen Type	Antimicrobial Susceptibility Specimen Type (e.g. Exudate, Blood, Serum, Urine)
PHVS_SusceptibilityTestResultQuantitative_TB	Antimicrobial Susceptibility Test Interpretation	Antimicrobial Susceptibility Test Interpretation (e.g. Susceptible, Resistant, Intermediate, Not tested)
PHVS_SusceptibilityTestMethod_TB	Antimicrobial Susceptibility Test Method	Antimicrobial Susceptibility Test Method (e.g. E-Test, MIC, Disk Diffusion)
PHVS_GeneName_TB	Gene Identifier	Gene identifier - Please report the full test results for the samples that have unique features, such as specimen type (sputum or another anatomic site), test type (sequencing or non-sequencing) or mutation (detected or not detected). There is no need to report test results that differ only by date or laboratory and where all other aspects are identical in regards to specimen type, test type, and/or the results of mutation.
N/A	Molecular Susceptibility Specimen Collection Date	Molecular Susceptibility Specimen Collection Date
N/A	Molecular Susceptibility Date Reported	Molecular Susceptibility Date Reported
PHVS_MicroscopicExamCultureSite_TB	Molecular Susceptibility Specimen Type	Molecular Susceptibility Specimen Type
PHVS_MolecularTestResults_TB	Molecular Susceptibility Test Result	Molecular Susceptibility Test Result
N/A	Molecular Susceptibility Nucleic Acid Change	Molecular Susceptibility Nucleic Acid Change
N/A	Molecular Susceptibility Amino Acid Change	Molecular Susceptibility Amino Acid Change
PHVS_MolecularIndel_TB	Molecular Susceptibility Indel	Molecular Susceptibility Indel
PHVS_MolecularTestMethods_TB	Molecular Susceptibility Test Method	Molecular Susceptibility Test Method
PHVS_YesNoUnknown_CDC	Culture Conversion Documented	Did the patient's sputum become culture negative?

N/A	Date of First Consistently Negative Culture	Date the first consistently negative sputum culture was collected.
PHVS_SputumCultureConversionNotDocumentedReason_TB	Reason for Not Documenting Sputum Culture Conversion	Indicate the one reason for not documenting the sputum culture conversion.
PHVS_YesNoUnknown_CDC	Patient Move During TB Therapy	Did the patient move during therapy?
PHVS_MovedWhereDuringTherapy_TB	Moved to Where	If the patient moved to a different reporting area during TB therapy, select all that apply to where the patient moved.
PHVS_State_FIPS_5-2	Out of State Move	If moved out of state, then specify the new state jurisdiction.
PHVS_Country_ISO_3166-1	Out of Country Move	If moved out of country, then specify the new country jurisdiction.
PHVS_YesNoUnknown_CDC	Transnational Referral	If moved out of the US, indicate whether a transnational referral was made.
PHVS_YesNoUnknown_CDC	History of Treatment	History of treatment before current episode with second-line TB drugs for the treatment of TB disease (not LTBI)
N/A	Date MDR Treatment Started	Date MDR TB therapy started for current episode
PHVS_Medications_TB	Drug Used to Treat MDR TB	Drugs ever used for MDR TB treatment, from MDR start date: Please provide a response for each medication in the value set with an associated indicator. Medications should be recorded as part of the regimen beginning with the MDR TB therapy start date.
PHVS_LengthofTimeDrugTaken_TB	Length of Time Drug Was Administered	Indicate length of time drug was taken or if it was not taken
N/A	Date Injectable Medication Stopped	Date injectable medication stopped. If no injectable drugs were used leave blank.
PHVS_YesNoUnknown_CDC	Surgery to Treat MDR TB	Surgery to Treat MDR TB
N/A	Surgery to Treat MDR TB Date	Surgery to Treat MDR TB Date
PHVS_SideEffectofTreatment_TB	Adverse Event Description	Did patient experience any of the following side effects during treatment that resulted in a permanent discontinuation of medication or at the end of treatment were there any of the following side effects related to MDR-TB treatment present? Please provide a response for all side effects in the value set with an associated indicator.
PHVS_YesNoUnknown_CDC	Adverse Event Indicator	Side Effects of Treatment Indicator
PHVS_SideEffectTimetoOnset_TB	Adverse Event Manifestation Time	Did the side effect manifest during treatment or at the end of treatment?
Usual Occupation and Industry	Usual occupation and industry	TBD
Meets Binational Reporting Criteria	Does case meet binational reporting criteria?	PHVS_YesNoUnknown_CDC
Patient Treated as MDR Case	Was the Patient Treated as an MDR TB Case	PHVS_YesNoUnknown_CDC

	(Regardless of DST Results?	

TB Infection: 51 Data Elements

51 data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for TB Infection. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: TB Infection is under standardized surveillance following a recommendation from CSTE. The majority of the selected data elements are identical to the elements selected in collaboration with state and local partners for TB Disease surveillance. A small number of additional TB Infection-specific elements are included to collect information on TB Infection treatment regimens and case outcome information, which are substantially different from the corresponding information collected for TB Disease cases.

Value Set Code	**Data Element Name**	**Data Element Description**
N/A	TB State Case Number	State case number for the case specific to TB investigations (4 digit report year + 2 letter state + 9 digit alphanumeric number)
N/A	City or County Case Number	City or county case number assigned to this case
PHVS_Sex_MFU	Birth Sex	What was the patient's sex at birth?
PHVS_CaseCount Status_TB	Previously Counted Case	Has this case already been counted by another reporting area?
N/A	Previously Reported State Case Number	If case previously counted, provide the state case number from the other reporting area.
PHVS_BirthCountry_CDC	Country of Verified Case	If the case was previously reported by another country, specify the country.
N/A	Patient Address City	Patient address city
PHVS_YesNoUnknown_CDC	Inside City Limits	Is the patient's residence within city limits?
N/A	Census Tract of Case-Patient Residence	Census tract where the address is located is a unique identifier associated with a small statistical subdivision of a county. Census tract data allows a user to find population and housing statistics about a specific part of an urban area.
PHVS_Race_CDC	Detailed Race	Provide the detailed race information for the patient.
N/A	Date Arrived in US	If country of birth is NOT United States, regardless of citizenship, indicate the date when the patient first arrived in the US.
PHVS_YesNoUnknown_CDC	US Born	Was the patient eligible for US citizenship at birth?
PHVS_BirthCountry_CDC	Primary Guardian(s) Country of Birth	Indicates the birth country of the primary guardian(s) of patient (pediatric [<15 years old] cases only)

PHVS_YesNoUnknown_CDC	Remain in US After Report	If not US reporting area, did patient remain in the United States for >= 90 days after report date?
PHVS_PrimaryReasonForEvaluation_TB	Initial Reason for Evaluation	What was the initial reason the patient was evaluated for TB?
PHVS_LabTestType_TB	Test Type	Epidemiologic interpretation of the type of test(s) performed for this case. Please provide a response for each of the main test types (culture, smear, pathology/cytology, NAA, TST, IGRA, HIV, diabetes) If test was not done please indicate so.
PHVS_LabTestInterpretation_TB	Test Result	Epidemiologic interpretation of the results of the test(s) performed for this case - This is a qualitative test result. (e.g., positive, detected, negative)
N/A	Date/Time of Lab Result	Date result sent from reporting laboratory. Time of result is an optional addition to date.
PHVS_MicroscopicExamCultureSite_TB	Specimen Source Site	This indicates the anatomical source of the specimen tested.
N/A	Specimen Collection Date/Time	Date of collection of laboratory specimen used for diagnosis of health event reported in this case report. Time of collection is an optional addition to date.
N/A	Test Result Quantitative	Quantitative test result value
PHVS_UnitofMeasure_TB	Result Units	Units of measure for the Quantitative Test Result Value
PHVS_TypeofRadiologyStudy_CDC	Type of Chest Study	Indicate the type of chest study performed. Please provide a response for each of the main test types (plain chest radiograph, chest CT Scan) and if test was not done please indicate so.
PHVS_ResultofRadiologyStudy_TB	Result of Chest Study	Result of chest diagnostic testing
PHVS_YesNoUnknown_CDC	Evidence of Cavity	Did test show evidence of cavity?
PHVS_YesNoUnknown_CDC	Evidence of Miliary TB	Did test show evidence of miliary TB?
N/A	Date of Chest Study	Date of the chest diagnostic study
N/A	Current Occupation	This data element is used to capture the narrative text of a subject's current occupation.
PHVS_Occupation_CDC_Census2010	Current Occupation Standardized	This data element is used to capture the CDC NIOSH standard occupation code based upon the narrative text of a subject's current occupation. (The National Institute for Occupational Safety and Health (NIOSH) has developed a web-based software tool designed to translate industry and occupation text to standardized Industry and Occupation codes. The NIOSH Industry and Occupational Computerized Coding System (NIOCCS) is available here: http://www.cdc.gov/niosh/topics/coding/overview.html

N/A	Current Industry	This data element is used to capture the narrative text of subject's current industry.
PHVS_Industry_CDC_Census2010	Current Industry Standardized	This data element is used to capture the CDC NIOSH standard industry code based upon the narrative text of a subject's current industry. (The National Institute for Occupational Safety and Health (NIOSH) has developed a web-based software tool designed to translate industry and occupation text to standardized Industry and Occupation codes. The NIOSH Industry and Occupational Computerized Coding System (NIOCCS) is available here: http://www.cdc.gov/niosh/topics/coding/overview.html
PHVS_EpidemiologicalRiskFactors_TB	Patient Epidemiological Risk Factors	Exposed risk factors for the patient - Please provide a response for all risk factors in the value set with an associated indicator
PHVS_YesNoUnknown_CDC	Patient Epidemiological Risk Factors Indicator	Provide a response for each value in the patient epidemiological risk factors value set
PHVS_CorrectionalFacilityType_NND	Type of Correctional Facility	If patient was a Resident of Correctional Facility at Diagnostic Evaluation, indicate the type of correctional facility.
PHVS_LongTermCareFacilityType_NND	Type of Long-Term Care Facility	If patient was a Resident of Long Term Care Facility at Diagnostic Evaluation, indicate the type of long term care facility.
PHVS_SmokingStatus_CDC	Smoking Status	What is the patient's current tobacco smoking status?
PHVS_YesNoUnknown_CDC	Patient lived outside of US for more than 2 months	Residence or Travel in countries other than the United States, Canada, Australia, New Zealand, or countries in northern or western Europe for >60 consecutive days at any point in the patient's lifetime.
PHVS_YesNoUnknown_CDC	Identified During Contact Investigation	Was the patient identified during the contact investigation around the likely source case?
PHVS_YesNoUnknown_CDC	Evaluation During Contact Investigation	If patient was identified during contact investigation, was the patient evaluated for TB during the contact investigation?
N/A	Linked Case Number	State case numbers for epidemiologically linked cases
N/A	Date Treatment or Therapy Started	Date the initial treatment regimen was started
PHVS_TreatmentAdministrationType_TB	Treatment Administration Type	Choose all treatment administration types that apply to the case, such as DOT, eDOT, or SAT.
N/A	Date Treatment or Therapy Stopped	Date treatment stopped
PHVS_YesNoUnknown_CDC	Treatment Started	Was treatment started for LTBI?
PHVS_LTBIDrugRegimen_TB	Initial LTBI Drug Regimen	If treatment was started indicate the initial LTBI drug regimen.
PHVS_ReasonLTBINotStarted_TB	Primary Reason LTBI Treatment Not Started	If treatment was not started, what was the primary reason LTBI treatment was not started?
PHVS_ReasonLTBITreatmentStopped_TB	Reason LTBI Treatment Stopped	Reason LTBI treatment stopped

N/A	NTSS State Case Number	If patient developed TB from LTBI, list the NTSS state case number
PHVS_AdverseEventSeverity_TB	Adverse Event Severity	If treatment was stopped due to adverse event from LTBI treatment indicate the severity.
Usual Occupation and Industry	Usual occupation and industry	TBD
Meets Binational Reporting Criteria	Does case meet binational reporting criteria?	PHVS_YesNoUnknown_CDC

STEC: 2 Data Elements

2 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for STEC. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC would like to collect information about travel and epidemiologic exposure windows, and would like to add 2 data elements with a numeric response option to obtain this information. The exact timeframe for exposures can vary between states and it is necessary for CDC to know of the differences in timeframe as this influences the analyses that can be conducted at CDC. Multiple states have already reported a deviation from the recommended CDC timeframe during an external review of program data elements. By adding in these two data elements, CDC will be better able to determine the relationships of travel and epidemiologic exposure to illness and can work to create timeframe standards in the future.

Value Set Code	**Data Element Name**	**Data Element Description**
N/A	Specify Different Exposure Window	If the epidemiologic exposure window used by the jurisdiction is different from that stated in the exposure questions, specify the time interval in days here. Otherwise, leave blank.
N/A	Specify Different Travel Exposure Window	If the travel exposure window used by the jurisdiction is different from that stated in the travel exposure questions, specify the time interval in days here. Otherwise, leave blank.

Salmonellosis: 1 Data Element

1 new data element that was not included in the previously reviewed ICR or approved through non-substantive change requests was added for Salmonellosis. Names, descriptions, value set codes, and justification for the addition of the new data elements are below:

Justification: CDC would like to collect information about the travel exposure window, and would like to add 1 data element with a numeric response option to obtain this information. The exact timeframe for exposures can vary between states and it is necessary for CDC to know of the differences in timeframe as this influences the analyses that can be conducted at CDC. Multiple states have already reported a deviation from the recommended CDC timeframe during an external review of program data elements. By adding in this data element CDC will be better able to determine the relationship of travel to illness and can work to create timeframe standards in the future.

Value Set Code	Data Element Name	Data Element Description
N/A	Specify Different Travel Exposure Window	If the travel exposure window used by the jurisdiction is different from that stated in the travel exposure questions, specify the time interval in days here. Otherwise, leave blank.

Shigellosis: 4 Data Elements

4 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Shigellosis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC would like to collect information about domestic and international travel exposure. By knowing travel history, CDC will be able to determine where a person may have been exposed to Shigella, which is important for contact tracing, public health follow up, and understanding geographic patterns of disease and antimicrobial resistance. The exact timeframe for exposures can vary between states and it is necessary for CDC to know of the differences in timeframe as this influences the analyses that can be conducted at CDC. Multiple states have already reported a deviation from the recommended CDC timeframe during an external review of program data elements. By adding in these data elements CDC will be better able to determine the relationship of travel to illness.

Value Set Code	Data Element Name	Data Element Description
PHVS_YesNoUnknown_CDC	Did The Case Travel Domestically Prior To Illness Onset?	Did the case patient travel domestically within program specific timeframe?

N/A	Specify Different Travel Exposure Window	If the travel exposure window used by the jurisdiction is different from that stated in the travel exposure questions, specify the time interval in days here. Otherwise, leave blank.
PHVS_State_FIPS_5-2	Travel State	Domestic destination, state(s) traveled to
PHVS_Country_ISO_3166-1	International Destination(S) Of Recent Travel	International destination or countries the patient traveled to

Campylobacteriosis: 2 Data Elements

2 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Campylobacteriosis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC would like to distinguish cases that meet probable case criteria by epidemiologic linkage from those that qualify by laboratory data. This is necessary to assist in outbreak detection and investigation and to make appropriate adjustments to estimates of incidence and disease burden, as these types of probable cases are handled differently.

Value Set Code	**Data Element Name**	**Data Element Description**
PHVS_YesNo_HL7_2x	Probable – Laboratory Diagnosed	Probable case is laboratory diagnosed
PHVS_YesNo_HL7_2x	Probable – Epi Linked	Probable case is epi linked

Cryptosporidiosis: 1 Data Element

1 new data element that was not included in the previously reviewed ICR or approved through non-substantive change requests were added for Cryptosporidiosis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC would like to collect information about the epidemiologic exposure window, and would like to add 1 data element with a numeric response option to obtain this information. The exact timeframe for exposures can vary between states and it is necessary for CDC to know of the differences in timeframe as this influences the analyses that can be conducted at CDC. Multiple states have already reported a deviation from

the recommended CDC timeframe during an external review of program data elements. By adding in this data element CDC will be better able to determine the relationship of travel to illness and can work to create timeframe standards in the future.

Value Set Code	Data Element Name	Data Element Description
N/A	Specify Different Exposure Window	If the epidemiologic exposure window used by the jurisdiction is different from that stated in the exposure questions, specify the time interval in days here. Otherwise, leave blank.

Cyclosporiasis: 3 Data Elements

3 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Cyclosporiasis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC would like to collect information about domestic travel exposure. By knowing travel history, CDC will be able to determine where a person may have been exposed to Cyclosporiasis, which is important for contact tracing, public health follow up, and understanding geographic patterns of disease and antimicrobial resistance. Additionally, CDC would like to collect 2 numeric variables related to the travel exposure and epidemiologic exposure timeframes. The exact timeframe for exposures can vary between states and it is necessary for CDC to know of the differences in timeframe as this influences the analyses that can be conducted at CDC. Multiple states have already reported a deviation from the recommended CDC timeframe during an external review of program data elements. By adding in these data elements CDC will be better able to determine the relationship of travel to illness.

Value Set Code	Data Element Name	Data Element Description
N/A	Specify Different Exposure Window	If the epidemiologic exposure window used by the jurisdiction is different from that stated in the exposure questions, specify the time interval in days here. Otherwise, leave blank.

N/A	Specify Different Travel Exposure Window	If the travel exposure window used by the jurisdiction is different from that stated in the travel exposure questions, specify the time interval in days here. Otherwise, leave blank.
PHVS_YesNoUnknown_CDC	Did The Case Travel Domestically Prior To Illness Onset?	Did the case patient travel domestically within program specific timeframe?

Cholera: 1 Data Element

1 new data element that was not included in the previously reviewed ICR or approved through non-substantive change requests was added for Cholera. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC would like to collect information about the epidemiologic exposure window, and would like to add 1 data element with a numeric response option to obtain this information. The exact timeframe for exposures can vary between states and it is necessary for CDC to know of the differences in timeframe as this influences the analyses that can be conducted at CDC. Multiple states have already reported a deviation from the recommended CDC timeframe during an external review of program data elements. By adding in this data element CDC will be better able to determine the relationship of travel to illness and can work to create timeframe standards in the future.

Value Set Code	**Data Element Name**	**Data Element Description**
N/A	Specify Different Exposure Window	If the epidemiologic exposure window used by the jurisdiction is different from that stated in the exposure questions, specify the time interval in days here. Otherwise, leave blank.

Vibriosis: 1 Data Element

1 new data element that was not included in the previously reviewed ICR or approved through non-substantive change requests was added for Vibriosis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC would like to collect information about the epidemiologic exposure window, and would like to add 1 data element with a numeric response option to obtain this information. The exact timeframe for exposures can vary between states and it is necessary for CDC to know of the differences in timeframe as this influences the analyses that can be conducted at CDC. Multiple states have already reported a deviation from the recommended CDC timeframe during an external review of program data elements. By adding in this data element CDC will be better able to determine the relationship of travel to illness and can work to create timeframe standards in the future.

Value Set Code	Data Element Name	Data Element Description
N/A	Specify Different Exposure Window	If the epidemiologic exposure window used by the jurisdiction is different from that stated in the exposure questions, specify the time interval in days here. Otherwise, leave blank.

<u>*S*. Typhi Infection: 4 Data Elements</u>

4 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for *S*. Typhi Infection. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC would like to collect information about the travel exposure window, and would like to add 1 data element with a numeric response option to obtain this information. The exact timeframe for exposures can vary between states and it is necessary for CDC to know of the differences in timeframe as this influences the analyses that can be conducted at CDC. Multiple states have already reported a deviation from the recommended CDC timeframe during an external review of program data elements. By adding the "Specify Different Travel Exposure Window" data element, CDC will be better able to determine the relationship of travel to illness and can work to create timeframe standards in the future. CDC would like to also collect the following risk factors: (a) health care worker, (b) day care attendee and (c) day care worker as suggested by the position statement.

Value Set Code	Data Element Name	Data Element Description
N/A	Specify Travel Different Exposure Window	If the travel exposure window used by the jurisdiction is different from that stated in the travel

		exposure questions, specify the time interval in days here. Otherwise, leave blank.
TBD	Health care worker	Was the patient a health care provider?
TBD	Day care attendee	Was the patient a day care attendee?
TBD	Day care worker	Was the patient a day care provider?

S. Paratyphi Infection: 60 Data Elements

60 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for *S*. Paratyphi Infection. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: In addition to 56 data elements previously approved for Typhoid Fever (renamed *S*. Typhi in this ICR) which are also necessary for national surveillance of *S*. Paratyphi infections, CDC would like to collect information about the patient travel exposure window, and would like to add 1 data element, with a numeric response option, to obtain this information. The calculation of the timeframe for exposures can vary between states so it is necessary for CDC to know of the differences in timeframes since they can influence the data analyses that can be conducted at CDC. During an external review of program data elements, multiple states reported a deviation from the recommended CDC travel exposure timeframe. By adding the "Specify Different Travel Exposure Window" data element, CDC will be better able to determine the relationship of travel to illness, and can work to create timeframe standards in the future. CDC would also like to collect the following risk factors: (a) health care worker, (b) day care attendee and (c) day care worker, as suggested by the 2018 CSTE position statement.

Value Set Code	**Data Element Name**	**Data Element Description**
TBD	Formtype	Type of form reported on
TBD	CDCNUM	CDC Number
TBD	StateEpiNumber	State Epi Number
TBD	SLABSID	State Lab Isolate ID Number
TBD	SLABSID2	State Lab Isolate ID Number 2, if another entry is associated in NARMS data

TBD	SpecNumber	NARMS Isolate Identification Number
TBD	SpecNumber2	NARMS Isolate Identification Number- for duplicate sample from a single patient
TBD	SpecNumber3	NARMS Isolate Identification Number- for duplicate sample from a single patient
TBD	Year	Year of report (based on date onset)
TBD	Date Entered	Date Form was entered into database
TBD	Date Rec CDC	Date Form was received to CDC
TBD	Name	First three letters of patient's last name
TBD	Foodhand	Work as foodhandler?
TBD	Citizen	U.S. Citizen?
TBD	Othcitzn	Other citizenship
TBD	Ill	Ill with paratyphoid fever?
TBD	Dtonset	Date of onset of Symptoms
TBD	Outcome	Outcome of case
TBD	Dtisol	Date Salmonella first isolated
TBD	Site	Sites of isolation
TBD	Othsite	Other site of isolation
TBD	Serotype	Serotype of isolate
TBD	Sensi	Was sensitivity testing done?
TBD	Ampr	Resistant to ampicillin?
TBD	Chlorr	Resistant to chloramphenicol?
TBD	Tmpsmxr	Resistant to trimethoprim-sulfamethoxazole?
TBD	quinol	Resistant to fluoroquinolone on?
TBD	Ceft	Resistant to ceftriaxone?
TBD	outbreak	Did case occur as part of outbreak?
TBD	vac5yr	Vaccinated within 5 yrs?
TBD	stanvax	Standard Killed typhoid shot?

TBD	yrstanvx	Year standard vaccine received
TBD	ty21vax	Oral Ty 21a or Vivotof four pill series?
TBD	yrty21	Year of Oral Ty 21a or Vivotof four pill series received
TBD	vicps	VICPS or Typhium VI shot?
TBD	yrvicps	Year VICPS or Typhium VI shot received
TBD	outus	Travel outside of US?
TBD	country1	Country 1 visited
TBD	country2	Country 2 visited
TBD	country3	Country 3 visited
TBD	country4	Country 4 visited
TBD	country1oth	Country 1 other
TBD	country2oth	Country 2 other
TBD	country3oth	Country 3 other
TBD	country4oth	Country 4 other
TBD	dtentus	Date of most return or entry in the US
TBD	business	Business is purpose of international travel?
TBD	tourism	Tourism is purpose of international travel?
TBD	visitfam	Visiting relatives or friends is purpose of international travel?
TBD	immigrat	Immigration to the US is purpose of international travel?
TBD	othtrav	Other travel is purpose of international travel?
TBD	travreas	Reason for other travel
TBD	anycarr	Case traced to typhoid carrier?
TBD	prevcarr	Carrier previously known to health dept?
TBD	comment	Comments
TBD	dtform	Date PH Dept completed form
TBD	Specify Different Travel Exposure Window	If the travel exposure window used by the jurisdiction is different from that stated in the travel exposure

		questions, specify the time interval in days here. Otherwise, leave blank.
TBD	Health care worker	Was the patient a health care provider?
TBD	Day care attendee	Was the patient a day care attendee?
TBD	Day care worker	Was the patient a day care provider?

Lyme disease: 7 Data Elements

7 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Lyme disease. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The data elements included in this change request will contribute to enhanced surveillance efforts on the part of the CDC program and allow the program to perform additional epidemiological analyses for Lyme disease. The new data elements collect information about where exposure occurred, if symptom onset was greater than 30 days before specimen collection date, and medication type, date and duration. The clinical manifestation and clinical manifestation indicator data elements update how clinical information is collected.

Value Set Code	**Data Element Name**	**Data Element Description**
TBD	Exposure in high incidence state	Did patient live in or visit a state defined as high incidence within 30 days prior to onset of symptoms?
TBD	Symptom onset greater than 30 days	Did onset of symptoms occur more than 30 days prior to diagnosis?
TBD	Clinical Manifestation	Clinical manifestation of Lyme disease
TBD	Clinical Manifestation Indicator	For each clinical manifestation reported, indicate whether the subject developed the specified manifestation as a result of the illness.
TBD	Medication Administered	What antibiotic did the patient receive for this episode?

TBD	Date Treatment or Therapy Started	Date the treatment or therapy was initiated
TBD	Treatment Duration	Number of days the patient actually took the antibiotic referenced

Invasive *Haemophilus influenzae* Disease: 33 Data Elements

33 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Invasive *Haemophilus influenzae* disease. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The inclusion of the *Haemophilus influenzae* disease specific elements will contribute to enhanced surveillance efforts on the part of the CDC program and allow for timely public health action. Included variables aim to identify secondary transmission of non-b *H. influenzae*, confirm laboratory testing conducted by the states, link the laboratory data to epidemiological data, and provide vaccination information.

Value Set Code	**Data Element Name**	**Data Element Description**
PHVS_InfectionType_RIBD	Bacterial Infection Syndrome	Types of infection caused by organism
PHVS_PregnacyStatus_RIBD	Pregnancy Status at the Time of First Positive Culture	At the time of first positive culture, was the patient pregnant or postpartum? (The postpartum period is defined as the 30 days following a delivery or miscarriage)
PHVS_FetalOutcome_RIBD	Pregnancy Outcome	If pregnant or postpartum, what was the outcome of fetus?
N/A	Gestational Age	If patient <1 month of age, indicate gestational age (in weeks)
N/A	Birth Weight	If patient <1 month of age, indicate birth weight
PHVS_WeightUnit_UCUM	Birth Weight Units	Birth Weight Units
PHVS_YesNoUnknown_CDC	Previous Contact With Hib Disease	Is there a known previous contact(s) with Hib disease within the preceding two months?
PHVS_ContactType_RIBD	Hib Contact Type	Type of previous contact(s) with Hib disease within the preceding two months.

PHVS_YesNoUnknown_CDC	Previous Contact With Non-b or Nontypeable H. influenzae Case	Did patient have known previous contact(s) with a non-b or nontypeable case of H. influenzae disease within the preceding 2 months?
PHVS_ContactType_RIBD	Non-b or Nontypeable Contact Type	Specify type of contact(s) with non-b or nontypeable case of H. influenzae
PHVS_YesNoUnknown_CDC	Recurrent Disease with Same Pathogen	Does this case have recurrent disease with the same pathogen? (For Streptococcus pneumoniae, the specimen from the current case must have been isolated 8 or more days after any previous case due to the same pathogen. For all other pathogens, the specimen from the current case must have been isolated 30 or more days after any previous case due to the same pathogen.)
N/A	Previous State ID (Recurrent Case)	StateID of 1st occurrence for this pathogen and person.
PHVS_FormStatus_RIBD	Case Report Form Status	Case Report Form Status
N/A	Illness Onset Age	Illness onset age
PHVS_AgeUnit_UCUM	Illness Onset Age Units	Illness onset age units
PHVS_ResidenceLocation_RIBD	Residence	Where was the patient a resident at time of initial culture?
PHVS_YesNoUnknown_CDC	Premature Infant	Premature at birth (for children ≤2 years old)
PHVS_YesNoUnknown_CDC	Epi-Linked to a Laboratory-Confirmed Case	Is this case epi-linked to a laboratory-confirmed case?
PHVS_YesNoUnknown_CDC	ABCs Case	ABCs case
N/A	ABCs State ID	ABCs State ID
PHVS_YesNoUnknown_CDC	Laboratory Testing Performed	Was laboratory testing done to confirm the diagnosis?
PHVS_YesNoUnknown_CDC	Laboratory Confirmed	Was the case laboratory confirmed?
N/A	Test Manufacturer	Test Manufacturer

N/A	Lab Accession Number	Lab Accession Number (including CDC Lab ID)
PHVS_YesNoUnknown_CDC	Did the Subject Ever Receive a Vaccine Against This Disease	Did the subject ever receive a vaccine against this disease?
N/A	Date of Last Dose Prior to Illness Onset	Date of last vaccine dose against this disease prior to illness onset
N/A	Vaccination Doses Prior to Onset	Number of vaccine doses against this disease prior to illness onset
N/A	Vaccine History Comments	Vaccine History Comments
N/A	Age at Vaccination	The persons age at the time the vaccine was given
PHVS_AgeUnit_UCUM	Age at Vaccination Units	The age units of the person at the time the vaccine was given
PHVS_InformationSource_RIBD	Vaccine History Information Source	What sources were used for vaccination history?
PHVS_YesNoUnknown_CDC	Vaccine Information Source Indicator	Vaccination History Information Source Indicator
PHVS_YesNoUnknown_CDC	Susceptibility Test	Was any susceptibility data available?

Meningococcal Disease: 37 Data Elements

37 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for meningococcal disease. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The inclusion of meningococcal disease specific elements will contribute to enhanced surveillance efforts on the part of the CDC program and allow for timely public health action. Included variables aim to evaluate the effectiveness of routine public health management of meningococcal disease cases, define the population at increased risk of meningococcal disease, assess the impact vaccine recommendations, link the laboratory data to epidemiological data, and monitor resistance.

Value Set Code	Data Element Name	Data Element Description
PHVS_InfectionType_RIBD	Bacterial Infection Syndrome	Types of infection caused by organism
N/A	Gestational Age	If patient <1 month of age, indicate gestational age (in weeks)
N/A	Birth Weight	If patient <1 month of age, indicate birth weight (grams)
PHVS_WeightUnit_UCUM	Birth Weight Units	Birth Weight Units
PHVS_YesNoUnknown_CDC	Secondary Case	Is this a secondary case?
PHVS_YesNoUnknown_CDC	Recurrent Disease with Same Pathogen	Does this case have recurrent disease with the same pathogen? (For Streptococcus pneumoniae, the specimen from the current case must have been isolated 8 or more days after any previous case due to the same pathogen. For all other pathogens, the specimen from the current case must have been isolated 30 or more days after any previous case due to the same pathogen.)
N/A	Previous State ID (Recurrent Case)	StateID of 1st occurrence for this pathogen and person.
PHVS_FormStatus_RIBD	Case Report Form Status	Case Report Form Status
PHVS_YNRD_CDC	Had Sex with a Male within the Past 12 Months	Had sex with a male within the past 12 months?
PHVS_YNRD_CDC	Had Sex with a Female within the Past 12 Months	Had sex with a female within the past 12 months?
N/A	Number of Male Sexual Partners	In the 3 months prior to the onset of symptoms, number of male sex partners the person had?
PHVS_HIVStatus_STD	HIV Status	Documented or self-reported HIV status at the time of event
PHVS_YesNoUnknown_CDC	Homeless	Was the patient homeless at time of symptom onset?
PHVS_SignsSymptoms_RIBD	Signs and Symptoms	Indicate what symptoms of interest the patient had during the course of the illness

PHVS_YesNoUnknown_CDC	Signs and Symptoms Indicator	Indicator for associated sign and symptom
PHVS_YesNoUnknown_CDC	Eculizumab	Was the patient taking eculizumab/Soliris at the time of disease onset?
N/A	Illness Onset Age	Illness onset age
PHVS_AgeUnit_UCUM	Illness Onset Age Units	Illness onset age units
PHVS_ResidenceLocation_RIBD	Residence	Where was the patient a resident at time of initial culture?
PHVS_YesNoUnknown_CDC	Epi-Linked to a Laboratory-Confirmed Case	Is this case epi-linked to a laboratory-confirmed case?
PHVS_YesNoUnknown_CDC	ABCS Case	ABCs Case
N/A	ABCS State ID	ABCS State ID
PHVS_YesNoUnknown_CDC	Laboratory Testing Performed	Was laboratory testing done to confirm the diagnosis?
PHVS_YesNoUnknown_CDC	Laboratory Confirmed	Was the case laboratory confirmed?
PHVS_SerogroupMethod_RIBD	Serogroup Method	Serogroup method
N/A	Test Manufacturer	Test Manufacturer
N/A	Lab Accession Number	Lab Accession Number (including CDC Lab ID)
PHVS_YesNoUnknown_CDC	Susceptibility Test	Was any susceptibility data available?
PHVS_YesNoUnknown_CDC	Did the Subject Ever Receive a Vaccine Against This Disease	Did the subject ever receive a vaccine against this disease?
N/A	Date of Last Dose Prior to Illness Onset	Date of last vaccine dose against this disease prior to illness onset
N/A	Vaccination Doses Prior to Onset	Number of vaccine doses against this disease prior to illness onset
N/A	Vaccine History Comments	Vaccine History Comments
N/A	Vaccine Name	Vaccine Name

N/A	Age at Vaccination	The persons age at the time the vaccine was given
PHVS_AgeUnit_UCUM	Age at Vaccination Units	The age units of the person at the time the vaccine was given
PHVS_InformationSource_RIBD	Vaccine History Information Source	What sources were used for vaccination history?
PHVS_YesNoUnknown_CDC	Vaccine Information Source Indicator	Vaccination History Information Source Indicator

Invasive Pneumococcal Disease: 32 Data Elements

32 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Invasive Pneumococcal Disease. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The inclusion of Invasive Pneumococcal Disease-specific elements will contribute to enhanced surveillance efforts on the part of the CDC program and allow for timely public health action. Included data elements aim to identify risk factors such as daycare facilities, underlying conditions and illness onset, risk factors for infection, determine disease severity and how the case was discovered, vaccination information and monitor for resistance.

Value Set Code	**Data Element Name**	**Data Element Description**
PHVS_YesNoUnknown_CDC	In Day Care	Does this patient attend a day care facility?
PHVS_UnderlyingConditions_RIBD	Underlying Condition(s)	Listing of underlying causes or prior illnesses
PHVS_YesNoUnknown_CDC	Underlying Conditions Indicator	Underlying Conditions Indicator
N/A	Illness Onset Age	Illness onset age
PHVS_AgeUnit_UCUM	Illness Onset Age Units	Illness onset age units
PHVS_YesNoUnknown_CDC	Hospital ICU	During any part of the hospitalization, did the subject stay in an Intensive Care Unit (ICU) or a Critical Care Unit (CCU)

PHVS_ResidenceLocation_RIBD	Residence	Where was the patient a resident at time of initial culture?
PHVS_PregnacyStatus_RIBD	Pregnancy Status at the Time of First Positive Culture	At the time of first positive culture, was the patient pregnant or postpartum? (The postpartum period is defined as the 30 days following a delivery or miscarriage)
PHVS_FetalOutcome_RIBD	Pregnancy Outcome	If pregnant or postpartum, what was the outcome of fetus?
N/A	Gestational Age	If patient <1 month of age, indicate gestational age (in weeks)
N/A	Birth Weight	If patient <1 month of age, indicate birth Weight
PHVS_WeightUnit_UCUM	Birth Weight Units	Birth Weight Units
PHVS_YesNoUnknown_CDC	Premature Infant	Premature at birth (for children ≤2 years old)
PHVS_InsuranceType_RIBD	Insurance	Insurance
PHVS_YesNoUnknown_CDC	Epi-Linked to a Laboratory-Confirmed or Probable Case	Is this case Epi linked to a confirmed or probable case?
PHVS_YesNoUnknown_CDC	ABCs Case	ABCs case
N/A	ABCs State ID	ABCs State ID
PHVS_YesNoUnknown_CDC	Recurrent Disease with Same Pathogen	Does this case have recurrent disease with the same pathogen? (For Streptococcus pneumoniae, the specimen from the current case must have been isolated 8 or more days after any previous case due to the same pathogen. For all other pathogens, the specimen from the current case must have been isolated 30 or more days after any previous case due to the same pathogen.)
N/A	Previous State ID (Recurrent Case)	StateID of 1st occurrence for this pathogen and person.
PHVS_YesNoUnknown_CDC	Laboratory Testing Performed	Was laboratory testing done to confirm the diagnosis?
PHVS_YesNoUnknown_CDC	Laboratory Confirmed	Was the case laboratory confirmed?

N/A	Test Manufacturer	Test Manufacturer
N/A	Lab Accession Number	Lab Accession Number (including CDC Lab ID)
PHVS_YesNoUnknown_CDC	Did the Subject Ever Receive a Vaccine Against This Disease	Did the subject ever receive a vaccine against this disease?
N/A	Date of Last Dose Prior to Illness Onset	Date of last vaccine dose against this disease prior to illness onset
N/A	Vaccination Doses Prior to Onset	Number of vaccine doses against this disease prior to illness onset
N/A	Vaccine History Comments	Vaccine History Comments
N/A	Age at Vaccination	The persons age at the time the vaccine was given
PHVS_AgeUnit_UCUM	Age at Vaccination Units	The age units of the person at the time the vaccine was given
PHVS_InformationSource_RIBD	Vaccine History Information Source	What sources were used for vaccination history?
PHVS_YesNoUnknown_CDC	Vaccine Information Source Indicator	Vaccination History Information Source Indicator
PHVS_YesNoUnknown_CDC	Susceptibility Test	Was any susceptibility data available?

<u>Psittacosis: 27 new data elements</u>

27 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Psittacosis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The inclusion of the Psittacosis disease-specific elements will contribute to enhanced surveillance efforts on the part of the CDC program and allow for timely public health action. New data elements include patient signs, symptoms, treatment, and exposure history to identify underlying risk factors. Additional elements address current challenges with diagnostic testing and prevention and control strategies.

Value Set Code	Data Element Name	Data Element Description
PHVS_SignsSymptoms_RIBD	Signs and Symptoms	Indicate what symptoms of interest the patient had during the course of the illness
PHVS_YesNoUnknown_CDC	Signs and Symptoms Indicator	Indicator for associated sign and symptom
N/A	Highest Measured Temperature	What was the subject's highest measured temperature during this illness?
PHVS_TemperatureUnit_UCUM	Temperature Units	Units for highest measured temperature
PHVS_YesNoUnknown_CDC	Antibiotics given	Did the subject take antibiotics as treatment for this illness?
N/A	Treatment Start Date	Start date of antibiotic
N/A	Treatment End Date	Stop date of antibiotic
N/A	Treatment Duration	Number of days the patient actually took the antibiotic
PHVS_YesNoUnknown_CDC	Hospital ICU	During any part of the hospitalization, did the subject stay in an Intensive Care Unit (ICU) or a Critical Care Unit (CCU)?
PHVS_YesNoUnknown_CDC	Laboratory Testing Performed	Was laboratory testing done to confirm the diagnosis?
PHVS_YesNoUnknown_CDC	Laboratory Confirmed	Was the case laboratory confirmed?
N/A	Test Manufacturer	Test Manufacturer
PHVS_SpecimenSite_RIBD	Autopsy Specimen Type	Type of autopsy specimen
N/A	Autopsy Result	Autopsy result
N/A	Date of Autopsy	Date of autopsy (date autopsy specimen collected)

N/A	Autopsy Laboratory Name	Autopsy Laboratory Name
PHVS_Industry_CDC_Census2010	Industry at Date of Onset	Industry at date of onset
PHVS_PersonalProtectiveEquipment_RIBD	Personal Protective Equipment	At the time of exposure, which of the following personal protective equipment was used by the patient?
PHVS_RespiratoryProtectiveEquipment_RIBD	Respiratory Protective Equipment	If respiratory protective equipment was used at the time of exposure, specify what kind
PHVS_YesNoUnknown_CDC	Annual Respirator Fit Testing and Training	Does the patient get annual respirator fit testing and training?
PHVS_GloveMaterial_RIBD	Glove Material	If gloves were used, specify glove material
PHVS_ContactType_RIBD	Contact Type	Indicate which of the following contacts patient had during 5 weeks prior to onset
PHVS_BirdType_RIBD	Bird Type	What type of bird did the patient have contact with during the 5 weeks prior to onset?
N/A	Bird Species	Bird species
N/A	Number of Birds	Approximate number of birds
N/A	Illness Onset Age	Illness onset age
PHVS_AgeUnit_UCUM	Illness Onset Age Units	Illness onset age units

Legionellosis: 38 Data Elements

38 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Legionellosis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The inclusion of these disease specific elements for Legionellosis will contribute to enhanced surveillance efforts on the part of the CDC program and allow for timely public health action. Included variables aim to better characterize patient's exposure history, identify underlying risk factors, and confirm whether the patient sample was taken during the acute or convalescent phase, which is required to satisfy the case definition.

Value Set Code	Data Element Name	Data Element Description
N/A	Illness Onset Age	Age at illness onset
PHVS_AgeUnit_UCUM	Illness Onset Age Units	Age units at illness onset
N/A	Accommodation Comments	Comments or information about nights away from home not collected elsewhere
N/A	Address of Healthcare Facility	Street Address of healthcare facility visited by the patient in the 10 days before onset
N/A	Zip Code of Healthcare Facility	Zip code of healthcare facility visited by the patient in the 10 days before onset
N/A	Healthcare Setting Exposure Comments	Comments or information about healthcare setting exposure not collected elsewhere
PHVS_YesNoUnknown_CDC	Healthcare Facility Water Management Program	Did the healthcare facility have a water management program to reduce the risk of Legionella growth and spread in place?
N/A	Street Address of Assisted/Senior Living Facility	Street address of assisted/senior living facility visited/lived in by the patient during exposure
N/A	Zip Code of Assisted/Senior Living Facility	Zip code of assisted/senior living facility visited/lived in by the patient during exposure
N/A	Assisted/Senior Living Facility Comments	Comments or information about assisted/senior living facility exposure not collected elsewhere
PHVS_YesNoUnknown_CDC	Assisted/Senior Living Facility Water Management Program	Did the assisted/senior living facility have a water management program to reduce the risk of Legionella growth and spread in place?
PHVS_LegionellaExposure_RIBD	Exposure	Was the patient exposed to any of the following during the 10 days prior to onset?
PHVS_YesNoUnknown_CDC	Exposure Indicator	Exposure Indicator

N/A	Location of Exposure	Location of exposure (e.g. facility name, city , state)
N/A	Date(s) of Exposure	Date(s) of exposure
PHVS_YesNoUnknown_CDC	Recent Cruise Travel	In the 10 days before onset, did patient take a cruise?
PHVS_CruiseLine_RIBD	Name of Cruiseline	Name of cruiseline patient sailed with
N/A	Name of Ship	Name of ship patient sailed on
N/A	Cruise Departure City	Cruise departure city
PHVS_State_FIPS_5-2	Cruise Departure State	Cruise departure state
PHVS_Country_ISO_3166-1	Cruise Departure Country	Cruise departure country
N/A	Date of Cruise Departure	Cruise departure date
N/A	Cruise Return City	Cruise return city
PHVS_State_FIPS_5-2	Cruise Return State	Cruise return state
PHVS_Country_ISO_3166-1	Cruise Return Country	Cruise return country
N/A	Date of Cruise Return	Cruise return date
N/A	Cabin Number	Patient's cruise ship cabin number
N/A	Port of Call City	Port of call city
PHVS_Country_ISO_3166-1	Port of Call Country	Port of call country
PHVS_State_FIPS_5-2	Port of Call State	Port of call state
N/A	Port of Call Date	Date for port of call
N/A	CDC NORS Outbreak ID#	CDC National Outbreak Reporting System (NORS) Outbreak ID#
PHVS_YesNoUnknown_CDC	Did Underlying Condition(s) Exist	Did the patient have any underlying causes or prior illnesses?
PHVS_UnderlyingConditions_RIBD	Underlying Condition(s)	Listing of underlying causes or prior illnesses
PHVS_YesNoUnknown_CDC	Underlying Conditions Indicator	Underlying conditions indicator

PHVS_TiterTestType_RIBD	Titer Test Type	If this is a titer, indicate if this is an initial/acute or convalescent titer (Titer Test Type)
N/A	Test Manufacturer	Test Manufacturer
N/A	Test Brand Name	Test Brand Name

TBRD: 35 Data Elements

35 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for TBRD. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: These new data elements will contribute to enhanced surveillance efforts on the part of the CDC program and allow the program to perform additional epidemiological analyses for TBRD. The data elements Physician Name and Physician Phone are collected on case-patients to inform prevention and control efforts, allowing for targeted outreach to at-risk populations. The CSTE position statements for TBRD surveillance indicates clinical manifestation criteria for the diagnosis and classification of cases. The information collected by Clinical Manifestation and Clinical Manifestation Indicator are key data elements of the case definitions and is essential both for case management and surveillance. Data elements Experienced Complication and Type of Complication are collected as markers of severity and are used to assess the burden of TBRD. The Patient Immunocompromised data element collects information on immune status of cases. Patients who are immunocompromised have been shown to be more likely to have severe illness and complications from TBRD, and these data are used to assess burden of TBRD. Treatment Drug Indicator, Medication Administered, Date Treatment or Therapy Started, and Treatment Duration data elements are collected to determine healthcare provider awareness and knowledge of these potentially fatal conditions. Risk factor data elements (Occupation related to exposure, Travel, International Destination(s) of Recent Travel, Travel State, Travel Country, Date of Arrival to Travel Destination, Date of Departure from Travel Destination, Tick Bite Location, Tick Bite Date) are needed to provide information on the temporal, geographic, and demographic occurrence of TBRD to facilitate its prevention and control. There have been known cases of transfusion- and transplant-related cases of TBRD. Data elements related to blood product transfusions, organ transplants, and blood donations (Blood Transfusion, Blood Transfusion Date, Transfusion Associated, Transfused Product, Organ Transplant, Transplant type, Transplant Date, Transplant Associated infection, Blood Donor, Blood Donation Date, Blood Donor Implicated During Investigation, Donated Product, Blood bank notified) are needed to inform decisions regarding blood screening policies that may be developed, as well as other intervention strategies. There have been documented cases of TBRD co-infections with Lyme and Babesiosis. The Co-infection and Co-infection type

data elements are needed to provide information on the temporal, geographic, and demographic occurrence of these co-infections to facilitate its prevention and control.

Value Set Code	Data Element Name	Data Element Description
TBD	Physician Name	Name of subject's clinician/provider of care Provide the name in the following format: <last name>, <first name>
TBD	Physician Phone	Phone number of subject's clinician/provider of care
TBD	Clinical Manifestation	Clinical manifestation of TBRD
TBD	Clinical Manifestation Indicator	For each clinical manifestation reported, indicate (YNU) whether the subject developed the specified manifestation as a result of the illness.
TBD	Experienced Complication	Did the subject experience any complications due to this episode?
TBD	Type of Complication	If the subject experienced complications due to this episode, what was the complication?
TBD	Patient Immunocompromised	At the time of diagnosis, was the subject immunocompromised?
TBD	Treatment Drug Indicator	Did the subject receive antimicrobial treatment for this infection?
TBD	Medication Administered	What antibiotic did the patient receive for this episode?
TBD	Date Treatment or Therapy Started	Date the treatment was initiated
TBD	Treatment Duration	Number of days the patient actually took the antibiotic referenced
TBD	Occupation related to exposure	Is the subject's current occupation related to the exposure?
TBD	Travel	In the two weeks before symptom onset or diagnosis (use earlier date), did the subject travel out of their county, state, or country of residence?
TBD	International Destination(s) of Recent Travel	International destination, countries traveled to
TBD	Travel State	Domestic destination, state(s) traveled to
TBD	Travel County	Intrastate destination, counties traveled to

TBD	Date of Arrival to Travel Destination	If the subject traveled, when did they arrive to their travel destination?
TBD	Date of Departure from Travel Destination	If the subject traveled, when did they depart from their travel destination?
TBD	Tick Bite Location	If subject noticed tick bite, where did the bite occur (geographic location)?
TBD	Tick Bite Date	If subject noticed tick bite, when did the bite occur?
TBD	Blood Transfusion	In the year before symptom onset or diagnosis (use earlier date), did the subject receive a blood transfusion?
TBD	Blood Transfusion Date	Date(s) of blood transfusion(s)
TBD	Transfusion Associated	Was the subject's infection transfusion associated?
TBD	Transfused Product	If a transfused blood product was implicated in an investigation, specify which type(s) of product.
TBD	Organ Transplant	In the year before symptom onset or diagnosis (use earlier date), did the subject receive an organ transplant(s)?
TBD	Transplant type	If the subject received an organ transplant, what was the organ?
TBD	Transplant date	Date(s) of organ transplant(s)
TBD	Transplant associated infection	Was the subject's infection transplant-related?
TBD	Blood Donor	Did the subject donate blood in the 30 days prior to symptom onset?
TBD	Blood Donation Date	Date(s) of blood donation(s)
TBD	Blood Donor Implicated During Investigation	Was the subject a blood donor identified during a transfusion investigation (i.e., had positive test results and was linked to an infected recipient)?
TBD	Donated Product	If a donated blood product was implicated in an investigation, specify which type(s) of product.
TBD	Blood bank notified	Was the blood bank/hospital/transplant service notified?
TBD	Co-infection	Was the subject diagnosed with a co-infection?
TBD	Co-infection type	Specify coinfection

Hepatitis: 5 Data Elements

5 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Hepatitis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The inclusion of these disease specific elements for Hepatitis A will contribute to enhanced surveillance efforts on the part of the CDC program and allow for timely public health action. Included variables aim to better characterize patient's status and identify an underlying risk factor, which is required to satisfy the case definition:

Value Set Code	**Data Element Name**	**Data Element Description**
PHVS_LabTestResultQualitative_CDC	hepatitis A RNA	Nucleic acid amplification test (NAAT; such as PCR or genotyping) for hepatitis A virus RNA
N/A	Date of hepatitis A RNA test	Date of hepatitis A RNA test
N/A	Total bilirubin	Total bilirubin levels
N/A	Date of bilirubin test	Date of bilirubin test
PHVS_YesNoUnknown_CDC	Experienced homelessness	In the 2-6 weeks prior to symptom onset, was the patient homeless?