Birth Certificate Data Matching for the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program: Survey of State and City Departments of Public Health

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Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products. Mini-Sentinel is one piece of the Sentinel Initiative, a multi-faceted effort by the FDA to develop a national electronic system that will complement existing methods of safety surveillance. Mini-Sentinel Collaborators include Data and Academic Partners that provide access to healthcare data and ongoing scientific, technical, methodological, and organizational expertise. The Mini-Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223200910006.

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I. EXECUTIVE SUMMARY

A. OVERVIEW OF PROJECT

The Food and Drug Administration's (FDA) Mini-Sentinel is a pilot program that aims to conduct active surveillance to detect and refine safety signals that emerge for marketed medical products. The Post-Licensure Rapid Immunization Safety Monitoring (PRISM) network is a program for vaccine safety surveillance within the Mini-Sentinel program. It includes national Data Partners, state and city immunization registries, and vaccine safety investigators.

The goals of this Mini-Sentinel task order activity are to: 1) identify states for potential matching of health plan to birth certificate and fetal death certificate data; 2) gather information about the feasibility and process of conducting matches with birth and fetal death certificate data in selected states; 3) develop a standard file structure for birth and fetal death certificate data within the Mini-Sentinel Common Data Model; and 4) support one or more PRISM Data Partners to conduct birth and fetal death certificate data matching with up to 10 states and create a Mini-Sentinel file with these data. This interim report summarizes the findings of the first two goals of the task order, and provides information to assist FDA and PRISM leaders and Data Partners in the selection of the final states for which one Data Partner will conduct birth and fetal death certificate data matching.

B. SUMMARY OF FINDINGS

Of the 20 state and city departments of public health (DPHs) contacted, 15 returned a completed questionnaire, 2 responded that resources were not available to respond to the request or perform subsequent activities to extract and transfer data for PRISM activities, and 3 did not return a questionnaire. The majority of DPHs (n=12) responded that the preferred process to provide birth or fetal death certificate data to the Data Partner would be for the Data Partner to provide information on the mothers/infants of interest and the state would perform the matching and transfer data only for the infants/fetal deaths successfully matched. In terms of recency of data, eight states (Arizona, California, Colorado, Connecticut, Florida, Indiana, Utah, and Virginia) had 2011 data available as of the date of return of the questionnaire. Most states indicated that institutional review board (IRB) oversight would be necessary or that additional information would be required for specific activities to determine whether IRB oversight would be necessary for use of the data. Eight DPHs indicated that the estimated timeline for submission of an application/request for data to the receipt of data was generally 2 months or less (Colorado, Connecticut, Florida, Indiana, North Carolina, Pennsylvania, Utah, and Virginia); another state (California) indicated a wider range (1 week to 6 months), depending on the review process needed.

C. RECOMMENDATION FOR STATES TO SELECT FOR DATA MATCHING AS PART OF THE CURRENT FEASABILITY PROJECT

Important considerations for selection of the 10 states for final matching as part of the current feasibility project include: 1) the numbers of births within each state for the Data Partner participating in the project; 2) the states for which the Data Partner currently conducts matches with state immunization registry data as part of ongoing projects; 3) availability of variables for characteristics of potential interest (e.g., maternal smoking, gestational age, specific congenital anomalies); 4) whether there is preference for the state (vs. Data Partner) to perform the matching; 5) the complexity of the administrative process and expected time line to obtain data; 6) availability of recent data; and 7) ability

to write birth and fetal death data to a common data format, thus streamlining the work for Data Partners. While the numbers of births within the state is likely a primary consideration, responses to items on the questionnaire provide information to address the latter issues.

All states currently provide information related to gestational age, birth defects, and maternal smoking status. Differences or changes in the availability or formatting of these variables across states (or over time within the same state) generally reflect differences as states transition from the 1989 U.S. standard certificate of birth and report of fetal death formats to adoption of the 2003 U.S. standard certificate formats. One exception is that North Carolina data only captures maternal smoking status and congenital anomalies beginning midyear 2010 and not for earlier periods. Three DPHs, California, Florida, and North Carolina, responded that the preferred process for matching would be for the state to transmit data files for all births and fetal deaths occurring in the state during the years of interest to the Data Partner, allowing the Data Partner to perform the matching; however, the Florida DPH also indicated that it would be possible for the state to perform the matching. Thus, given the project time line (completion in June 2013), in addition to considering states with the highest numbers of births and matches with state immunization registry data, we recommend consideration of the 8 states for which DPHs indicated that the estimated timeline for submission of an application/request for data to the receipt of data was generally 2 months or less (Colorado, Connecticut, Florida, Indiana, North Carolina, Pennsylvania, Utah, and Virginia), particularly the 6 states (Colorado, Connecticut, Florida, Indiana, Utah, and Virginia) that currently have 2011 data available. Two of these states (Florida and Utah) also indicated the capacity to write to a file format (specific data file specifications) requested by PRISM.

II. BACKGROUND

The FDA-sponsored Mini-Sentinel is a pilot program whose aim is to help develop a large-scale active surveillance system to monitor the safety of marketed medical products. The Post-licensure Rapid Immunization Monitoring (PRISM) system, which conducts the vaccine-related activities of the Mini-Sentinel, is a partnership between the FDA, four large national health plans, eight state/city immunization registries, and the Harvard Pilgrim Health Care Institute, which acts as the study coordinating center. PRISM uses computerized claims data from health plans and computerized vaccine data from state and city immunization registries that are linked and updated quarterly.

PRISM investigators are currently building the capacity to study the safety of vaccines in pregnant populations. As part of these efforts, the current workgroup was convened to assess the feasibility of incorporating computerized birth and fetal death certificate data to provide crucial information on factors that may affect adverse pregnancy outcomes and birth outcomes, such as maternal demographics, pregnancy-related conditions, and gestational age at birth or fetal death. Incorporating birth and fetal death registry data would greatly enhance Mini-Sentinel's capability to study the safety of medical products in pregnant women, as birth and fetal death certificates contain information not captured by other computerized data sources. As an initial step in the assessment of the feasibility of birth and fetal death certificate matching, the workgroup gathered information on the process for obtaining the data, as well as data specifications and availability, from select state and city departments of public health (DPHs). This information will be used to assist FDA and PRISM leaders and Data Partners in the selection of the final states for which one Data Partner will conduct birth and fetal death certificate data matching.

III. METHODS

A. OVERVIEW OF DESIGN

The Mini-Sentinel Birth Certificate Matching for PRISM project is a collaboration between the PRISM leaders at FDA and the Mini-Sentinel Operations Center (MSOC), PRISM Data Partners (Aetna, HealthCore, Humana) and selected Academic Partners at the Meyers Primary Care Institute, Group Health Research Institute, and Harvard Pilgrim HealthCare Institute.

PRISM leaders at the MSOC and FDA and Data Partners identified 20 states to be contacted to obtain information on the feasibility of birth and fetal death certificate matching. The workgroup, with input from the PRISM leaders at the MSOC and Data Partners, designed a data collection form to systematically collect information related to the process and requirements for conducting birth certificate and fetal death data matches in the 20 selected states. The questionnaire and other relevant explanatory documents were e-mailed to the state and city DPHs; the initial contact was followed by additional contacts by e-mail or telephone, as needed.

B. PROCESS FOR THE SELECTION OF STATES

PRISM leaders at the MSOC, FDA and Data Partners selected 20 states to be contacted to obtain information on the feasibility of birth and fetal death certificate matching. The final list of states was based upon evaluation of: 1) the states with the highest number of births for each of the Data Partners; 2) the states for which Data Partners conduct matches with state immunization registry data as part of ongoing projects; and 3) the workgroup's prior experience with obtaining birth certificate data as part of Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP) activities.[1]

C. DATA COLLECTION

The workgroup, with input from the PRISM leaders at the MSOC and Data Partners, designed a data collection form to systematically collect information about the feasibility of, and requirements for, conducting birth certificate and fetal death data matches in the states selected (**Appendix A**). Areas of information requested from the state and city DPHs included the process for birth and fetal death certificate matching and file transfer, data specifications and availability, and the administrative process for data release, including requirements for IRB review.

Contacts at each of the selected states were identified through DPH websites. The project manager (KH) initially contacted each state DPH by e-mail. In addition to a cover letter and the questionnaire, the DPH contact was also provided with a packet of documents that clarifies that Mini-Sentinel activities are public health activities and do not require institutional review board (IRB) oversight (**Appendix B**). We followed up with additional e-mails to contacts for states for which we received no response. After multiple e-mail contacts (minimum of 3) with no response, we followed up by telephone.

D. ANALYSIS

For states that returned a completed questionnaire, responses to questionnaire items were compiled. In addition, based upon the data dictionaries or worksheets provided by each state, we determined the availability of specific variables included in the MEPREP birth certificate data file specifications and/or of interest to PRISM MSOC leaders; this information was summarized for both birth and fetal death certificate data.

IV. RESULTS

A. STATE AND CITY DEPARTMENTS OF PUBLIC HEALTH CONTACTED

The **Table 1** shows the 20 state and city DPHs contacted to obtain information related to the process and feasibility for acquisition of birth and fetal death certificate data for PRISM activities. Overall, 15 DPHs (75%) returned a completed questionnaire, 2 DPHs (10%) responded that resources were not available to respond to the request or perform subsequent activities to extract and transfer data for PRISM activities, and 3 DPHs (15%) did not return a questionnaire.

B. BIRTH AND FETAL DEATH CERTIFICATE MATCHING PROCESS AND FILE TRANSFER

Overall, 12 DPHs responded that the preferred process to provide birth or fetal death certificate data to the Data Partners would be for the Data Partner to provide information on the mothers/infants of interest and the state would perform the matching and then transfer data only for the infants/fetal deaths successfully matched (**Table 2**). Three DPHs (California, Florida and North Carolina) responded that the preferred process would be for the state to transmit data files for all births and fetal deaths occurring in the state during the years of interest to the Data Partner, allowing the Data Partner to perform the matching. Of these, two states (California and North Carolina) indicated that the state would not perform the matching, and the other state (Florida) stated there would be additional costs if the state performed the matching.

Table 2 describes additional information related to the process for file transfer.

Several states (Florida, Louisiana, North Carolina, New York, and Utah) indicated the capacity to write to a file format (specific data file specifications) requested by PRISM; however, states indicated that the capacity may depend on the scope of the effort and the request might take additional time to complete.

While the majority of states do not currently have Health Level Seven (HL7) messaging ability for data exchange or transmit records to State and Territorial Exchange of Vital Events (STEVE) system (**Table 2**) the majority indicated the capability to transmit birth records using Interstate Exchange File formats.

C. DATA SPECIFICATIONS AND AVAILABILITY

While most states indicated that the time lag before data are available for a given year is generally 10 months or less, only 8 states (Arizona, California, Colorado, Connecticut, Florida, Indiana, Utah, and Virginia) had 2011 data available as of the date of return of the questionnaire (**Table 3**); however, the dates of return varied (from July to October 2012).

Many states reported changes in the availability or formatting of variables related to gestational age measurement, birth defects, or maternal smoking status during the period 2004 to present. These reported changes generally reflected changes to variables due to transition from the 1989 U.S. standard certificate of birth and report of fetal death formats to adoption of the 2003 U.S. standard certificate formats. These differences include changes to the information on the method of estimating gestational age (clinical vs. obstetric), descriptions of congenital anomalies (e.g., unspecified cleft lip/palate vs. separate variables for cleft palate alone and cleft lip with/without cleft palate), and timing for capturing maternal smoking status (any time during pregnancy vs. separate variables for each trimester).

Additional differences include: 1) North Carolina data only captures maternal smoking status and congenital anomalies beginning midyear 2010 and not for earlier periods; 2) New York City data includes the method of diagnosis for each congenital abnormality beginning in 2008. **Appendices C** and **D** describe the availability of specific variables in the birth and fetal death certificate files for 13 states providing data dictionaries or worksheets.

Fetal death certificate data are not available for one state (New York). The definition for fetal death varies considerably across states, with some states specifying gestational age/weight requirements and others including deaths regardless of the duration of pregnancy (**Appendix E**).

D. ADMINISTRATIVE PROCESS FOR DATA RELEASE

Table 4 describes the requirements and administrative process for data release for each state/city. Three DPHs indicated that IRB review and oversight would be necessary (Connecticut, Florida, New York) and 4 DPHs responded that additional information would be required for specific activities to determine whether IRB oversight would be necessary (Arizona, Louisiana, North Carolina, and Virginia). Eight DPHs indicated that the estimated timeline for submission of an application/request for data to the receipt of data was generally 2 months or less (Colorado, Connecticut, Florida, Indiana, North Carolina, Pennsylvania, Utah, and Virginia); another state (California) indicated a wider range (1 week to 6 months), depending on the review process needed. All DPHs indicated that a contract, data use agreement and/or confidentiality agreement would possibly be required or would generally be executed prior to release of data, although the specific agreements/forms differed across states. Many DPHs indicated that a data use agreement broad enough to encompass all PRISM/MS activities might potentially be executed, but specific language would need to be reviewed when the request for data release is submitted.

V. SUMMARY AND RECOMMENDATIONS

Of the 20 state and city DPHs contacted, 15 returned a completed questionnaire. Questionnaire responses provide important information for the selection of the 10 states for final birth and fetal death certificate matching as part of the current feasibility project, as well as describing the processes and requirements for data acquisition from the states.

The majority of DPHs (n=12) responded that the preferred process to provide birth or fetal death certificate data to the Data Partner would be for the Data Partner to provide information on the mothers/infants of interest, and the state would perform the matching and transfer data only for the infants/fetal deaths successfully matched. While several DPHs responded that the state could potentially transmit data for all births and fetal deaths occurring in the state during the years of interest to the Data Partner, most of these states indicated that additional requirements or caveats would possibly be necessary for approval. Thus, if PRISM prefers to have the Data Partners perform the data matching rather than transmitting information on the infants/mothers of interest to the DPHs, the requirements may be more stringent and data would be available from less than half the selected states.

All states currently provide information related to gestational age, birth defects, and maternal smoking status. Differences or changes in the availability or formatting of variables across states (or over time within the same state) generally reflect differences as states transition from the 1989 U.S. standard certificate of birth and report of fetal death formats to adoption of the 2003 U.S. standard certificate

formats. One exception is that North Carolina data only captures maternal smoking status and congenital anomalies beginning midyear 2010 and not for earlier periods. In addition, one state (New York) does not have fetal death certificate available. Eight states (Arizona, California, Colorado, Connecticut, Florida, Indiana, Utah, and Virginia) had 2011 data available on the date of return of the questionnaire.

Administrative processes for the release for data varied across states. Most states indicated that IRB oversight would be necessary or that additional information would be required for specific activities to determine whether IRB oversight would be necessary for use of the data. Eight DPHs indicated that the estimated timeline for submission of an application/request for data to the receipt of data was generally 2 months or less (Colorado, Connecticut, Florida, Indiana, North Carolina, Pennsylvania, Utah, and Virginia). However, North Carolina would require the Data Partner to perform the matching and Florida would prefer this approach, which is would be more labor intensive for the Data Partner and thus may be less desirable.

Selection of the 10 states for final matching as part of the current feasibility project should entail assessment of the numbers of births within the state for the participating Data Partner, as well as whether or not the Data Partner conducts matches with state immunization registry data. In addition, given the project timeline (completion in June 2013), the complexity of administrative processes, expected time line to obtain data, and the availability of recent data are additional important considerations. Thus, we recommend consideration of the 8 states reporting the shortest timelines for processing and transmitting the data (Colorado, Connecticut, Florida, Indiana, North Carolina, Pennsylvania, Utah, and Virginia), particularly the 6 states Colorado, Connecticut, Florida, Indiana, Utah, and Virginia) that currently have 2011 data available. Two of these states (Florida and Utah) also indicated the capacity to write to a file format (specific data file specifications) requested by PRISM.

VI. ACKNOWLEDGMENTS

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VII. REFERENCES

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Table 1. State Departments of Public Health Contacted

	AZ	CA	CO	CT	FL	GA	IL	IN	KS	KY	LA	MO	NC	NY	NYC	OH	PA	TX	UT	VA
Responded	X	X	X	X	X	X		X			X	X	X	X	X		X		X	X
Responded but cannot participate										X								X		
No Response							X		X							X				
Response Date	8/12	10/12	9/12	10/12	7/12	10/12		10/12		8/12	7/12	9/12	7/12	8/12	8/12		8/12	8/12	9/12	9/12

AZ=Arizona; CA=California; CO=Colorado; CT=Connecticut; FL=Florida; GA=Georgia; IL=Illinois; IN=Indiana; KS=Kansas; KY=Kentucky; LA=Louisiana; MO=Missouri; NC=North Carolina; NY=New York state; NYC=New York City; OH=Ohio; PA=Pennsylvania; TX=Texas; UT=Utah; VA=Virginia

Table 2. Birth and Fetal Death Certificate Matching Process and File Transfer (continued below)

	AZ	CA	CO	CT	FL	GA	IN	LA
State performs matching	Preferred	No	Preferred	Preferred	Possible, additional costs	Preferred	Preferred	Preferred
Variables used for matching	Name, gender, DOB, birth facility number or name, address, SSN.	n/a	Required: Mom name, DOB, SSN, baby DOB. If available: Baby name, birth facility name/code.	Names, DOB; if possible mother maiden name and SSNs	Name, DOB, SSN, birth facility name & NPI.	Name, DOB	Names, DOB, possible SSN	Name, DOB, SSN, birth facility name & NPI, race, sex.
Process for file transfer	SFTP	n/a	SFTP preferred	No preference	SFTP	CD		CD
File size restrictions	None	n/a	None	None	None	None		None
File type preference	SAS, flat text	n/a	SAS preferred, text file possible	SAS, flat text	Flat text	SAS		Flat text
DP performs matching	Possible, with caveats	Preferred	No	Possible, with caveats	Preferred	No	No	No
Variables shared with DP for matching	Name, gender, DOB, birth facility number/name, address, SSN	Varies. SSN not provided.	n/a		Whatever DUA covers	n/a	n/a	n/a
Process for file transfer	SFTP	SFTP or secure email	n/a		SFTP	n/a	n/a	n/a
Expected size of annual file		500-550,000 births annually; 200 MB	n/a		220,000 births	n/a	n/a	n/a
File type provided to DP	SAS, flat text	SAS, comma delimited, or flat text.	n/a		Flat text	n/a	n/a	n/a
Capacity to write to PRISM's file specifications		*Can provide alternative formats of text*	*Can output to SAS, text, excel, access*	Standard state format provided	Able to customize files/specs			Possible, will take longer

	AZ	CA	CO	CT	FL	GA	IN	LA
		such as flat text or SAS files.						
HL7 messaging ability for data exchange	Yes	No	No	No	No		No	Unknown
Transmit records to STEVE system	Yes	Yes	No (future plans to implement)	No (future plans to implement)	No (future plans to implement)		Yes	Unknown
Transmit birth records using Interstate Exchange File formats	Yes	No	Yes	Yes	Yes		Yes	Unknown

Table 2 (continued)

	MO	NC	NY	NYC	PA	UT	VA
State performs matching	Preferred	No	Preferred	Preferred	Preferred	Preferred	Preferred
Variables used for matching	Name, DOB, SSN, birthplace, Mom name/ maiden name, Dad name, zip code, county of residence.	n/a		Required: Name and DOB If available: SSN, Address, Phone, Baby Name, Birthing Facility.	Name, DOB, SSN, Sex.	Required: Mom and Baby Name, DOB. If available: SSN, birth facility.	SSN or Name & DOB
Process for file transfer	CD preferred, SFTP possible	n/a	CD	SFTP (specific delivery service)	CD	SFTP	CD, Zip drive, SFTP
File size restrictions	None	n/a	None	None	None	None	None
File type preference	SAS preferred, text file possible	n/a	SAS	SAS, flat text	Flat text	SAS preferred, text file possible	ACSII
DP performs matching	No	Preferred	No	No	No	Possible, with caveats	Possible, with caveats
Variables shared with DP for matching	n/a	Names, DOB, addresses. SSN cannot be released.	n/a	n/a	n/a		
Process for file transfer	n/a	SFTP or CD	n/a	n/a	n/a		
Expected size of annual file	Approx. 80,000 live births	Approx. 130,000 births	n/a	n/a	n/a		
File type provided to DP	n/a	SAS	n/a	n/a	n/a		
Capacity to write to PRISM's file specifications	*Can export data to any format via SAS*	Dependent on scope and availability	Can write to any file format		Cannot write to external formats; standard	Can write to any file format	*ascii, spss, excel, access, word*

	MO	NC	NY	NYC	PA	UT	VA
					format and specs provided		
HL7 messaging ability for data exchange	Yes	No	Yes	No	No	No	Yes
Transmit records to STEVE system	Yes	No	No	No (expected in 2013)	No	Yes	No (expected soon)
Transmit birth records using Interstate Exchange File formats	Yes	Yes	Yes	Yes (upon request)	Yes	Yes	Yes

AZ=Arizona; CA=California; CO=Colorado; CT=Connecticut; FL=Florida; GA=Georgia; IL=Illinois; IN=Indiana; KS=Kansas; KY=Kentucky; LA=Louisiana; MO=Missouri; NC=North Carolina; NY=New York state; NYC=New York City; OH=Ohio; PA=Pennsylvania; TX=Texas; UT=Utah; VA=Virginia

Table 3. Data Specifications and Availability (continued below)

	AZ	CA	CO	CT	FL	GA	IN	LA
Most recent year birth & fetal death data are available	2011	2012	2011	2011	2012	2010	2011	Birth: 2009; Fetal death: 2010
Time lag before data are available for given year	1.5 years	3-6 months	6 months	6 months for in-state data	< 6 months	Varies	6 months	Varies (system transition)
Year of format changes or availability of gestational age measurement	2012-2013	2007	2007	No changes	No changes			December 2010
Availability and/or format changes of birth defects	2012-2013	2006	2007	No changes	No changes			December 2010
Availability and/or format changes of maternal smoking	2012-2013	2007	2007	No changes	2011			December 2010
Fetal death certificate data availability	Available	Available	Available	Available	Available	Available	Available	Available

Table 3(continued)

	MO	NC	NY	NYC	PA	UT	VA
Most recent year birth & fetal death data are available	2010 (2011 almost complete)	2010	Birth: 2010; Fetal death: n/a	2010	2010	2011	2011
Time lag before data are available for given year	8-10 months	6-8 months	10 months	Up to 18 months	6 months	9 months	6 months
Year of format changes or availability of gestational age measurement	No changes	No changes	No changes	2007	No changes	2009	No changes
Availability and/or format changes of birth defects	2010	2010	No changes	2008	No changes	2009	No changes
Availability and/or format changes of maternal smoking	2010	2010	No changes	2008	No changes	2009	No changes
Fetal death certificate data availability	Available	Available	Not available	Available	Available	Available	Available

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Table 4. Administrative Process for Data Release (continued below)

Administrative Process	AZ	CA	CO	CT	FL	GA	IN	LA
IRB oversight required	Additional information required to confirm.	No	No	Yes	Yes			Additional information required to confirm.
Estimated timeline from application submission through receipt of data	More information required to estimate.	Between 1 week and 6 months, depending on review process needed.	Typically takes about 1 month.	Typically takes about 1 month.	Typically between 6-8 weeks, assuming revisions aren't needed.	Typically it takes 7 business days to receive data after data file submission.	Typically takes about 4 weeks.	Unknown; approval needed from other offices, though file preparation doesn't take long.
Contract or confidentiality agreement required, prior to release of data	Possibly - Additional human subject exemption forms may be required, depending on how linked data are made available to researchers or stake-holders.	Yes - Data Access Agreement in accordance with Health and Safety Code 102230 through 102231.	Yes - After an online data request form is submitted, a data use agreement will be sent to requestor along with a request packet.	Yes – specified with the IRB approval	Yes	Yes – A data use agreement is required.	Yes – There is a standard state form to complete.	Yes - Confidentiality Assurance form must be signed by anyone with access to data.
Possible to keep data use language general, covering all PRISM/MS activities	Possibly - this would need to be reviewed.	Each project requires a separate application, protocol, and IRB/Staff approval process.	No - each activity must be specified clearly in any request or agreement. New activities would need to be addressed as they arise.	Should specify with application, may need amendments.	No - agreements must be specific to the activities for which they are being requested.	Possibly.		Yes - as long as enough information & documentation is provided for the Registrar to review and approve.

Table 4 (continued)

Administrative Process	MO	NC	NY	NYC	PA	UT	VA
IRB oversight required	No	Additional information required to confirm.	Yes	No	No	No	Additional information required to confirm.
Estimated timeline from application submission through receipt of data	3-6 months, assuming payment is made promptly after invoicing.	1-2 months.	More information required to estimate.	Depends on permissions required, number of years, data items and complexity of dataset.	Typically 3-4 weeks, varies depending upon workload and priorities.	Typically takes a couple of weeks.	Typically about 1 month
Contract or confidentiality agreement required, prior to release of data	Yes - signed Confidentiality Pledge and Agreement for Oversight form must be completed if the application for non-research use of vital records data is approved.	Yes - F-14 and confidentiality agreement are required.	Yes	Possibly - contracts, MOUs or other agreements may be required, depending on data request and scope.	Yes - refer to the Application for Access to Protected Data for details.	No - contract is not required, although requestor of data generally drafts a contract to specify specific services.	Yes
Possible to keep data use language general, covering all PRISM/MS activities	Possibly - application language would need to be reviewed, a different purpose or project requires a different application.	No - a data use agreement is necessary for each individual study.	Possibly - this would need to be reviewed.	Possibly - this would need to be reviewed.	Possibly - description of activities and uses of the data must specify how the data may be used. However, it may indicate additional activities in the	Possibly - All data activities should be cited when describing use of data.	Yes – this is possible.

Administrative Process	MO	NC	NY	NYC	PA	UT	VA
					future, provided use of data is consistent.		

AZ=Arizona; CA=California; CO=Colorado; CT=Connecticut; FL=Florida; GA=Georgia; IL=Illinois; IN=Indiana; KS=Kansas; KY=Kentucky; LA=Louisiana; MO=Missouri; NC=North Carolina; NY=New York state; NYC=New York City; OH=Ohio; PA=Pennsylvania; TX=Texas; UT=Utah; VA=Virginia

VIII. APPENDICES

A. APPENDIX A. BIRTH CERTIFICATE AND FETAL DEATH CERTIFICATE DATA MATCHING QUESTIONNAIRE

Birth Certificate and Fetal Death Certificate Data Matching Questionnaire: Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program & Mini-Sentinel

IRB OVERSIGHT

1. After reviewing the U.S. Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) documentation, including Exhibits 1 through 3 (see Appendix), please confirm whether Mini-Sentinel and PRISM activities, including obtaining birth and fetal death certificate data from the State, are public health activities that will not need IRB oversight:
    a. ☐ Agree, activities will NOT need IRB oversight (if checked, skip to question 3)
       ☐ Require further information from IRB before confirming
       ☐ IRB oversight will be required
    b. Additional comments: _____

2. If additional questions and/or clarification are needed to answer question 1 or IRB oversight will be required, please provide the following information or direct us to where this information can be found online:
    a. IRB meeting schedule: _____
    b. Additional comments: _____

3. Contact information for IRB Administrator: _____

BIRTH & FETAL DEATH CERTIFICATE MATCHING PROCESS & FILE TRANSFER

4. Check your state's preferred matching process:
    a. State performs matching - Data Partners (participating PRISM health plan research units) send file with members of interest to the state for matching:
        i. ☐ Yes ☐ No ☐ Not preferred method, but this is possible
        ii. Additional Comments: _____

    b. Data Partner performs matching - State sends data on all births and fetal deaths from state in a file to the Data Partner for matching:
        i. ☐ Yes ☐ No ☐ Not preferred method, but this is possible
        ii. Additional Comments: _____

    c. Other process (please describe): _____

5. If State performs matching, please provide the following information, or describe where it can be found if available online or as a separate attachment:
    a. Specific variables required for matching (e.g., social security number [SSN], names, date of birth [DOB], birth facility name, birth facility National Provider Identifier [NPI]): _____

b. Process for file transfer (e.g., CD-ROM, secure website): _____
c. Restrictions on file size or number of records per file: _____
d. File type preference (e.g., SAS, flat text, etc.): _____

6. If Data Partner performs the matching, please provide the following information, or describe where it can be found if available online or as a separate attachment:
   a. Specific variables that State is able to share with Data Partners for all births (e.g., SSN, names, DOB, addresses, birth facility name , birth facility NPI): _____
   b. Process for file transfer (e.g., CD-ROM, secure website): _____
   c. Expected size of an annual file, including approximate number of births and electronic file size in megabytes: _____
   d. File type provided by the State (e.g., SAS, flat text, etc.): _____

7. Describe your State's capacity to write to a file format (specific data file specifications) of PRISM/Mini-Sentinel's choosing: _____

8. Does your State have HL7 messaging ability for data exchange?
   a. ☐ Yes ☐ No Additional comments: _____

9. Does your State transmit records to the State and Territorial Exchange of Vital Events (STEVE) system?
   a. ☐ Yes ☐ No Additional comments: _____

10. Does your state transmit birth records using the Interstate Exchange File formats?
    a. ☐ Yes ☐ No Additional comments: _____

DATA SPECIFICATIONS & AVAILABILITY

11. What is the most recent year of birth and fetal death certificate data currently available? _____

12. What is the usual time lag before data are available for a given calendar year? _____

13. Please provide all data dictionaries and standard file formats in use from 2004 to present, as well as information regarding any formatting or coding changes during this time. Describe where this information can be found, or provide the link if available online: _____

14. Describe any changes from calendar year 2004 to present related to the availability or formatting of the following variables:
    a. Gestational age measurement: _____
    b. Birth defects: _____
    c. Maternal smoking: _____

15. What is your State's definition of "fetal death", including gestational age and/or birth weight criteria? _____

COSTS, APPLICATIONS & ADMINISTRATIVE PROCESSES FOR DATA RELEASE

16. Provide the estimated costs for obtaining data: _____

17. Provide the expected timeline from application submission through receipt of data, assuming the application is approved with no need for clarification and/or modifications: _____

18. Does your State require a contract or confidentiality agreement to release data?
    a. ☐ Yes ☐ No (if No, skip to question 20)
    b. If yes, please describe: _____

19. Please describe if it is possible to keep data use language in such an agreement general, covering all PRISM and Mini-Sentinel activities, rather than identifying a specific activity/investigation (this would mean that a new application or amendment would not be required for other Mini-Sentinel activities studying different drugs or vaccines in pregnancy): _____

20. Please provide applications for use of birth certificate data and fetal death data, or describe where these can be found: _____

21. Please provide samples of birth certificate and fetal death certificate parent and medical worksheets, or describe where these can be found: _____

ADDITIONAL COMMENTS & CONTACT INFORMATION

Please provide any additional comments or general information that would be helpful for us to know, in preparation for this anticipated request: _____

Please provide contact information for an individual that we might e-mail or telephone in the event that we need clarification on any responses:

Name: _____ **Email:** _____ **Telephone:** _____

THANK YOU FOR YOUR HELP!

Please email your completed questionnaire to Katie_Haffenreffer@hphc.org.

B. APPENDIX B. DOCUMENTS INCLUDED WITH QUESTIONNAIRE SENT TO STATE AND CITY DEPARTMENTS OF PUBLIC HEALTH

July 16th, 2012
[DPH contact information]
Via email
Dear [DPH contact],

We are writing to ask your help with an important public health activity. The U.S. Food and Drug Administration (FDA) is developing resources to evaluate vaccine safety in pregnant women through the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program. We are requesting that you complete a questionnaire to help us determine the feasibility of incorporating birth certificate and fetal death certificate data into the PRISM Program to help with immunization safety monitoring in pregnant women. This is an important new area for vaccine safety surveillance, and birth and fetal death data are critical to provide more complete information.

The PRISM Program is part of the FDA's Mini-Sentinel project, a national pilot project to help create a large-scale active surveillance system to monitor the safety of vaccines, drugs, and other FDA-regulated medical products. PRISM includes data on a large US general population cohort which will be used for active surveillance of vaccine safety; the Program uses data from health plans and state and city immunization registries that are linked and updated quarterly. For additional information on the PRISM Program, please visit the Mini-Sentinel Publications website.

Mini-Sentinel activities are considered public health practice and not research. Thus, these activities do not require Institutional Review Board (IRB) review, since they are considered to be part of FDA's public health mission. For more information, please see the attached documentation from the Office for Human Research Protections (OHRP) and FDA (Exhibits 1 through 3), as well as Mini-Sentinel's Principles and Policies document.

We hope that you will be willing to complete the attached questionnaire, or provide us with a contact at the [DPH] who can assist us. The questionnaire includes items related to IRB oversight, the process for data matching, specific data that are available, costs, and the application process. We would be glad to discuss the project with you and answer any questions you may have. If you prefer, we can administer the questionnaire by telephone.

Thank you very much for considering our request. Please don't hesitate to contact the study team project manager, Katie Haffenreffer, at katie_haffenreffer@hphc.org or 617-509-9807, with any questions or comments.

Sincerely,

Susan E Andrade

Susan E. Andrade, ScD
Senior Research Associate and
Research Associate Professor of Medicine
Meyers Primary Care Institute
University of Massachusetts Medical School

Exhibit 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
Rockville, Maryland 20852

JAN 19 2010

Rachel E. Behrman, M.D., M.P.H.
Acting Associate Director of Medical Policy
Center for Drug Evaluation and Research
Food and Drug Administration
Bldg 22, Room 4208
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Dr. Behrman:

The Office for Human Research Protections has determined that the regulations this office administers (45 CFR part 46) do not apply to the activities that are included in the Food and Drug Administration's Sentinel Initiative.

Do not hesitate to contact us if we can be of any further assistance.

Sincerely,

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections

cc: Joanne Less, FDA

Exhibit 2

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

April 2, 2010

Dr. Richard Platt
Professor and Chair of the Department of Ambulatory Care and Prevention
Harvard Medical School and Harvard Pilgrim Health Care
133 Brookline Ave
Boston, MA 02215

Dear Dr. Platt:

The attached letter from the Office for Human Research Protections states: "The Office for Human Research Protections has determined that the regulations this office administers (45 CFR Part 46) do not apply to the activities that are included in the Food and Drug Administration's Sentinel Initiative."

This assessment applies to the work being conducted by you and your subcontractors under contract number HHSF223200910006I, as the purpose of this contract is to carry out activities that are included in the Food and Drug Administration's Sentinel Initiative.

Please let me know if you have any questions.

Rachel E. Behrman, MD, MPH
Sentinel Initiative, Executive Sponsor

Exhibit 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

July 19, 2010

Dr. Richard Platt

Professor and Chair of the Department of Ambulatory Care and Prevention

Harvard Medical School and Harvard Pilgrim Health Care

133 Brookline Ave

Boston, MA 02215

Re: HIPAA Compliance for Data Sources Participating in the Mini-Sentinel Pilot Project

Dear Dr. Platt:

This letter affirms that the activities performed by the Mini-Sentinel Coordinating Center (MSCC) and its Collaborating Institutions,[1] in fulfillment of contract number HHS F223200910006I, are

[1] The Collaborating Institutions include:
1. America's Health Insurance Plans (AHIP)
2. Brigham and Women's Hospital Division of General Medicine
3. Brigham and Women's Hospital Division of Pharmacoepidemiology & Pharmacoeconomics
4. CIGNA Healthcare
5. Cincinnati Children's Hospital Medical Center
6. Columbia University Department of Statistics
7. Critical Path Institute (C-Path)
8. Duke University School of Medicine
9. HealthCore, Inc.
10. HMO Research Network including: Group Health Research Institute (GHRI) at the University of Washington (UW); Harvard Pilgrim Health Care Institute (HPHCI); Health Partners Research Foundation; Henry Ford Health Systems; Lovelace Clinic Foundation; Marshfield Clinic Research Foundation; Meyers Primary Care Institute (Fallon)
11. Humana-Miami Health Services Research Center (HSRC)
12. Kaiser Permanente Center for Safety and Effectiveness Research (CESR) including: Northern California (KPNC); Southern California (KPSC); Colorado (KPCO); Northwest (KPNW); Georgia (KPSE); Hawaii (KPHI); Ohio (KPOhio); MidAtlantic (KPMidAtlantic)
13. Outcome Sciences, Inc. (Outcome)
14. Risk Sciences International (RSI)
15. Rutgers University Institute for Health
16. University of Alabama at Birmingham (UAB)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

public health activities for which HIPAA permits covered entities to disclose Protected Health Information (PHI) without individual authorization and without the need to obtain approval by or waiver of HIPAA authorization from an Institutional Review Board or Privacy Board.

The HIPAA Privacy Rule, at 45 C.F.R. § 164.512(b)(1)(i), permits covered entities to disclose PHI to a public health authority. The FDA is a public health authority, and has legal authority under Section 905 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. No. 110-85) to conduct activities related to the project entitled, *Detection and Analysis of Adverse Events related to Regulated Products in Automated Healthcare Data. Efforts to Develop the Sentinel Initiative* (the Mini-Sentinel pilot project).

Under 45 C.F.R. § 164.501, a "public health authority" includes the FDA and "a person or entity acting under a grant of authority from or contract with" the FDA. Harvard Pilgrim Health Care is acting under the above-referenced contract with FDA to operate the MSCC. The Collaborating Institutions are under subcontract to Harvard Pilgrim Health Care to conduct activities in furtherance of FDA's Mini-Sentinel pilot project. As such, MSCC and the Collaborating Institutions are all acting under a grant of authority from FDA and have the status of public health authorities under the HIPAA Privacy Rule for purposes of carrying out their responsibilities under the Mini-Sentinel pilot project.

HIPAA covered entities are required to verify that a person requesting PHI for public health purposes is a public health authority. For this purpose, HIPAA covered entities are entitled to rely on a written statement on appropriate government letterhead that the person is acting under the government's authority (see 45 C.F.R. § 164.514(h)(2)(ii)(C)). This letter serves to provide the necessary written statement of authority to the MSCC and the Collaborating Institutions.

The HIPAA Privacy Rule also requires covered entities to comply with the minimum necessary rule at 45 C.F.R. § 164.502, but permits covered entities to rely on representations by a public health authority that it is requesting only the minimum amount of PHI necessary to carry out its public health mission (see 45 C.F.R. 164.514(d)(3)(iii)(A)). The Mini-Sentinel pilot project policies require MSCC and the Collaborating Institutions to request only the minimum necessary information that is required for purposes of carrying out their responsibilities. Thus, HIPAA covered entities may determine that requests from the MSCC and its Collaborating Institutions meet the minimum necessary standard.

Finally, because disclosures of PHI for the Mini-Sentinel pilot project are for public health activities, it is not necessary for HIPAA covered entities to obtain approval by their IRBs or

17. University of Illinois at Chicago (UIC)
18. University of Iowa, College of Public Health
19. University of Pennsylvania School of Medicine
20. Vanderbilt University School of Medicine
21. Weill Cornell Medical College

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

waiver of HIPAA authorization to provide data for Mini-Sentinel. The HHS Office for Human Research Protections (OHRP) has concluded that the regulations found in 45 CFR Part 46 (the "Common Rule") do not apply to activities related to the Sentinel Initiative and thus review by an IRB is not required by that rule.

Rachel E. Behrman, MD, MPH

Sentinel Initiative, Executive Sponsor

C. APPENDIX C. BIRTH CERTIFICATE DATA AVAILABILITY

KEY:

Y= Yes (available)

C = Yes (can be calculated from other available variables)

U = Unclear, but possibly available

N = No (not available)

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO - 2006 and earlier	CO - 2007 to present	FL	GA	IN
GENERAL BIRTH INFORMATION										
StudyID	Disguised member ID									
BDOB	Date of Birth	Y	Y	Y	Y	Y	Y	Y	Y	Y
BSEX	Sex of member	Y	Y	Y	Y	Y	Y	Y	Y	Y
GESTCLIN	Gestational age clinical estimate, in weeks	Y	N	N	N	Y	Y*	Y	N	N
GESTMENS	Gestational age based on last mens, in weeks	C	C	Y	Y	C	C	Y	N	C
GESTOBSTET	Gestational age based on obstetric estimate	N	Y	N	Y	N	Y*	N	N	Y
DAYSGEST_OTH	Days of Gestation	N	N	N	N	N	N	N	Y	N
HOW	how lmp/gest was arrived at (GESTMENS was arrived at)	N	N	N	N	N	N	N	N	N
DELIVMETH	Delivery method	Y	Y	Y	Y	Y	Y	Y	Y	Y
BWEIGHT	Birthweight in grams	Y	Y	Y	Y	Y	Y	Y	Y	Y
PLURALITY	single, twin, etc	Y	Y	Y	Y	Y	Y	U	Y	Y
APGAR5	APGAR score at 5 minutes	Y	Y	N	Y	Y	Y	Y	Y	Y
APGAR10	APGAR score at 10 minutes	N	Y	N	Y	N	Y	Y	N	Y

Variable Name	Definition	LA	MO - 2009 and earlier	MO - 2010 to present	NYC	NY	PA	UT - 2009 to present	VA
GENERAL BIRTH INFORMATION									
StudyID	Disguised member ID								
BDOB	Date of Birth	Y	Y	Y	Y	Y	Y	Y	Y
BSEX	Sex of member	Y	Y	Y	Y	Y	Y	Y	Y
GESTCLIN	Gestational age clinical estimate, in weeks	Y	Y	N	Y	Y	N	N	Y
GESTMENS	Gestational age based on last mens, in weeks	C	C	C	C	C	C	C	C
GESTOBSTET	Gestational age based on obstetric estimate	N	N	Y	N	N	Y	Y	N
DAYSGEST_OTH	Days of Gestation	N	N	N	N	N	N	N	N
HOW	how lmp/gest was arrived at (GESTMENS was arrived at)	N	N	N	N	N	N	N	N
DELIVMETH	Delivery method	Y	Y	Y	Y	Y	Y	Y	Y
BWEIGHT	Birthweight in grams	Y	Y	Y	Y	Y	Y	Y	Y
PLURALITY	single, twin, etc	Y	Y	Y	Y	Y	Y	Y	Y
APGAR5	APGAR score at 5 minutes	Y	Y	Y	Y	Y	Y	Y	Y
APGAR10	APGAR score at 10 minutes	N	N	Y	Y	Y	Y	Y	N

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO - 2006 and earlier	CO - 2007 to present	FL	GA	IN
MOTHER AND FATHER INFORMATION										
MDOB	Mother's Date of Birth	Y	Y	Y	Y	Y	Y	Y	N	Y
MMAILZIP	Mother	Y	Y	N*	N*	Y	Y	Y	N*	Y
MMARSTATUS	Mother's marital status	Y	Y	N	N	Y	Y	Y	Y	Y
MENSDT	Mother's date of last menses	Y	Y	Y	Y	Y	Y	Y	N	Y
PRENATMON	Month prenatal care began	Y	C	Y	Y	Y	Y	Y	Y	C
PRENATNUM	Number of prenatal care visits	Y	Y	Y	Y	Y	Y	Y	Y	Y
MGRAVIDITY	Mom - Gravidity (total pregnancies)	C	C	Y	Y	C	C	C	C	C
MPARITY	Mom - Parity (TPAL format)	N	N	N	N	N	N	N	N	N
NUM_BTHS	previous live births	C	C	Y	Y	C	C	C	C	C
PLIV_DEAD	previous live births now dead	Y	Y	Y	Y	Y	Y	Y	N	Y
PLIV_LIV	previous live births now living	Y	Y	Y	Y	Y	Y	Y	N	Y
NUM_TRMS	previous other pregnancy outcomes (fetal deaths/ terminations/ spontaneous or induced losses or ectopic pregnancies)	Y	Y	C	C	Y	Y	Y	Y	Y
MRACE1-X	Mother's race	Y	U	Y	Y	Y	Y	Y	Y	Y
FRACE1-X	Father's race	Y	U	Y	Y	Y	Y	Y	Y	Y
HISP_MOM	hispanic origin - mother	Y	U	Y	Y	Y	Y	Y	Y	Y
HISP_DAD	hispanic origin - father	Y	U	Y	Y	Y	Y	Y	Y	Y
AGE_MOM	age of mother at birth of child	C	C	Y	Y	C	C	Y	Y	C
AGE_DAD	age of father at birth of child	C	C	Y	Y	C	C	Y	Y	C
EDUC_MOM	education of mother	Y	U	Y	Y	Y	Y	U	Y	Y
EDUC_DAD	education of father	Y	U	Y	Y	Y	Y	U	Y	Y
TOBACCO	mother was a smoker	Y	C	Y	Y	Y	C	Y	Y	C
MCIGNUM	Number of cigarettes daily during preg	Y	C	N	C	Y	C	Y	Y	C
CIGPREPREG	Number of cigarettes daily pre-pregnancy	N	Y	N	Y	N	Y	Y	N	Y

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO - 2006 and earlier	CO - 2007 to present	FL	GA	IN
CIGTRIM1	Number of cigarettes daily during 1st 3 months of pregnancy	N	Y	N	Y	N	Y	Y	N	Y
CIGTRIM2	Number of cigarettes daily during 2nd 3 months of pregnancy	N	Y	N	Y	N	Y	Y	N	Y
CIGTRIM3	Number of cigarettes daily during 3rd trimester	N	Y	N	Y	N	Y	Y	N	Y
ALCOHOL	Mother drank alcohol	Y	N	N	N	Y	C	Y	Y	N
DRINKS	number drinks consumed per week	Y	N	N	N	Y	C	U	Y	N
WGT_PRE_PREG	maternal weight pre-pregnancy	N	Y	N	Y	N	Y	Y	N	Y
HGT_MOM	maternal height	N	Y	N	Y	N	Y	Y	N	Y
WGT_GAIN	maternal weight gain in pounds	Y	C	N	C	Y	C	C	N	C
PRV_LT37	previous infant - <37 wks	N#	Y	Y	Y	N#	Y	Y	N#	Y
GT4000	previous infant - 4000+ grams	Y	N	Y	N	Y	Y	N	Y	N
PRVSMALL	previous infant small for gest age	N	N	N	N	N	N	N	N	N

Variable Name	Definition	LA	MO - 2009 and earlier	MO - 2010 to present	NYC	NY	PA	UT - 2009 to present	VA
MOTHER AND FATHER INFORMATION									
MDOB	Mother's Date of Birth	Y	Y	Y	Y	Y	Y	Y	N
MMAILZIP	Mother	N*	Y	Y	N*	Y	Y	Y	N*
MMARSTATUS	Mother's marital status	Y	Y	Y	N	N	Y	Y	N
MENSDT	Mother's date of last menses	Y	Y	Y	Y	Y	Y	Y	Y
PRENATMON	Month prenatal care began	Y	Y	C	C	Y	C	C	Y
PRENATNUM	Number of prenatal care visits	Y	Y	Y	Y	Y	Y	Y	Y
MGRAVIDITY	Mom - Gravidity (total pregnancies)	C	C	C	C	Y	C	C	C
MPARITY	Mom - Parity (TPAL format)	N	N	N	N	N	N	N	N
NUM_BTHS	previous live births	C	C	C	Y	Y	C	C	C
PLIV_DEAD	previous live births now dead	Y	Y	Y	Y	Y	Y	Y	Y
PLIV_LIV	previous live births now living	Y	Y	Y	Y	Y	Y	Y	Y
NUM_TRMS	previous other pregnancy outcomes (fetal deaths/ terminations/ spontaneous or induced losses or ectopic pregnancies)	Y	Y	Y	Y	C	Y	Y	Y
MRACE1-X	Mother's race	Y	Y	Y	Y	Y	Y	Y	Y
FRACE1-X	Father's race	Y	Y	Y	Y	Y	Y	Y	Y
HISP_MOM	hispanic origin - mother	Y	Y	Y	Y	Y	Y	Y	Y
HISP_DAD	hispanic origin - father	Y	Y	Y	Y	Y	Y	Y	Y
AGE_MOM	age of mother at birth of child	Y	Y	Y	C	Y	Y	Y	Y
AGE_DAD	age of father at birth of child	Y	Y	Y	C	Y	Y	Y	Y
EDUC_MOM	education of mother	Y	Y	Y	Y	Y	Y	Y	Y
EDUC_DAD	education of father	Y	Y	Y	Y	Y	Y	Y	Y
TOBACCO	mother was a smoker	Y	Y	C	Y	C	C	Y	Y
MCIGNUM	Number of cigarettes daily during preg	Y	Y	C	C	C	C	C	Y
CIGPREPREG	Number of cigarettes daily pre-pregnancy	N	N	Y	Y	Y	Y	Y	N

Variable Name	Definition	LA	MO - 2009 and earlier	MO - 2010 to present	NYC	NY	PA	UT - 2009 to present	VA
CIGTRIM1	Number of cigarettes daily during 1st 3 months of pregnancy	N	N	Y	Y	Y	Y	Y	N
CIGTRIM2	Number of cigarettes daily during 2nd 3 months of pregnancy	N	N	Y	Y	Y	Y	Y	N
CIGTRIM3	Number of cigarettes daily during 3rd trimester	N	N	Y	Y	Y	Y	Y	N
ALCOHOL	Mother drank alcohol	Y	Y	N	Y	N	N	N	Y
DRINKS	number drinks consumed per week	Y	Y	N	N	N	N	N	Y
WGT_PRE_PREG	maternal weight pre-pregnancy	N	Y	Y	Y	Y	Y	Y	N
HGT_MOM	maternal height	N	Y	Y	Y	Y	Y	Y	N
WGT_GAIN	maternal weight gain in pounds	Y	Y	C	C	C	C	Y	Y
PRV_LT37	previous infant - <37 wks	N#	N#	Y	Y	Y	Y	Y	N#
GT4000	previous infant - 4000+ grams	Y	Y	N	N	N	N	Y	Y
PRVSMALL	previous infant small for gest age	N	N	N	N	N	N	N	N

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO - 2006 and earlier	CO - 2007 to present	FL	GA	IN
CONGENITAL ANOMALIES										
NO_CONG_AN	No congenital anomalies listed	Y	Y	Y	Y	Y	Y	Y	N	Y
BIFIDA	spina bifida/meningocele	Y	N	Y	Y	Y	Y	Y	Y	Y
ANENCEPH	anencephalus	Y	N	Y	Y	Y	Y	Y	Y	Y
HYDROCEPH	hydrocephalus	Y	N	Y	N	Y	N	N	Y	N
MICROCEPH	microcephalus	Y	N	Y	N	Y	N	N	Y	Y
OTH_CENT_NERV	other central nervous system anomalies	Y	N	Y	N	Y	N	N	Y	N
MALF_HRT	heart malformations	Y	N	Y	N	Y	N	N	Y	N
CYAN_CONG_HEART	Cyanotic congenital heart disease	N	Y	N	Y	N	Y	Y	N	Y
PAT_DUCT	patent ductus arteriosis	N	N	Y	N	N	N	N	N	N
CIRC_RESP_ANOMAL	other circulatory/respiratory	Y	N	Y	N	Y	Y	N	Y	N
OMPHALO	Omphalocele	N	Y	N	Y	N	Y	Y	N	Y
GASTROSCH	Gastroschisis	N	Y	N	Y	N	Y	Y	N	Y
OMPHALO_UNSP	unspecified omphalocele/gastroschisis	Y	N	Y	N	Y	N	N	Y	N
TRACH_ESO_FISTUL	tra/esophageal fistula, atresia	Y	N	Y	Y	Y	N	N	Y	N
RECT_ATRES	rectal atresis/stenosis	Y	N	Y	N	Y	N	N	Y	N
OTH_GASTR	other gastrointestinal anomalies	Y	N	Y	N	Y	N	N	Y	N
HYPOSPAD	hypospadias	N	Y	Y	Y	N	Y	Y	N	Y
MALF_GENITAL	malformed genitals	Y	N	N	N	Y	N	N	Y	N
REN_AGEN	renal agenesis	Y	N	Y	N	Y	N	N	Y	N
OTH_UROGEN	other urogenital anomalies	Y	N	Y	N	Y	Y	N	Y	N
C_LIP	Cleft lip with or without cleft palate	Y	N	Y	Y	N	Y	Y	N	Y
PALATE_ONLY	Cleft palate alone	N	N	Y	Y	N	Y	Y	N	Y
PALATE _UNSP	unspecified cleft lip/palate	N	Y	N	N	Y	N	N	Y	N
POLYDAC	poly/syndactyly	Y	N	Y	N	Y	N	N	Y	N
LIMB_RED	Limb reduction defect	N	Y	Y	Y	N	Y	Y	N	Y
CLUB_FOOT	club foot	Y	N	N	N	Y	N	N	Y	N
DIAPH_HERNIA	Diaphragmatic hernia	Y	N	Y	Y	Y	Y	Y	Y	Y

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO - 2006 and earlier	CO - 2007 to present	FL	GA	IN
DISLOC_HIP	congenital dislocation of the hip	N	N	Y	N	N	N	N	N	N
OTH_MUSC_INTEG	other muscloskeletal/integumental anomalies	Y	N	Y	N	Y	Y	N	Y	N
DOWNS	Downs syndrome	Y	N	Y	Y	Y	Y	Y	Y	Y
OTHERCHR	other chromosomal anomalies	Y	N	Y	Y	Y	Y	Y	Y	Y
OTHERANO	other congenital anomalies	Y	N	Y	Y	Y	Y	Y	N	N
COMPLICATIONS OF PREGNANCY AND CONCURRENT ILLNESSES										
DIABETES	medical risk factor during pregnancy - diabetes	Y	C	Y	C	C	C	C	Y	C
CHYPER	medical risk factor during pregnancy - chronic hypertension	Y	Y	Y	Y	Y	Y	Y	Y	Y
PIH	pregnancy induced hypertension/preeclampsia	Y	Y	Y	Y	Y	Y	Y	Y	Y
ECLAMP	medical risk factor during pregnancy - eclampsia	Y	Y	Y	Y	Y	Y	Y	Y	Y

Variable Name	Definition	LA	MO - 2009 and earlier	MO - 2010 to present	NYC	NY	PA	UT - 2009 to present	VA
CONGENITAL ANOMALIES									
NO_CONG_AN	No congenital anomalies listed	Y	N	N	Y	Y	Y	Y	Y
BIFIDA	spina bifida/meningocele	Y	Y	Y	Y	Y	Y	Y	Y
ANENCEPH	anencephalus	Y	Y	Y	Y	Y	Y	Y	Y
HYDROCEPH	hydrocephalus	Y	Y	N	N	N	N	Y	Y
MICROCEPH	microcephalus	Y	Y	N	N	N	N	Y	Y
OTH_CENT_NERV	other central nervous system anomalies	Y	Y	N	N	N	N	Y	Y
MALF_HRT	heart malformations	Y	Y	N	N	N	N	N	Y
CYAN_CONG_HEART	Cyanotic congenital heart disease	N	N	Y	Y	Y	Y	Y	N
PAT_DUCT	patent ductus arteriosis	N	N	N	N	N	N	U	N
CIRC_RESP_ANOMAL	other circulatory/respiratory	Y	Y	N	N	N	N	Y	Y
OMPHALO	Omphalocele	N	N	Y	Y	Y	Y	Y	N
GASTROSCH	Gastroschisis	N	N	Y	Y	Y	Y	Y	N
OMPHALO_UNSP	unspecified omphalocele/gastroschisis	Y	Y	N	N	N	N	N	Y
TRACH_ESO_FISTUL	tra/esophageal fistula, atresia	Y	Y	N	N	N	N	Y	Y
RECT_ATRES	rectal atresis/stenosis	Y	Y	N	N	N	N	Y	Y
OTH_GASTR	other gastrointestinal anomalies	Y	N	N	N	N	N	Y	Y
HYPOSPAD	hypospadias	N	N	Y	Y	Y	Y	Y	N
MALF_GENITAL	malformed genitals	Y	Y	N	N	N	N	Y	Y
REN_AGEN	renal agenesis	Y	Y	N	N	N	N	Y	Y
OTH_UROGEN	other urogenital anomalies	Y	Y	N	N	N	N	Y	Y
C_LIP	Cleft lip with or without cleft palate	N	N	Y	Y	Y	Y	Y	N
PALATE_ONLY	Cleft palate alone	N	N	Y	Y	Y	Y	Y	N
PALATE _UNSP	unspecified cleft lip/palate	Y	Y	N	N	N	N	N	Y
POLYDAC	poly/syndactyly	Y	Y	N	N	N	N	Y	Y
LIMB_RED	Limb reduction defect	N	N	Y	Y	Y	Y	Y	N
CLUB_FOOT	club foot	Y	Y	N	N	N	N	Y	Y
DIAPH_HERNIA	Diaphragmatic hernia	Y	Y	Y	Y	Y	N	Y	Y

Variable Name	Definition	LA	MO - 2009 and earlier	MO - 2010 to present	NYC	NY	PA	UT - 2009 to present	VA
DISLOC_HIP	congenital dislocation of the hip	N	N	N	N	N	N	Y	N
OTH_MUSC_INTEG	other muscloskeletal/integumental anomalies	Y	Y	N	N	N	N	Y	Y
DOWNS	Downs syndrome	Y	Y	Y	Y	Y	C	Y	Y
OTHERCHR	other chromosomal anomalies	Y	Y	Y	Y	Y	C	Y	Y
OTHERANO	other congenital anomalies	Y	N	N	N	N	N	Y	Y
COMPLICATIONS OF PREGNANCY AND CONCURRENT ILLNESSES									
DIABETES	medical risk factor during pregnancy - diabetes	Y	C	C	C	C	C	Y	Y
CHYPER	medical risk factor during pregnancy - chronic hypertension	Y	Y	Y	Y	Y	Y	Y	Y
PIH	pregnancy induced hypertension/preeclampsia	Y	Y	Y	Y	Y	Y	Y	Y
ECLAMP	medical risk factor during pregnancy - eclampsia	Y	Y	Y	Y	Y	N	Y	Y

AZ=Arizona; CA=California; CO=Colorado; CT=Connecticut; FL=Florida; GA=Georgia; IL=Illinois; IN=Indiana; KS=Kansas; KY=Kentucky; LA=Louisiana; MO=Missouri; NC=North Carolia; NY=New York state; NYC=New York City; OH=Ohio; PA=Pennsylvania; TX=Texas; UT=Utah; VA=Virginia

* residence of zip code available
# previous preterm infant or SGA combined in one category

Source of data:
ARIZONA: data dictionary (current and proposed)
CALIFORNIA: data dictionaries

COLORADO:	worksheets
FLORIDA:	data dictionaries, but in some cases, worksheet had different variables (obstetric estimate of gestational age, etc)
GEORGIA:	data dictionary
INDIANA:	worksheet
LOUISIANA:	data dictionary (in unclear cases, also used worksheet; e.g. 'gestation')
MISSOURI:	data dictionary
NEW YORK CITY:	worksheet
NEW YORK STATE:	data dictionary
PENNSYLVANIA:	data dictionary
UTAH:	data dictionary (in unclear cases, also used worksheet; e.g. 'gestation')
VIRGINIA:	data dictionary

D. APPENDIX D. FETAL DEATH CERTIFICATE DATA AVAILABILITY

KEY:
Y= Yes (available)
C = Yes (can be calculated from other available variables)
U = Unclear, but possibly available
N = No (not available)

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO	FL - 2005 and earlier	Fl -2006 to present	GA	IN
GENERAL BIRTH INFORMATION										
StudyID	Disguised member ID									
BDOB	Date of Delivery	Y	Y	Y	Y	Y	Y	Y	Y	Y
BSEX	Sex of member	Y	Y	Y	Y	Y	Y	Y	Y	Y
GESTCLIN	Gestational age clinical estimate, in weeks	Y	N	N	N	Y	Y	Y	N	N
GESTMENS	Gestational age based on last mens, in weeks	C	C	Y	Y	C	C	Y	N	C
GESTOBSTET	Gestational age based on obstetric estimate	N	Y	N	Y	N	N	N	N	Y
DAYSGEST_OTH	Days of Gestation	N	N	N	N	N	N	N	Y	N
HOW	how lmp/gest was arrived at (GESTMENS was arrived at)	N	N	N	N	N	N	N	N	N
DELIVMETH	Delivery method	Y	Y	Y	Y	Y	Y	Y	Y	Y
BWEIGHT	Birthweight in grams	Y	Y	Y	Y	Y	Y	Y	Y	Y
PLURALITY	single, twin, etc	Y	Y	Y	Y	Y	Y	Y	Y	Y

Variable Name	Definition	LA	MO - 2010 and earlier	MO - 2011 to present	NYC	PA	UT -2007 to present	VA
GENERAL BIRTH INFORMATION								
StudyID	Disguised member ID							
BDOB	Date of Delivery	Y	Y	Y	Y	Y	Y	Y
BSEX	Sex of member	Y	Y	Y	Y	Y	Y	Y
GESTCLIN	Gestational age clinical estimate, in weeks	Y	Y	N	N	N	N	Y
GESTMENS	Gestational age based on last mens, in weeks	C	C	C	C	C	C	C
GESTOBSTET	Gestational age based on obstetric estimate	N	N	Y	Y	N	Y	N
DAYSGEST_OTH	Days of Gestation	N	N	N	N	Y (METHOD NOT SPECIFIED	N	N
HOW	how lmp/gest was arrived at (GESTMENS was arrived at)	N	N	N	N	N	N	N
DELIVMETH	Delivery method	Y	Y	Y	Y	Y	Y	Y
BWEIGHT	Birthweight in grams	Y	Y	Y	Y	Y	Y	Y
PLURALITY	single, twin, etc	Y	Y	Y	Y	Y	Y	Y

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO	FL - 2005 and earlier	Fl -2006 to present	GA	IN
MOTHER AND FATHER INFORMATION										
MDOB	Mother's Date of Birth	Y	Y	Y	Y	Y	Y	Y	N	Y
MMAILZIP	Mother	Y	N*	N*	N*	N*	N*	N*	N*	N*
MMARSTATUS	Mother's marital status	Y	Y	N	N	Y	Y	Y	Y	Y
MENSDT	Mother's date of last menses	Y	Y	Y	C	Y	Y	Y	N	Y
PRENATMON	Month prenatal care began	Y	C	Y	Y	Y	Y	Y	Y	C
PRENATNUM	Number of prenatal care visits	Y	Y	Y	Y	Y	Y	Y	Y	Y
MGRAVIDITY	Mom - Gravidity (total pregnancies)	C	C	Y	Y	C	C	C	N	C
MPARITY	Mom - Parity (TPAL format)	N	N	N	N	N	N	N	N	N
NUM_BTHS	previous live births	C	C	Y	Y	C	C	C	N	y
PLIV_DEAD	previous live births now dead	Y	Y	Y	Y	Y	Y	Y	N	Y
PLIV_LIV	previous live births now living	Y	Y	Y	Y	Y	Y	Y	N	Y
NUM_TRMS	previous other pregnancy outcomes (fetal deaths/ terminations/ spontaneous or induced losses or ectopic pregnancies)	Y	Y	C	C	Y	Y	Y	Y	Y
MRACE1-X	Mother's race	Y	U	Y	Y	Y	Y	Y	Y	Y
FRACE1-X	Father's race	Y	U	Y	Y	Y	Y	Y	Y	N
HISP_MOM	hispanic origin - mother	Y	U	Y	Y	Y	Y	Y	Y	Y
HISP_DAD	hispanic origin - father	Y	U	Y	Y	Y	Y	Y	N	N
AGE_MOM	age of mother at birth of child	C	C	Y	Y	C	Y	Y	Y	C
AGE_DAD	age of father at birth of child	C	C	Y	Y	C	Y	Y	Y	C
EDUC_MOM	education of mother	Y	U	Y	Y	Y	Y	Y	Y	Y
EDUC_DAD	education of father	Y	U	Y	Y	Y	Y	Y	Y	N
TOBACCO	mother was a smoker	Y	C	Y	Y	Y	Y	Y	Y	C
MCIGNUM	Number of cigarettes daily during preg	Y	C	N	C	Y	Y	Y	Y	C
CIGPREPREG	Number of cigarettes daily pre-pregnancy	N	Y	N	Y	N	N	N	N	Y

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO	FL - 2005 and earlier	Fl -2006 to present	GA	IN
CIGTRIM1	Number of cigarettes daily during 1st 3 months of pregnancy	N	Y	N	Y	N	N	N	N	Y
CIGTRIM2	Number of cigarettes daily during 2nd 3 months of pregnancy	N	Y	N	Y	N	N	N	N	Y
CIGTRIM3	Number of cigarettes daily during 3rd trimester	N	Y	N	Y	N	N	N	N	Y
ALCOHOL	Mother drank alcohol	Y	N	N	N	Y	Y	N	Y	N
DRINKS	number drinks consumed per week	Y	N	N	N	Y	Y	N	Y	N
WGT_PRE_PREG	maternal weight pre-pregnancy	N	Y	N	Y	N	N	Y	N	Y
HGT_MOM	maternal height	N	Y	N	Y	N	N	Y	N	Y
WGT_GAIN	maternal weight gain in pounds	Y	C	N	C	Y	Y	C	N	C
PRV_LT37	previous infant - <37 wks	N#	Y	Y	Y	N#	N	Y	N#	Y
GT4000	previous infant - 4000+ grams	Y	N	Y	N	Y	Y	N	Y	N
PRVSMALL	previous infant small for gest age	N	N	N	N	N	N	N	N	N

Variable Name	Definition	LA	MO - 2010 and earlier	MO - 2011 to present	NYC	PA	UT -2007 to present	VA
MOTHER AND FATHER INFORMATION								
MDOB	Mother's Date of Birth	Y	Y	Y	Y	Y	Y	N
MMAILZIP	Mother	N*	N*	Y	N*	Y	N*	N
MMARSTATUS	Mother's marital status	Y	Y	Y	N	Y	Y	N
MENSDT	Mother's date of last menses	Y	Y	Y	Y	Y	Y	Y
PRENATMON	Month prenatal care began	Y	Y	C	C	C	C	Y
PRENATNUM	Number of prenatal care visits	Y	Y	Y	Y	Y	Y	Y
MGRAVIDITY	Mom - Gravidity (total pregnancies)	C	C	C	C	C	C	C
MPARITY	Mom - Parity (TPAL format)	N	N	N	N	N	N	N
NUM_BTHS	previous live births	C	C	C	Y	C	C	C
PLIV_DEAD	previous live births now dead	Y	Y	Y	Y	Y	Y	Y
PLIV_LIV	previous live births now living	Y	Y	Y	Y	Y	Y	Y
NUM_TRMS	previous other pregnancy outcomes (fetal deaths/ terminations/ spontaneous or induced losses or ectopic pregnancies)	Y	Y	Y	Y	Y	Y	Y
MRACE1-X	Mother's race	Y	Y	Y	Y	Y	Y	Y
FRACE1-X	Father's race	Y	Y	N	Y	Y	N	N
HISP_MOM	hispanic origin - mother	Y	Y	Y	Y	Y	Y	Y
HISP_DAD	hispanic origin - father	Y	Y	N	Y	Y	N	N
AGE_MOM	age of mother at birth of child	Y	Y	Y	Y	Y	Y	Y
AGE_DAD	age of father at birth of child	Y	Y	Y	Y	Y	Y	N
EDUC_MOM	education of mother	Y	Y	Y	Y	Y	Y	Y
EDUC_DAD	education of father	Y	Y	N	Y	Y	N	N
TOBACCO	mother was a smoker	Y	Y	C	Y	Y	Y	Y
MCIGNUM	Number of cigarettes daily during preg	Y	Y	C	C	Y	C	Y
CIGPREPREG	Number of cigarettes daily pre-pregnancy	N	N	Y	Y	N	Y	N
CIGTRIM1	Number of cigarettes daily during 1st 3 months of pregnancy	N	N	Y	Y	N	Y	N

Variable Name	Definition	LA	MO - 2010 and earlier	MO - 2011 to present	NYC	PA	UT -2007 to present	VA
CIGTRIM2	Number of cigarettes daily during 2nd 3 months of pregnancy	N	N	Y	Y	N	Y	N
CIGTRIM3	Number of cigarettes daily during 3rd trimester	N	N	Y	Y	N	Y	N
ALCOHOL	Mother drank alcohol	Y	Y	N	Y	Y	Y	Y
DRINKS	number drinks consumed per week	Y	Y	N	N	Y	N	Y
WGT_PRE_PREG	maternal weight pre-pregnancy	N	Y	Y	Y	N	Y	N
HGT_MOM	maternal height	N	Y	Y	Y	N	Y	N
WGT_GAIN	maternal weight gain in pounds	Y	Y	C	C	Y	C	Y
PRV_LT37	previous infant - <37 wks	N#	N#	Y	Y	N#	Y	N#
GT4000	previous infant - 4000+ grams	Y	Y	N	N	Y	N	Y
PRVSMALL	previous infant small for gest age	N	N	N	N	N	N	N

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO	FL - 2005 and earlier	Fl -2006 to present	GA	IN
CONGENITAL ANOMALIES										
NO_CONG_AN	No congenital anomalies listed	Y	Y	Y	Y	Y	Y	Y	N	Y
BIFIDA	spina bifida/meningocele	Y	N	Y	Y	Y	Y	Y	Y	Y
ANENCEPH	anencephalus	Y	N	Y	Y	Y	Y	Y	Y	Y
HYDROCEPH	hydrocephalus	Y	N	Y	N	Y	Y	N	Y	N
MICROCEPH	microcephalus	Y	N	Y	N	Y	Y	N	Y	N
OTH_CENT_NERV	other central nervous system anomalies	Y	N	Y	N	Y	Y	N	Y	N
MALF_HRT	heart malformations	Y	N	Y	N	Y	Y	N	Y	N
CYAN_CONG_HEART	Cyanotic congenital heart disease	N	Y	N	Y	N	N	Y	N	Y
PAT_DUCT	patent ductus arteriosis	N	N	Y	N	N	N	N	N	N
CIRC_RESP_ANOMAL	other circulatory/respiratory	Y	N	Y	N	Y	Y	N	Y	N
OMPHALO	Omphalocele	N	Y	N	Y	N	N	Y	N	Y
GASTROSCH	Gastroschisis	N	Y	N	Y	N	N	Y	N	Y
OMPHALO_UNSP	unspecified omphalocele/gastroschisis	Y	N	Y	N	Y	Y	N	Y	N
TRACH_ESO_FISTUL	tra/esophageal fistula, atresia	Y	N	Y	Y	Y	Y	N	Y	N
RECT_ATRES	rectal atresis/stenosis	Y	N	Y	N	Y	Y	N	Y	N
OTH_GASTR	other gastrointestinal anomalies	Y	N	Y	N	N	Y	N	Y	N
HYPOSPAD	hypospadias	N	Y	Y	Y	N	N	Y	N	Y
MALF_GENITAL	malformed genitals	Y	N	N	N	Y	Y	N	Y	N
REN_AGEN	renal agenesis	Y	N	Y	N	Y	Y	N	Y	N
OTH_UROGEN	other urogenital anomalies	Y	N	Y	N	Y	Y	N	Y	N
C_LIP	Cleft lip with or without cleft	N	N	Y	Y	N	N	Y	N	Y

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO	FL - 2005 and earlier	Fl -2006 to present	GA	IN
	palate									
PALATE_ONLY	Cleft palate alone	N	N	Y	Y	N	N	Y	N	Y
PALATE _UNSP	Unspecified cleft lip/palate	Y	Y	N	N	Y	Y	N	Y	N
POLYDAC	poly/syndactyly	Y	N	Y	N	Y	Y	N	Y	N
LIMB_RED	Limb reduction defect	N	Y	Y	Y	N	N	Y	N	Y
CLUB_FOOT	club foot	Y	N	N	N	Y	Y	N	Y	N
DIAPH_HERNIA	Diaphragmatic hernia	Y	N	Y	Y	Y	Y	Y	Y	Y
DISLOC_HIP	congenital dislocation of the hip	N	N	Y	N	N	N	N	N	N
OTH_MUSC_INTEG	other muscloskeletal/integumental anomalies	Y	N	Y	N	Y	Y	N	Y	N
DOWNS	Downs syndrome	Y	N	Y	Y	Y	Y	Y	Y	Y
OTHERCHR	other chromosomal anomalies	Y	N	Y	Y	Y	Y	Y	Y	Y
OTHERANO	other congenital anomalies	Y	Y	Y	Y	Y	Y	Y	N	N
COMPLICATIONS OF PREGNANCY AND CONCURRENT ILLNESSES										
DIABETES	medical risk factor during pregnancy - diabetes	Y	C	Y	C	C	Y	C	Y	C
CHYPER	medical risk factor during pregnancy - chronic hypertension	Y	Y	Y	Y	Y	Y	Y	Y	Y
PIH	pregnancy induced hypertension/preeclampsia	Y	Y	Y	Y	Y	Y	Y	Y	Y
ECLAMP	medical risk factor during pregnancy - eclampsia	Y	Y	Y	Y	Y	Y	Y	Y	Y

Variable Name	Definition	LA	MO - 2010 and earlier	MO - 2011 to present	NYC	PA	UT -2007 to present	VA
CONGENITAL ANOMALIES								
NO_CONG_AN	No congenital anomalies listed	Y	N	N	Y	Y	Y	Y
BIFIDA	spina bifida/meningocele	Y	Y	Y	Y	Y	Y	Y
ANENCEPH	anencephalus	Y	Y	Y	Y	Y	Y	Y
HYDROCEPH	hydrocephalus	Y	Y	N	N	Y	Y	Y
MICROCEPH	microcephalus	Y	Y	N	N	Y	Y	Y
OTH_CENT_NERV	other central nervous system anomalies	Y	Y	N	N	Y	Y	Y
MALF_HRT	heart malformations	Y	Y	N	N	Y	N	Y
CYAN_CONG_HEART	Cyanotic congenital heart disease	N	N	Y	Y	N	Y	N
PAT_DUCT	patent ductus arteriosis	N	N	N	N	N	N	N
CIRC_RESP_ANOMAL	other circulatory/respiratory	Y	Y	N	N	Y	N	Y
OMPHALO	Omphalocele	N	N	Y	Y	N	Y	N
GASTROSCH	Gastroschisis	N	N	Y	Y	N	Y	N
OMPHALO_UNSP	unspecified omphalocele/gastroschisis	Y	Y	N	N	Y	N	Y
TRACH_ESO_FISTUL	tra/esophageal fistula, atresia	Y	Y	N	N	Y	Y	Y
RECT_ATRES	rectal atresis/stenosis	Y	Y	N	N	Y	N	Y
OTH_GASTR	other gastrointestinal anomalies	Y	Y	N	N	Y	Y	Y
HYPOSPAD	hypospadias	N	N	Y	Y	N	Y	N
MALF_GENITAL	malformed genitals	Y	Y	N	N	Y	N	Y
REN_AGEN	renal agenesis	Y	Y	N	N	Y	N	Y
OTH_UROGEN	other urogenital anomalies	Y	Y	N	N	Y	Y	Y
C_LIP	Cleft lip with or without cleft palate	N	N	Y	Y	N	Y	N
PALATE_ONLY	Cleft palate alone	N	N	Y	Y	N	Y	N

Variable Name	Definition	LA	MO - 2010 and earlier	MO - 2011 to present	NYC	PA	UT -2007 to present	VA
PALATE _UNSP	unspecified- cleft lip/palate	Y	Y	N	N	Y	N	Y
POLYDAC	poly/syndactyly	Y	Y	N	N	Y	N	Y
LIMB_RED	Limb reduction defect	N	N	Y	Y	N	Y	N
CLUB_FOOT	club foot	Y	Y	N	N	Y	N	Y
DIAPH_HERNIA	Diaphragmatic hernia	Y	Y	Y	Y	Y	Y	Y
DISLOC_HIP	congenital dislocation of the hip	N	N	N	N	N	N	N
OTH_MUSC_INTEG	other muscloskeletal/integumental anomalies	Y	Y	N	N	Y	Y	Y
DOWNS	Downs syndrome	Y	Y	Y	Y	Y	Y	Y
OTHERCHR	other chromosomal anomalies	Y	Y	Y	Y	Y	Y	Y
OTHERANO	other congenital anomalies	Y	N	N	N	Y	Y	Y
COMPLICATIONS OF PREGNANCY AND CONCURRENT ILLNESSES								
DIABETES	medical risk factor during pregnancy - diabetes	Y	C	C	C	Y	C	Y
CHYPER	medical risk factor during pregnancy - chronic hypertension	Y	Y	Y	Y	Y	Y	Y
PIH	pregnancy induced hypertension/preeclampsia	Y	Y	Y	Y	Y	Y	Y
ECLAMP	medical risk factor during pregnancy - eclampsia	Y	Y	Y	Y	Y	Y	Y

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO	FL - 2005 and earlier	Fl -2006 to present	GA	IN
DEATH INFORMATION**										
INT_CAUSE_ICD_CODE	*immediate/initiating cause of death (ICD-10)*	*Y*	*U*	*Y*	*Y*	*U*		*U*		*U*
INT_CAUSE	*immediate/initiating cause (text)*								*Y*	
INT_CAUSE_MATERNAL	*immediate cause - maternal (Y/N)*	*Y*	*Y*					*Y*		*Y*
INT_CAUS_FETAL	*immediate cause - fetal (Y/N)*									
INT_CAUSE_DUETO_1	*immediate cause due to condition 1*	*Y*							*Y*	
INT_CAUSE_DUETO_1_MF	*immediate cause due to condition 1- maternal vs fetal*	*Y*								
INT_CAUSE_DUETO_2	*immediate cause due to condition 2*	*Y*							*Y*	
INT_CAUSE_DUETO_2_MF	*immediate cause due to condition 2- maternal vs fetal*	*Y*								
INT_COMP_PLAC	*complications of placenta, cord, membranes - immediate cause*		*Y*					*Y*		*C*
INT_RUPT_MEM_PRIOR	*rupture of membranes - immediate cause (Y/N)*		*Y*					*Y*		*Y*
INT_ABRUPTIO	*abruptio placenta - immediate cause (Y/N)*		*Y*					*Y*		*Y*
INT_PLACENTAL_INSUFF	*placental insufficiency - immediate cause (Y/N)*		*Y*					*Y*		*Y*
INT_PROLAPSED_CORD	*prolapsed cord - immediate cause (Y/N)*		*Y*					*Y*		*Y*
INT_TRU_KNOT_CORD	*true knot in cord- immediate cause*		*Y*							
INT_CHORIOAMNIONITIS	*chorioamnionitis - immediate cause*		*Y*					*Y*		*Y*
INT_OTH_OB_COMP	*other obstetrical complic - immediate cause (Y/N)*		*Y*					*Y*		*Y*
INT_FETAL_ANOM	*fetal anomaly - immediate cause*		*Y*					*Y*		*Y*
INT_FETAL_INJ	*fetal injury - immediate cause (Y/N)*		*Y*					*Y*		*Y*

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO	FL - 2005 and earlier	Fl -2006 to present	GA	IN
INT_FETAL_INF	*fetal infection - immediate cause*		*Y*					*Y*		*Y*
INT_OTH_FETAL_DIS	*other fetal condition- immediate cause (Y/N)*		*Y*					*Y*		*Y*
INT_CAUSE_UNKNOWN	*unknown immediate cause (Y/N)*		*Y*					*Y*		
OTH_CAUSE_ICD_CODE1	*other significant cause of death (ICD-10)*	*U*				*U*				*U*
OTH_CAUSE1	*other significant cause of death (text)*								*Y*	
OTH_CAUSE_MATERNAL1	*other significant cause - maternal*		*Y*					*Y*		*Y*
OTH_CAUS_FETAL1	*other significant cause - fetal (Y/N)*									
OTH_CAUSE_ICD_CODE2	*other significant cause of death (ICD-10)*								*Y*	
OTH_CAUSE2	*other significant cause of death (text)*									
OTH_CAUSE_MATERNAL2	*other significant cause - maternal*									
OTH_CAUS_FETAL2	*other significant cause - fetal (Y/N)*									
OTH_COMP_PLAC	*complications of placenta, cord, membranes - other significant cause (Y/N)*		*Y*					*Y*		*C*
OTH_RUPT_MEM_PRIOR	*rupture of membranes - other significant cause (Y/N)*		*Y*					*Y*		*Y*
OTH_ABRUPTIO	*abruptio placenta - other significant cause (Y/N)*		*Y*					*Y*		*Y*
OTH_PLACENTAL_INSUFF	*placental insufficiency - other significant cause (Y/N)*		*Y*					*Y*		*Y*
OTH_PROLAPSED_CORD	*prolapsed cord - other significant cause (Y/N)*		*Y*					*Y*		*Y*
OTH_TRU_KNOT_CORD	*true knot in cord- other significant cause (Y/N)*		*Y*							
OTH_CHORIOAMNIONITIS	*chorioamnionitis - other significant cause (Y/N)*		*Y*					*Y*		*Y*

Variable Name	Definition	AZ - current	AZ - proposed	CA - 2006 and earlier	CA - 2007 to present	CO	FL - 2005 and earlier	Fl -2006 to present	GA	IN
OTH_OTH_OB_COMP	*other obstetrical complic - other significant cause (Y/N)*		*Y*					*Y*		*Y*
OTH_FETAL_ANOM	*fetal anomaly - other significant cause (Y/N)*		*Y*					*Y*		*Y*
OTH_FETAL_INJ	*fetal injury - other significant cause*		*Y*					*Y*		*Y*
OTH_FETAL_INF	*fetal infection - other significant cause (Y/N)*		*Y*					*Y*		*Y*
OTH_OTH_FETAL_DIS	*other fetal condition- other significant cause (Y/N)*		*Y*					*Y*		*Y*
OTH_CAUSE_UNKNOWN	*unknown other significant cause*		*Y*					*Y*		
AUTOPSY	*autopsy performed*		*Y*	*Y*	*Y*	*Y*		*Y*		*Y*
AUTOPSY_DETERM	*autopsy or histologic exam used in the determinination of the cause of death*		*Y*		*Y*	*Y*		*Y*		*Y*

Variable Name	Definition	LA	MO - 2010 and earlier	MO - 2011 to present	NYC	PA	UT -2007 to present	VA
DEATH INFORMATION**								
INT_CAUSE_ICD_CODE	immediate/initiating cause of death (ICD-10)	Y	U	U	U	U	U	Y
INT_CAUSE	immediate/initiating cause (text)							
INT_CAUSE_MATERNAL	immediate cause - maternal (Y/N)			Y	Y		Y	
INT_CAUS_FETAL	immediate cause - fetal (Y/N)			Y				
INT_CAUSE_DUETO_1	immediate cause due to condition 1							
INT_CAUSE_DUETO_1_MF	immediate cause due to condition 1- maternal vs fetal							
INT_CAUSE_DUETO_2	immediate cause due to condition 2							
INT_CAUSE_DUETO_2_MF	immediate cause due to condition 2- maternal vs fetal							
INT_COMP_PLAC	complications of placenta, cord, membranes - immediate cause			Y	Y		C	
INT_RUPT_MEM_PRIOR	rupture of membranes - immediate cause (Y/N)				Y		Y	
INT_ABRUPTIO	abruptio placenta - immediate cause (Y/N)				Y		Y	
INT_PLACENTAL_INSUFF	placental insufficiency - immediate cause (Y/N)				Y		Y	
INT_PROLAPSED_CORD	prolapsed cord - immediate cause				Y		Y	
INT_TRU_KNOT_CORD	true knot in cord- immediate cause						N	
INT_CHORIOAMNIONITIS	chorioamnionitis - immediate cause				Y		Y	
INT_OTH_OB_COMP	other obstetrical complic - immediate cause (Y/N)			Y	Y		Y	
INT_FETAL_ANOM	fetal anomaly - immediate cause			Y	Y		Y	
INT_FETAL_INJ	fetal injury - immediate cause (Y/N)			Y	Y		Y	

Variable Name	Definition	LA	MO - 2010 and earlier	MO - 2011 to present	NYC	PA	UT -2007 to present	VA
INT_FETAL_INF	fetal infection - immediate cause			Y	Y		Y	
INT_OTH_FETAL_DIS	other fetal condition- immediate cause (Y/N)			Y	Y		Y	
INT_CAUSE_UNKNOWN	unknown immediate cause (Y/N)				Y		Y	
OTH_CAUSE_ICD_CODE1	other significant cause of death (ICD-10)			U			U	
OTH_CAUSE1	other significant cause of death (text)							
OTH_CAUSE_MATERNAL1	other significant cause - maternal			Y	Y		Y	
OTH_CAUS_FETAL1	other significant cause - fetal (Y/N)							
OTH_CAUSE_ICD_CODE2	other significant cause of death (ICD-10)							
OTH_CAUSE2	other significant cause of death (text)							
OTH_CAUSE_MATERNAL2	other significant cause - maternal							
OTH_CAUS_FETAL2	other significant cause - fetal (Y/N)							
OTH_COMP_PLAC	complications of placenta, cord, membranes - other significant cause (Y/N)				Y		C	
OTH_RUPT_MEM_PRIOR	rupture of membranes - other significant cause (Y/N)				Y		Y	
OTH_ABRUPTIO	abruptio placenta - other significant cause (Y/N)				Y		Y	
OTH_PLACENTAL_INSUFF	placental insufficiency - other significant cause (Y/N)				Y		Y	
OTH_PROLAPSED_CORD	prolapsed cord - other significant cause (Y/N)				Y		Y	
OTH_TRU_KNOT_CORD	true knot in cord- other significant cause (Y/N)						N	

Variable Name	Definition	LA	MO - 2010 and earlier	MO - 2011 to present	NYC	PA	UT -2007 to present	VA
OTH_CHORIOAMNIONITIS	chorioamnionitis - other significant cause (Y/N)				Y		Y	
OTH_OTH_OB_COMP	other obstetrical complic - other significant cause (Y/N)			Y	Y		Y	
OTH_FETAL_ANOM	fetal anomaly - other significant cause (Y/N)			Y	Y		Y	
OTH_FETAL_INJ	fetal injury - other significant cause			Y	Y		Y	
OTH_FETAL_INF	fetal infection - other significant cause (Y/N)			Y	Y		Y	
OTH_OTH_FETAL_DIS	other fetal condition- other significant cause (Y/N)			Y	Y		Y	
OTH_CAUSE_UNKNOWN	unknown other significant cause (Y/N)				Y		Y	
AUTOPSY	autopsy performed			Y	Y		Y	
AUTOPSY_DETERM	autopsy or histologic exam used in the determinination of the cause of death				Y		Y	

AZ=Arizona; CA=California; CO=Colorado; CT=Connecticut; FL=Florida; GA=Georgia; IL=Illinois; IN=Indiana; KS=Kansas; KY=Kentucky; LA=Louisiana; MO=Missouri; NYC=New York City; OH=Ohio; PA=Pennsylvania; TX=Texas; UT=Utah; VA=Virginia

* residence of zip code available
# previous preterm infant or SGA combined in one category
** variables related to death data are still under development; additional discussion with PRISM leaders will be necessary to finalize the list of variables of interest

Source of data:
ARIZONA: data dictionary (current and proposed)

CALIFORNIA:	data dictionaries
COLORADO:	worksheets
FLORIDA:	data dictionaries, but in some cases, worksheet had different variables (obstetric estimate of gestational age, etc)
GEORGIA:	data dictionary
INDIANA:	worksheet
LOUISIANA:	data dictionary (in unclear cases, also used worksheet; e.g. 'gestation')
MISSOURI:	data dictionary
NEW YORK CITY:	worksheet
PENNSYLVANIA:	data dictionary
UTAH:	data dictionary (in unclear cases, also used worksheet; e.g. 'gestation')
VIRGINIA:	data dictionary

E. APPENDIX E. FETAL DEATH DEFINITIONS

Fetal Death Definitions

	Fetal Death Definitions
AZ	20 completed weeks of gestation or, if the gestational period is unknown, the fetal death certificate should be filed if the fetus weighs more than 350 grams. In addition to spontaneous stillbirths, any induced termination of pregnancy at 20 or more weeks of gestation (or, if the gestation period is unknown, when the weight of the product of human conception is more than 350 grams) also requires the filing of a fetal death certificate.
CA	California's definition of fetal death is: Death prior to the complete expulsion or extraction from its mother of a product of conception. The death is indicated by the fact that after such separation, the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Birthweight is not a criteria used for the definition or decision to report as a fetal death. Fetal deaths of 20 weeks or more gestation are required to be registered on a California fetal death certificate. However, some fetal deaths of less than 20 weeks are sometimes registered. These are included on our fetal death data files, but only those of 20 weeks and over are used in our reports and data tables. Fetal deaths of unknown gestation length are included in both the data files and reports.
CO	Death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy. The death is indicated by the fact that after such expulsion or extraction the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.
CT	20 or more completed weeks of gestation
FL	Death before the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.
GA	Death prior to the complete expulsion or extraction from its mother as a product of human conception (neither a live birth nor an induced termination of pregnancy), irrespective of the duration of the pregnancy
IN	Gestation of 20 + weeks with no signs of life once it is separate from the mother
LA	20 weeks or more duration of pregnancy, or a weight of 350 grams or more.
MO	A non-induced death prior to the complete expulsion or extraction from its mother of a fetus, irrespective of the duration of pregnancy; the death is indicated by fact that after such expulsion or extraction the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Each spontaneous fetal death of 20 completed weeks gestation or more, calculated from the date of last normal

	Fetal Death Definitions
	menstrual period began to the date of delivery, or a weight of 350 grams or more, shall be reported.
NC	Death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the gestation of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Consistent with North Carolina law, SCHS data include only fetal deaths that do not qualify as therapeutic abortions and that result from pregnancies of 20 or more weeks gestation.
NY	Not applicable. Fetal death data is not available.
NYC	New York City Health Code §203.01 (a) "Termination of pregnancy" means the expulsion or extraction of a conceptus, regardless of the duration of pregnancy, other than a live birth as defined in § 201.01(a), and includes fetal death. New York City Health Code Section §203.01 (b) "Spontaneous termination of pregnancy" means the unplanned termination of a pregnancy, including but not limited to an ectopic pregnancy, or such a termination associated with a cesarean section, or an operative procedure unrelated to pregnancy resulting in an inadvertent termination
PA	Expulsion or extraction from its mother of a product of conception after 16 weeks gestation, which shows no evidence of life after such expulsion or extraction.
UT	19 or more weeks duration of pregnancy.
VA	"Fetal death" means death prior to the complete expulsion or extraction from its mother of a product of human conception, regardless of the duration of pregnancy; death is indicated by the fact that after such expulsion or extraction the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.