National Notifiable Diseases Surveillance System (NNDSS)

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Circumstances of Change Request for OMB 0920-0728

This is a nonmaterial/non-substantive change request for OMB No. 0920-0728, expiration date 01/31/2019, for the reporting of Nationally Notifiable Diseases. The National Notifiable Diseases Surveillance System (NNDSS) is the nation's public health surveillance system that enables all levels of public health (local, state, territorial, federal and international) to monitor the occurrence and spread of the diseases and conditions that the Council of State and Territorial Epidemiologists (CSTE) has officially designated as either "nationally notifiable" or as under "national surveillance." The NNDSS facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 57 jurisdictions: health departments in every U.S. state, New York City, Washington DC, and 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands). NNDSS also facilitates relevant data management, analysis, interpretation and dissemination of the information. The data are used to monitor health occurrence of notifiable conditions and to plan and conduct prevention and control programs at the state, territorial, local and national levels.

Zika virus (ZIKV) is an emerging infection spread by mosquito vectors and whose incidence and prevalence has exploded in the Americas in 2015. Preliminary investigations demonstrate vertical transmission of ZIKV to the fetus in pregnant women. These *in utero* infections have been associated with the potential for devastating outcomes including microcephaly and spontaneous abortions. Because of these epidemiological and clinical features, the World Health Organization declared ZIKV disease a Public Health Emergency of International Concern under the International Health Regulations 2005 on February 1, 2016. Although not yet confirmed, there is increasing clinical and epidemiologic evidence to support ZIKV as a cause of significant congenital defects and fetal losses. Additionally, reports of increasing incidence of Guillain-Barre Syndrome (GBS) have surfaced in countries experiencing ZIKV epidemics and this syndrome is now being linked to ZIKV. Lastly, sexual transmission of ZIKV has been documented. The extent to which sexual transmission is driving the current outbreak is not known.

This request is for the addition of 6 disease-specific data elements for Arboviral diseases only. These new data elements in the table below have been added to collect the maternal, newborn and new transmission mode information associated with Zika virus disease and Congenital Zika virus infection.

Data Element Identifier	Data Element Name	Data Element Description				
INV908	Mother-Infant Case ID Linkage	Mother and Infant Case ID would be helpful to look in detail about maternal as well as newborn information. If the case is for mother, please put the related Infant case ID (s) which could include multiple case ID's in case of multiple births. If the case is for an infant or newborn, please put the Mom's Case ID.				
75203-0	Mother's Last Menstrual Period Before Delivery	Mother's last menstrual period (LMP) before delivery				
INV909	Pregnancy Complications	This data element won't be used for "congenital infection newborn cases". Complications of pregnancy such as Microcephaly, Intracranial Calcification, Fetal growth abnormality and Fetus with Central Nervous System (CNS) abnormalities.				
63893-2	Pregnancy Outcome	This maternal data element captures the pregnancy outcomes such as livebirth, premature birth, still birth, fetal loss, perinatal death and therapeutic abortion.				
32416-0	Newborn Complications	This data element would be used only for "Congenital / Neonatal cases" This could include findings such as Microcephaly, Intracranial calcification, Congenital anomaly of central nervous system, Intrauterine growth restriction, Ocular defects and Limb deformities.				
ARB051	Other Arboviral Disease Transmission Mode	Other Arboviral unusual and rare disease transmission modes. This variable is used to differentiate the "In Utero (Transplacental)" vs "Perinatal". This variable also can be used to capture more than one transmission mode. Other valid values such as blood donation, blood transfusion, lab acquired, organ transplant are not included in this value set as they exists as variables in the current guide as risk factors.				

<u>Burden</u>

The annualized burden hours and cost to reporting jurisdictions to submit these data to CDC does not change from the original estimates in the "Estimates of Annualized Burden Hours and Costs" section in A.12 of OMB No. 0920-0728. CSTE recommends that jurisdictions collect these data for their own surveillance purposes. Requesting jurisdictions to submit these data (that they will already collect) to CDC will not increase the burden to the jurisdictions.

A.12A. Estimates of Annualized Burden Hours

Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)							
Weekly and Annual Submissions											
States	50	52	10	26000							
Territories	5	52	5	1 300							
Cities	2	52	10	1040							
Total				28,340							

A.12B. Estimates of Annualized Cost Burden

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Respondent Cost
States	Weekly and Annual	50	52	10	26,000	\$35.63	\$926,380
Territories	Weekly and Annual	5	52	5	1,300	\$35.63	\$46,319
Cities	Weekly and Annual	2	52	2	1,040	\$35.63	\$37,055
Total							\$1,009,754