

Program Contact

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CDC requests approval for a non-substantive change to OMB Control No. 0920-0009; **National Disease Surveillance Program**

Form Name: **Acute Flaccid Myelitis: Patient Summary Form**

Justification for changes:

The adoption by the Council of State and Territorial Epidemiologists (CSTE) of a standardized case definition for AFM in 2015 and the inclusion of AFM in the Vaccine Preventable Disease Surveillance Coordinator project through the Epidemiologic and Laboratory Capacity (ELC) Program has helped establish surveillance for AFM following the large increase in cases during 2014. Data on cases are collected from state health departments using form 0920-0009, to help understand risk factors and determine an etiology. Another increase in cases occurred in 2016 and 2018 but the etiology, mode of transmission, and risk factors for AFM remain unknown.

Based on experience with AFM surveillance during the latest increase in cases in 2018, CDC is requesting a non-substantive change to 0920-0009 to continue collecting case report data from all states, to determine how often such cases occur in the United States. The proposed changes are requested to help better refine the information collected for patients suspected of having AFM to ensure that the most appropriate and useful clinical information necessary for classification of cases are collected. These changes will not change the current burden or length of the form. Supplemental clinical information is still requested as reports (attachments) to decrease the time needed to complete the form and report the case. However, the timing of submission of the supplemental clinical information has been modified to ensure that more complete information is provided to help better characterize patients with AFM.

Burden:

Estimates of annualized burden hours for this change request will stay the same. Because there are expected to be 100 responses per year for the Acute Flaccid Myelitis Patient Summary Form included in OMB Control No. 0920-0009, the total burden will be 80 hours per year, which is no change from the current burden.

	Form Name	No. of Respondents	No. of responses per respondent	Avg. burden per response (hours)	Total burden (hours)

Non-Substantive Change Request to OMB Control Number 0920-0009

Approved	Acute Flaccid Myelitis: Patient Summary Form	100	4	12/60	80
Requested	Acute Flaccid Myelitis: Patient Summary Form	100	4	12/60	80

Description of Changes:

The changes to the form are as follows:

- I. Revision of the box under the title of the form for persons completing the form to indicate what supplemental information is being included with the form.
- II. Question 24 has been deleted and replaced with the question: *Have pain in neck or back?*
- III. Question 25 has been modified to request onset date for question 24. The question now asks: *If yes, onset date* ____ / ____ / ____.
- IV. Section titled “Other patient information” has been revised to “Magnetic Resonance Imaging” to better reflect the types of questions in this section.
- V. New question has been added (question 30) to collect information on whether the patient had a lesion in at least some of the spinal cord gray matter. This question will help screen patients to see if they meet the AFM case classification criteria.
- VI. Original questions 30-32 have been renumbered to reflect addition of a new question 30.
- VII. Addition of a box above the “Acute Flaccid Myelitis Outcome” section of the form for persons completing the form to indicate what supplemental information is being included with the form at the time of the 60 day follow-up.
- VIII. Numbering for original questions 36-43 has been revised because the current form was mis numbered.
- IX. Original question 37 has been updated to be a sub question of Question 34 since this is asking for the date for one of the responses to question 34.
- X. Text in the “Acute Flaccid Myelitis case definition” section has been modified to be consistent with the new changes to the AFM case definition.
- XI. The websites for “Acute Flaccid Myelitis specimen collection information” and “Acute Flaccid Myelitis job aid” have been updated with the correct web link.