California Department of Public Health
Immunization Branch
850 Marina Bay Parkway
Richmond, CA 94804

Serious[1] non-GBS[2] Adverse Event Case Report

Note: This form is for serious[1], non-GBS[2] adverse event cases <u>after</u> administration of pandemic (H1N1) influenza vaccine

CDPH ID: AE - ___ ___ ___ ___ ___
(For CDPH Use Only)

[1] A serious event is defined as one in which one of the following outcomes is reported: death, life threatening illness, hospitalization ≥24 hours, prolongation of a hospitalization, permanent disability, congenital anomalies, or other medically important conditions.
[2] Guillain-Barre Syndrome (please contact GBSReport@cdph.ca.gov for information regarding reporting of GBS cases).

PATIENT INFORMATION

Last Name: _____ First Name: _____

Age: _____ DOB: _____/_____/_____ Occupation: _____

Address: _____

City: _____ Zip: _____ County: _____

Home #: (_____) _____ Work #: (_____)_____ Cell #: (_____)_____

Sex: ☐ Female ☐ Male ☐ Unknown

Ethnicity: ☐ Non-Hispanic ☐ Hispanic ☐ Unknown

Race: ☐ White ☐ Black ☐ Unk ☐ Asian ☐ Alaskan Native/Native Am. ☐ Other, *specify*: _____ ☐ Pacific Islander

PHYSICIAN INFORMATION (Required Information)

Reporting Physician Date CRF Submitted: ____/_____/_____

Name: _____ Healthcare Facility: _____

Work #: (_____)_____ Fax #: (_____)_____ E-mail: _____

If available: VAERS ID# _____ Date VAERS Submitted: _____/_____/_____

Primary Care Physician/Pediatrician (if different)

Name: _____ Healthcare Facility: _____

Work #: (_____)_____ Fax #: (_____)_____ E-mail: _____

Did this patient receive a dose(s) of pandemic (H1N1) vaccine within 30 days prior to the onset of adverse event?

☐ Yes – Continue filling out form with patient information.
☐ No – STOP filling out form. Patient is not eligible for reporting.
☐ Unknown – ⚠ Determine vaccine history of patient.

VACCINATION HISTORY

Pandemic (H1N1) Influenza Vaccine Information

	Date received	Brand / Lot #	Type (Select one)	Location where received vaccine:
Dose #1	____/____/_____	_____	☐ LAIV ☐ Inactivated	_____
Dose #2	____/____/_____	_____	☐ LAIV ☐ Inactivated	_____

Was the patient vaccinated with <u>any</u> other vaccines (seasonal influenza or non-influenza) within 6 weeks prior to the onset of adverse event symptoms? ☐ Yes ☐ No ☐ Unknown

If 'Yes', *specify* (Vaccine, Date, Location received): _____

_____

CLINICAL INFORMATION

Is the patient pregnant? ☐ Yes - gestation (weeks) _____ ☐ No ☐ Unknown

Note: Defined as pregnant at time of onset of adverse event.

Did the patient experience any of the following events within 30 days after vaccine receipt?
(Check all that apply)

☐ Bell's Palsy ☐ Encephalitis/myelitis ☐ Cerebrovascular accident ☐ Seizures
☐ Demyelinating diseases of the nervous system (including optic neuritis)
☐ Other, *specify* _____

Did the patient experience any of the following events within 7 days after vaccine receipt?
(Check all that apply)

If pregnant: ☐ Stillbirth ☐ Spontaneous abortion ☐ Pre-eclampsia & eclampsia

Other: ☐ Anaphylaxis ☐ Myocarditis ☐ Pericarditis

Was the patient hospitalized? ☐ Yes ☐ No ☐ Unknown

Admit Date: ___/___/_____ Healthcare Facility: _____

Was the patient in the ICU? ☐ Yes ☐ No ☐ Unknown

Discharge status? ☐ Still at admitting hospital ☐ Discharged to home
☐ Death (Death ___/___/_____) ☐ Discharged to another medical facility
☐ Unknown

At the time this form is submitted, what is the outcome of the patient?

☐ Not recovered ☐ Recovered ☐ Death (Date ___/___/_____) ☐ Unknown

CSF Results Date ___/___/___ RBC ____ Protein ____ WBC ____ Glucose ____ %Diff ____/____/____/____
seg lymph mono eos

Imaging studies Date ___/___/___

Electrophysiological studies Date ___/___/___

MEDICAL HISTORY

Has the patient been diagnosed with underlying/chronic condition? ☐ Yes ☐ No ☐ Unk

If 'Yes', *specify*: _____

Does the patient have any known allergies? ☐ Yes ☐ No ☐ Unk

If 'Yes', *specify*: _____

Has the patient had a previous allergic/other adverse event to any vaccine? ☐ Yes ☐ No ☐ Unk

If 'Yes', *specify* (vaccine, date, adverse event): _____

_____

Since Sept 1, 2009, was the patient diagnosed with seasonal or pandemic/H1N1 influenza?

☐ Yes Diagnosis Date: ___/___/___ ☐ No ☐ Unknown

CLINICAL SUMMARY / ADDITIONAL COMMENTS