



NCVIA REQUIREMENTS FOR CONTENT OF VACCINE INFORMATION MATERIALS UNDER THE ORIGINAL 1986 VS. AMENDED 1993 LAWS

Original Law: 1986

1. The frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine
2. The symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider
3. Precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur
4. Early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions
5. A description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities
6. A specification of when, how, and to whom legal representatives should report any major adverse reactions
7. The contraindications to (and bases for delay of) the administration of the vaccine
8. An identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population
9. A summary of:
 - a. Relevant federal recommendations concerning a complete schedule of childhood immunizations, and
 - b. The availability of the National Vaccine Injury Compensation Program
10. Such other relevant information as may be determined by the Secretary [of Health and Human Services]

Amended Law: 1993

1. A concise description of the benefits of the vaccine
2. A concise description of the risks associated with the vaccine
3. A statement of the availability of the National Vaccine Injury Compensation Program
4. Such other relevant information as may be determined by the Secretary

Rule Revision: 2016

In 2016 it was determined that, rather than creating these new documents, which might require periodic updates, the same end could be served by adding links from CDC's VIS webpage to other CDC webpages containing comparable information rather than providing a paper VIS to vaccine recipients.

