**Section 698.40 Health Record – Recording and Reporting**

All health care providers which administer pertussis vaccine shall maintain records of the administration of pertussis vaccine and reactions to the vaccine in the following manner:

a) *Upon administering a pertussis vaccine to a child in this State, a health care provider shall record and retain as part of the child's permanent health record* the following information:

1) *The date the vaccine was administered,*

2) *The manufacturer* of the vaccine administered,

3) *A lot number and any other available identifying information of the vaccine that was administered, and*

4) *The name*, address, telephone number, *and title of the health care provider who administered the vaccine.* (Section 7 of the Act.)

b) Recording and Reporting Major Adverse Reactions. *If, within 30 days of administering a pertussis vaccine the health care provider has reason to believe that the recipient of the vaccine has had a major adverse reaction, the health care provider shall* take the following action:

1) *Record all relevant information,* in the professional judgment of the health care provider*, in the child's permanent medical record, and*

2) *Report the information, including the manufacturer and lot number, to the Department.* (Section 8 (a) and (b) of the Act.) The written report shall be on forms provided by the Department containing the following information:

A) Name and address of the health care provider which administered the pertussis vaccine.

B) The age, weight, and sex of the recipient of the vaccine.

C) A description of the major adverse reaction experienced by the recipient of the vaccine and any other information the health care provider determines is relevant.

D) The manufacturer and lot number of the vaccine administered.

c) Reporting forms are as follows:

1) Adverse Reaction Report (Drugs and Biologicals) FDA 1639 (786) OMB No. 0910-0230, Department of Health and Human Services, Public Health Services Board and Drug Administration (HFN-730) Rockville, MD 20857

2) Report of Adverse Event Following Immunization CDC 71.19 Rev. 9-85-OMB No. 0920-0039 (9/87), Department of Health and Human Services, Center for Disease Control, Atlanta, GA 30333