American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Minnesota Chapter

Minnesota Childhood Immunization Coalition

Reasons why HF1978/SF1870 is unnecessary, burdensome, and unsafe

Each of the following requirements is unnecessary:

Subd. 2 requires health care providers to ***provide*** the patient (or parent/legal guardian) with the CDC-developed ***Vaccine Information Statements*** prior to administering a vaccine and subd. 3 requires healthcare providers to ***report vaccination adverse events*** to the federal Vaccine Adverse Events Reporting System. Each of these requirements is unnecessary because they are already mandated by federal law (see Section 2125 of the Public Health Service Act [42 U.S.C. §300aa-26]).

Each of the following requirements would be burdensome and potentially impact vaccination rates:

Subd. 2 also mandates that health care providers give a copy of the ***vaccine package insert*** to the parent/guardian of the child to be vaccinated. Package inserts are lengthy and written at a college reading level. For example, the package insert for the pneumococcal vaccine (Prevnar) is 44 pages long with double columns. It consists of 16, 287 words and has a reading level of 14.3 grade level as determined by Flesch-Kincaid readability tests. For infants receiving vaccines at 2, 4, and 6 months, the parent would be given a total of 145 pages for each visit of college-level text written for medical providers. On the other hand, the federally-mandated Vaccine Information Statement is a simple 2-sided page written for the public and most are available in over 30 languages. It should be noted, too, that health insurance programs require patient education materials to be at the 5th grade reading level.

Subd. 2 also requires ***written informed consent*** from the parent/guardian before the child may be vaccinated. Informed consent is part of all medical care. Written informed consent is reserved for procedures with a heightened level of risk, such as surgery and for interventions in which the risk-benefit ratio is unclear, such as in the use of experimental drugs. While vaccines are recognized by experts as safer than any other drug frequently prescribed for children, such as medications for ADHD, we do not require written consent for any of those products. Legislating written informed consent for vaccines sets immunizations apart, puts them in a special category of risk that will likely increase parental alarm, and could as an unintended consequence reduce immunization rates in a community. The bill would be setting a standard that would cripple not just preventive health care for children, but ultimately for all health care in Minnesota.

Subd. 4 ***mandates certain protections from professional licensing boards and employers*** for healthcare providers who give information to a patient about the risks and benefits of vaccine and for reporting an adverse event to VAERS. This is not necessary for several reasons.

- If the provider gives accurate information, there would be no basis for disciplinary action from the licensing board.
- If employers were prevented from penalizing employees who give inaccurate and misleading information to patients, the end result would
  - expose the employer to tort liability,
  - prevent one mechanism of control to protect consumers from being misinformed, and
  - inappropriately interfere in the right of employers to run their business and impose quality standards.
- Since reporting adverse events to vaccines is already required by federal law, there is no need to protect employees from complying with a federal mandate.

Please consider the unintended consequences of placing additional burdens on parents/guardians and clinicians which could lead to declining vaccination rates and increases in vaccine-preventable disease.