**EXECUTIVE SUMMARY**

Every aspect of this bill is problematic. (1) It would require health care providers to give patients Vaccine Information Statements and vaccine package inserts before vaccinating. Providers are already required by federal law to give the Vaccine Information Statement. Because of their technical nature, package inserts are not more informative for most people than Vaccine Information Statements, and they are far too long to read at an office visit. (2) The bill would require providers to get written consent before vaccinating. This would do nothing to educate patients but only add to the paperwork burden of healthcare and, more important, misrepresent to patients that routine vaccination is a high-risk undertaking on the order of participating in a clinical trial or having major surgery. It would deter vaccination and result in cases of disease. (3) The bill would require providers to report to VAERS anytime a patient "may have had" an adverse vaccine reaction. MDH already encourages providers to report all serious adverse events following vaccination, and federal law requires providers to report events that are listed on the Vaccine Injury Compensation Program's Vaccine Injury Table as known possible effects of vaccination. A legal obligation to report cases where causality is equivocal or implausible would be unenforceable because of the ambiguity of "may have had." (4) The bill would require providers to send the commissioner a copy of every VAERS report. MDH already has access to this data via a CDC database. Because of the rarity of vaccine adverse events, it unlikely that analyzing Minnesota data would return results superior to those of the three major federal vaccine safety programs' surveillance and investigation capabilities. (5) The bill would forbid employers and licensing boards from disciplining providers for expressing opinions about vaccines or making VAERS reports. To the extent that a provider's opinions contradict basic standards of care, they effectively constitute malpractice, and it makes no sense to say that the employer or licensor of a health care provider must allow the provider to disseminate those harmful views.

**RESPONSES TO BILL PROVISIONS**

**1. Before giving a vaccine, a health care provider must give the vaccinee/parent the manufacturer's package insert and the Vaccine Information Statement for that vaccine.**

Giving a Vaccine Information Statement is already required under the National Childhood Vaccine Injury Act of 1986 (NCVIA, 42 U.S.C. §300aa-26). MDH reminds immunization providers about this obligation via its provider newsletter every three months. Requiring providers to also give package inserts would be unhelpful for at least three reasons:

- Package inserts are written for health care professionals and regulators, not for the public. They would not likely be meaningful to most people.
- Package inserts are long documents. (Examples: MMR, 11 pages; meningococcal, 37 pages; PCV13, 44 pages) Reading one would take far longer than the typical office visit. Also, this copying volume would burden providers financially and logistically.
- Package inserts existed when the NCVIA was enacted. If Congress had thought they could help patients make educated decisions, it would probably have mandated that providers give package inserts instead of Vaccine Information Statements.

**2. Before giving a vaccine, a health care provider must obtain written informed consent from the vaccinee/parent.**

Providers must obtain informed consent from patients before performing any treatment. It is well established that implicitly or verbally expressed consent suffices for routine, low-risk procedures such as the administration of antibiotics for ear infections, steroids for asthma, or vaccines for disease prevention. Requiring health care providers to document patients' consent in writing every time they give vaccines would not make patients more informed, and it would have at least three negative effects:

- It would multiply providers' paperwork burden and add another to-do item to short office visits.
- It would create the false impression that vaccination is a high-risk procedure on the order of major surgery, possibly inducing them to decline vaccination, increasing their risks of suffering and transmitting vaccine-preventable diseases.
- It would mean that children who are brought to their appointments by caregivers other than parents or guardians – such as grandparents, older siblings, or nannies – would have to defer vaccination until their parents could come to the office, and remain susceptible to disease in the interim.

**3. Whenever a health care provider becomes aware that a patient "has or may have had" an adverse vaccine reaction, the provider must report it to VAERS.**

The NCVIA already requires a report to the Vaccine Adverse Event Reporting System (VAERS) when the reaction is one listed on the Vaccine Injury Table. The Table lists all circumstances under which there is a legal presumption, within the Vaccine Injury Compensation Program, that a vaccine was the cause of an adverse outcome. These are the only circumstances under which it is reasonable to expect a provider to draw the conclusion that an event was caused by a vaccine. That notwithstanding, MDH recommends to providers that they report any serious adverse event following vaccination, regardless of whether they believe the event was vaccine-related. The bill's requirement that a provider report to VAERS anytime a patient "may have had" an adverse reaction of any severity calls for speculation, is unenforceably vague, and disallows providers from drawing on their expertise and clinical judgment about whether it is plausible that an event was vaccine-related.

**4. A provider must furnish a copy of every VAERS report to the Commissioner of Health.**

MDH is already able to query VAERS data through the CDC WONDER electronic system. Sending copies of VAERS reports to the Commissioner would be redundant.

Moreover, because serious adverse events due to vaccines are quite rare, state-level VAERS data would not provide actionable information about adverse event patterns. Three national vaccine safety monitoring systems serve this function: VAERS identifies patterns of adverse events that occur too infrequently to be picked up at the clinical level, the Vaccine Safety Datalink (VSD) tests whether these events are actually vaccine-related, and the Clinical Immunization Safety Assessment (CISA) Network researches specific extremely rare adverse events and their occurrence in relation to specific individuals

and their specific biological make-up. In order to drive state participation in these national systems, MDH has staff specifically assigned to:

1. Ensure that messages regularly go out to providers about the importance of reporting to VAERS;
2. Coordinate reporting of an adverse event if a provider or a member of the public inquires about a possible vaccine reaction;
3. Collaborate with VAERS team investigations to ensure that CDC scientists have the information they need for a thorough investigation of a reported adverse event; and
4. Provide assistance to Minnesotans who want to file claims with the National Vaccine Injury Compensation program.

**5. Employers and licensing boards may not discipline providers for expressing their views on vaccine safety or making VAERS reports.**

Health care organizations would be less able to protect themselves from malpractice liability if they could not take action against employees who provided substandard care by their misrepresentations of vaccine safety. A patient who was injured by relying on such a misrepresentation would seek to hold the provider and the provider's employer liable; the employer has the right to define acts that are likely to constitute malpractice and require that its providers not engage in them. To forbid a health system from firing an MMR-bashing pediatrician would be as nonsensical as asserting that it had to retain a cardiologist who advocated for smoking or a midwife who encouraged patients to take up illegal drugs.

Licensing boards are similarly situated in their responsibility to protect the public from substandard care. While affording latitude for the exercise of professional judgment, they must have the power to discipline licensees whose professional advice is entirely lacking in scientific basis and represents a danger to the public.

***6. Required reporting of adverse reactions following vaccination to VAERS and to the "Minnesota Vaccine Adverse Reaction Database."***

*In addition to issues mentioned in numbers 3 and 4 above, having a state-level database is redundant and . VAERS data is already available to the public.*
*The phrase "immediately report" is vague and may not be feasible depending on the clinical situation.*
*Of deep concern is the release of to a non-medical, non-governmental entity for which there is no mechanism to protect the data. Moreover, there is no consent process to release this information.*
*How would a database run by a non-profit entity manage protected, private medical data? What legal mechanism is in place to ensure that data be kept confidential? How will this information be used and who will be accountable for how it is used and to whom?*

***7. Required Minnesota Vaccine Consent Form.***

*Information required for collection is intrusive, e.g., social security number, and is not required for major surgical procedures.*
*Several of the statements are inflammatory and untrue or out of context.*
*Unclear how this is to be retain and by whom. Who will bear the cost of this?*