2018 RIDOH PROGRAM LEGISLATION ANALYSIS

1. **Bill number:** H 7704

2. **Description of bill:** Require vaccine providers to obtain written consent from vaccine recipient, provide recipient a copy of the vaccine manufacturer's package insert and vaccine recipient shall have the lawful right to decline the vaccine by signing a vaccine exemption form approved by the department of health.

3. **Program analysis:**

   a. What does this bill seek to accomplish/why was it introduced? **The bill appears to seek written consent, as a way of informed consent for vaccination, to increase public awareness about the possible adverse effects of vaccinations. This bill represents the current tactic being employed by the anti-vaccine group to create hurdles in people getting vaccinated.**
   The requirements of this measure are duplicative of current Federally-mandated vaccine risk/benefit communication requirements, are excessively time-consuming, and would serve as a barrier to immunization. Currently, as required under the National Childhood Vaccine Injury Act [NCVIA] (42 U.S.C. §300aa-26, specified in the measure), all health care providers in the United States who administer, to any child or adult, any of the following vaccines – diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) – shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):
   o to the parent or legal representative of any child to whom the provider intends to administer such vaccine, or
   o to any adult to whom the provider intends to administer such vaccine.

   CDC-developed Vaccine Information Statements (VIS) serve as these vaccine information materials and provide individuals with

information on the benefit of vaccination ("Why get vaccinated?"), who should be vaccinated, contraindications to vaccination, risks associated with the vaccination (i.e., adverse events associated with the vaccination), what to do in the event of an adverse reaction, information regarding the Vaccine Adverse Event Reporting System (VAERS) and the National Vaccine Injury Compensation Program, as well as who to contact if individuals are interested in obtaining additional information about the vaccine. The VIS process provides individuals with current, relevant information regarding vaccinations in a brief, accessible format.
See link (https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf**) for an example of a current VIS. While VISs are written to fulfill the information requirements of the NCVIA and not as informed consent forms, they cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. Vaccination is a preventive service, not a medical procedure and no different than doing a strep swab or a PAP test – which do not require written consent. For vaccination parents/patients have the opportunity to refuse vaccination and opt-out by signing a refusal form used by providers and shared by the AAP to be kept in the patients file. The World Health Organization (WHO) states evidence suggests that consent procedures based on opt-out approaches are likely to result in higher acceptance of vaccination than using opt-in.**
(http://www.who.int/immunization/programmes_systems/policies_strategies/consent_note_en.pdf**).**

The bill also seeks to provide the patient/parent with the risks and benefits to vaccination through use of the vaccine package insert. The measure's requirement for the provision of vaccine manufacturer's product insert is of concern as the documents contain medical and legal terminology and are not written for general public consumption. Product inserts are legal documents regulated by the U.S. Food and Drug Administration and are intended to provide information to prescribing physicians. Vaccine manufacturers are required by law to report via the product insert any adverse event that occurred after the product was administered during clinical trials as well as post-market experience, whether causally related to the vaccination or not. In reality, provision of the product insert would likely mislead individuals and result in public misunderstanding regarding post-vaccination adverse events, causing unwarranted and excessive alarm that could result in the refusal of vaccinations. Depending on the format, vaccine manufacturer product information documents can also be quite lengthy. If parents/guardians must be provided "ample time" to review these documents for all vaccines to be administered during an office visit, the immunization process would be extraordinarily and unnecessarily time-consuming for both

parent/guardians and medical provider offices and would invariably reduce the limited time available for actual patient care.

The bill also seeks to include the language in a written consent form that states the patient has the lawful right to refuse vaccination and sign an exemption form by the Department of Health. The only RIDOH form that providers use in their office is the medical exemption form, which must be signed by a licensed practitioner for medical contraindications to vaccination. As stated, providers already use a refusal form, which is not a RIDOH form. Providers do not utilize or supply the RIDOH religious exemption form to parents or patients. This form is utilized in the school or childcare setting.

b. Who are the groups pushing for this bill/asked for it to be introduced? **It is suspected to be Rhode Islanders for Vaccine Choice. This group grew from Rhode Islanders Against Mandatory HPV Vaccination. It is my understanding that they now stand on a platform with the National Vaccine Information Center, dedicated to preventing vaccine injuries and deaths through public education and advocating for informed consent protections in medical policies and public health laws. They assert that vaccination is a medical procedure and there should be written consent.**

c. Which groups would support/oppose this legislation? **RI Medical Society, RIAAP, RIAAFP and other regarded physician/medical groups would oppose this legislation. The small group, RI for Vaccine Choice, would support it.**

d. Would this legislation require additional regulations? **It would not require new regulations, but would require revising current regulations and all associated communication materials.**

e. Would this bill have a fiscal impact on your program? RI Businesses? RI Taxpayers? **None for the Department but the bill's extensive and burdensome "informed consent" process would have a fiscal impact on all health care provider offices as this proposed process will take additional office time (inside and outside of the patient visit) to coordinate the signing and filing of written consent for every vaccination, and the physician offices would need to provide copies of the vaccine package insert which is not available for every vaccination as vaccine comes in multiple dose packs with one package insert. This insert contains a substantial amount of information that cannot be copied efficiently.**

f. If this bill is signed into law, would RI be an outlier among other states? **Yes, RI would be an outlier. No other states or jurisdictions have this law or requirement. Hawaii has seen the same type of bill introduced but it never passed.**

g. Do other states have similar laws? Does Massachusetts or Connecticut? Which states? **No, and other state programs that I have spoken to do not support such a bill.**

h. What is the back story on this bill? **There is a push from the antivax community to push for informed consent for vaccination, which already happens, but this group want it to come in the form of written consent. They feel many people are not fully aware of the risks and benefits of vaccinations and these changes will help them make an informed decision. However, provider already provide verbal consentSome groups assert that vaccination is a "medical procedure" that requires written consent, however vaccination is no different than a throat swab or pap test, for example.**

i. Has this bill been introduced in the past? **No**

j. What is the difference between the original bill and the Sub A version if applicable?

k. Is there anything else the Director should know about this bill?

With the threat of vaccine-preventable infectious diseases making a resurgence, including a severe nationwide influenza season, the Office of Immunization opposes a measure that may discourage vaccination. This measure jeopardizes the health of our community as it has the potential to mislead parents into the decision to forgo vaccinations. The maintenance of high immunization rates is important because vaccines provide both individual and community protection. Most vaccine-preventable diseases are transmitted from person-to-person. When a sufficiently large proportion of individuals in a community are immunized, those persons serve as a protective barrier against the likelihood of transmission of the disease in the community, thus indirectly protecting those who are not immunized and those who received the vaccine but have not responded and therefore have no antibodies or protection (vaccine failures). This phenomenon is referred to as "herd immunity." On an individual level, parental decisions regarding vaccination can have both immediate and lifelong ramifications, affecting children in infancy as well as years later, should exposure to disease occur.

4. **Program Position:** Support/**Oppose**/Support with Amendments/No Opinion