Environmental Scan for the Minnesota Immunization Information Connection

An Analysis of an Immunization Information System (IIS) in Legal, Economic, and Political Context

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Executive Summary

Historically, immunizations have been tremendously successful in the United States, reducing childhood vaccine preventable diseases by 97–100 percent. However, vaccine preventable diseases remain. Immunization Information Systems play a critical role in maintaining and improving vaccination coverage and reducing vaccine preventable diseases in the United States. An Immunization Information System (IIS), also known as an immunization registry, is a confidential, computerized, population-based information system that collects and consolidates vaccination data from vaccine providers and provides tools for designing and sustaining effective immunization strategies at the provider and program levels.

This report provides an environmental scan of IIS and their role in U.S. immunization strategy. More specifically, it discusses Minnesota law and practice regarding its IIS, the Minnesota Immunization Information Connection (MIIC), and discusses implementation of IIS within Minnesota’s legal, cultural, political, and economic context.

In particular, the report analyzes patient consent models for including immunization data in an IIS. States employ three models for including immunization data in an IIS. These models reflect a continuum with regard to requirements for explicit individual consent – from mandatory participation in an IIS, to inclusion in an IIS unless the individual requests otherwise (implied consent or “opt-out”), to inclusion in an IIS only with the individual’s express consent (“opt-in”).

A. Research Methods

The authors of this report employed a variety of research methods. They used standard legal research and analysis methods, accompanied by a literature review. In addition, they conducted interviews with key informants. Key informants were selected from among officials involved with administration of state IIS that have changed their consent practices, as well as representatives from opt-in, opt-out, and mandatory IIS states. A list of key informants interviewed for the report is included in Appendix A.

B. Benefits of IIS

IIS provide numerous benefits, including:

1. Consolidating immunization information from multiple sources into one record.
2. Ensuring that vaccination is complete, timely, and appropriate.
3. Providing convenience for adult vaccine recipients, parents, health care providers, schools, child care providers, health departments, and others.
4. Assisting health care providers and health plans.
5. Protecting the community against vaccine preventable diseases.
6. Promoting vaccine safety.
7. Improving response to a vaccine shortage.
8. Supporting effective response to public health and other emergencies.
9. Saving money.

C. Public Attitudes and IIS

Generally, parents support their child’s participation in IIS, but may be concerned about privacy and the opportunity to choose whether to participate. Public health agencies are entrusted with access to private and sensitive information about individuals; they must be good stewards of the information. IIS have technical, physical and administrative safeguards to prevent inappropriate disclosure of information or inappropriate access by unauthorized persons or organizations. To protect the community against vaccine-preventable diseases, policy decisions about IIS consent models require consideration of many factors, including ease of implementation, effectiveness, and cost, as well as individual liberty.
D. State of IIS Across the Nation

For the most part, IIS are established and maintained by state governments. Forty-nine states, the District of Columbia, and three cities (New York, Philadelphia, and San Antonio) currently operate an IIS. The CDC has announced findings from a 2012 survey regarding specific IIS authorization, reporting requirements for immunization providers, and consent provisions for including a child’s or adult’s immunization data in the IIS. CDC warns that it has not finalized this data, so it is subject to change.

For the most part, consent for including an individual’s immunization information in an IIS is based on state law. There are three models for including an individual’s immunization data in an IIS:

- **Mandatory participation.** For this model, information is automatically included in the IIS without consent of the individual or parent. No option is provided for the individual or parent to exclude their immunization data.

- **Opt-out, also known as voluntary exclusion.** This model is based on implied consent. Information is automatically included in the IIS without the express consent of the individual or parent. The individual or parent may choose to exclude themselves or their children from participating in an IIS by “opting-out.”

- **Opt-in, also known as voluntary inclusion.** This model is based on express consent. Immunization information is included only if the parent or individual provides express consent.

With the exception of four states (Arkansas, Arizona, New Jersey and New York), the consent models for children and adults within each state are the same.

According to the CDC’s 2012 survey, for children:

- Forty-seven states (counting the District of Columbia) automatically include immunization information in their IIS without the parent’s explicit authorization. :
  - For 11 states participation is mandatory and the parents cannot opt-out.
  - For the remaining 36 states (including Minnesota), the parent may opt-out or restrict access to information.
  - New Hampshire law provides for an opt-out model, but it was not included in total states in the CDC survey because it was not operating an IIS

- Only three states (Kansas, Montana, and Texas) employed an opt-in procedure for children, requiring explicit consent before a child’s information is included. Kansas and Texas require that the parent consent to IIS inclusion in writing. Montana accepts either written or verbal consent.

E. Federal Law Regarding Consent to Inclusion in IIS

Two federal laws establish national standards for the disclosure of identifiable information: the federal Privacy Rule, adopted by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA) and the Family Educational Rights and Privacy Act (FERPA). In general, neither law should impact the reporting by a health care provider of immunization information to an IIS.

F. Minnesota Immunization Information Connection

The Minnesota Immunization Information Connection (MIIC) is a network of regional immunization service providers coordinated by the Minnesota Department of Health. MIIC provides a confidential, computerized information system that contains shared immunization records in order to provide authorized users with secure, accurate, complete, and up-to-date immunization data. Collection of and access to immunization data in Minnesota is governed by state law. Minnesota has many stakeholders whose input must be considered when determining laws and policies related to immunization, IIS, and consent practices for IIS.
Minnesota’s Immunization Data Sharing Law defines immunization data and sets forth the persons who may share immunization data without first obtaining consent. Under the law, “immunization data” includes both information about the patient and information about the immunization. The Immunization Data Sharing Law authorizes providers, group purchasers, elementary or secondary schools or child care facilities, public or private postsecondary educational institutions, boards of health, community action agencies, and the commissioner of health to share immunization data with one another without obtaining the patient’s consent, if the person requesting access to the data provides services on behalf of the patient.

The Commissioner of Health has the duty to develop and maintain programs to protect, maintain, and improve the health of the state’s citizens. Together with the Immunization Data Sharing Law, the Commissioner’s duty to protect health, authority to collect and analyze health data, and mission to coordinate activities with other government agencies, use technology to improve performance of departmental duties, and prevent wasteful expenditures of public funds provide the parameters of the legal authority, goals, and practices for implementing MIIC.

G. Costs and Benefits of IIS Consent Models

There is not a great deal of current research comparing benefits and costs of IIS consent models. Much of the research is either dated or relates to IIS or immunization more generally. That said, it seems clear that an opt-in consent process is more costly and more cumbersome (for both staff and users) to operate than an opt-out or mandatory participation process. The substantial cost differences are despite roughly comparable rates of participation in IIS under either an express or implied consent approach.

H. National Trends in Implementation of IIS

A number of clear trends in state implementation of IIS were observed in the literature and in the key informant interviews, especially with respect to implementation of consent practices. Notable trends include the following:

1. Adoption of Explicit Statutory or Administrative Authority for IIS
2. Very High Levels of Participation, Regardless of Consent Method
3. Adoption of Implied Consent Model
4. Expansion of IIS to Cover the Lifespan
5. Use of Vital Records to Create a Population-based IIS
6. Differing Practices to Provide Notice of IIS and of Opt-In or Opt-out
7. Differing Criteria to Exercise Right to Opt Out from an IIS
9. Mandated Provider Participation
10. Transitions in Software or Technology Platform Used
11. Role of Community Partners and Champions
12. Expanded Use of IIS for Child Health Profiles

IIS programs increasingly: are operated under explicit statutory authority; garner very high participation; and do not require people to actively opt in to the system, but operate based upon implied consent. Best practices related to consent practices for patients, parents, and health care providers continue to develop.
I. Implications for Minnesota’s Administration of MIIC

Minnesota is addressing many of the same key implementation issues addressed in the key informant interviews and identified as trends in other states. Practices in other states may provide models for implementation of the opt-out process, or for mandatory participation by patients and/or providers.

Appendix B provides samples of the opt-out forms collected from the websites of a number of states in March, 2014. Review of these forms may provide insight for Minnesota’s implementation of decisions by patients or their parents to opt out of MIIC.

J. Conclusions

IIS provide considerable public health benefits, and do so at a relatively low cost when based upon implied consent to participation by patients, including the parents of patients who are children. As states shift to IIS based upon implied consent beginning at birth and continuing throughout the lifespan, implementation practices are shifting to provide efficient and effective notice and implementation of opt-out procedures. Minnesota’s use of an implied consent system through MIIC appears to be consistent with the legal, political, and economic climate of the state. Some states are just beginning to explore mandatory participation for health care providers and use of IIS for child health profiles, though by and large, Minnesota has not.
I. NATIONAL PERSPECTIVE

Immunization Information Systems have been – and continue to be – key to maintaining and improving vaccination coverage and reducing vaccine preventable diseases in the United States. An Immunization Information system (IIS), also known as an immunization registry, is a confidential, computerized, population-based information system that collects and consolidates vaccination data from vaccine providers and provides tools for designing and sustaining effective immunization strategies at the provider and program levels. While IIS were originally created to benefit children, today most systems cover the whole lifespan. Some have additional functions to help protect the public’s health. For example, newer uses include vaccine inventory and management, vaccine coverage reports, vaccine safety reporting, integration of child health information systems to ensure timely delivery of child health services, interoperability with electronic medical records, and emergency response assistance.

A. Introduction

Children typically are entered into an IIS at birth through a linkage with electronic birth records. Alternatively, a health care provider can enter a child into an IIS at the time of the child’s first immunization. For children and adults, the provider enters information into an IIS at the point of care. This information may include the patient’s name, date of birth, contact information, vaccine, date administered, manufacturer and lot number, as well as other information depending on the system. An IIS manages this information for effective use at provider and population levels:

- At the point of clinical care, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate patient vaccinations.
- At the population level, an IIS provides aggregate data on vaccinations to determine vaccine coverage, inform program operations, and to guide public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease.

This report provides an environmental scan of IIS in the United States generally and its role in U.S. immunization strategy. More specifically, it covers Minnesota law and practice regarding its IIS, the Minnesota Immunization Information Connection (MIIC), and discusses the IIS within Minnesota’s legal, cultural, political, and economic context. The report analyzes patient consent models for including immunization data in an IIS to achieve immunization goals in an efficient and cost-effective manner. States employ three models for including immunization data in an IIS. These models reflect a continuum with regard to requirements for explicit individual consent – from mandatory participation in an IIS, to inclusion in an IIS unless the individual requests otherwise (“opt-out”), to inclusion in an IIS only with the individual’s express consent (“opt-in”).

Finally, the report includes experiences shared by selected states about their IIS law, consent models, and practices for including immunization information in their system, and implications for Minnesota’s implementation of MIIC.

B. Research Methods

The authors of this report employed a variety of research methods. They used standard legal research and analysis methods, accompanied by a literature review. In addition, they conducted interviews with key informants. Key informants were selected from among officials involved with administration of state IIS that have changed their consent practices, as well as representatives from opt-in, opt-out, and mandatory IIS states. A list of key informants interviewed for the report is included in Appendix A.

C. Background

Historically, immunizations have been tremendously successful in the United States, reducing childhood vaccine preventable diseases by 97–100 percent. However, vaccine preventable diseases remain. Every day in the United States, almost 11,000 babies are born who must be vaccinated against them. Some diseases have been so well...
controlled by the use of vaccines that the public and many healthcare providers have no memory of them ever existing. Ignored, this loss of awareness can lead to public apathy about the need for vaccination or unwarranted conclusions that vaccine risk outweighs disease risk. More dangerously, it can lead to a loss of political will to sustain vital immunization interventions.\textsuperscript{25}

Achieving high levels of vaccination in the community directly protects the individuals who are vaccinated and indirectly protects others who are not exposed to infectious organisms, including adults, those with weak immune systems, and those who cannot be vaccinated. Children with weakened immune systems due to an illness or a medical treatment, such as chemotherapy, may not be able to safely receive some vaccines. They depend on vaccination of a sufficient proportion of their community to prevent the spread of disease to which they have no immunity, minimizing their risk of exposure.

Childhood immunization rates are one of the leading health indicators used to assess the health of the nation as part of the U.S. Department of Health and Human Services’ Healthy People Initiative. Nationally, coverage rates for children meet Healthy People 2020 targets for most vaccines. However, rates are well below targets for new vaccines, such as rotavirus, and vaccines that require multiple shots.\textsuperscript{26}

Even though national rates are high for most routine vaccines, vaccine coverage varies by state and clusters of unvaccinated children in geographically localized areas leave communities vulnerable to outbreaks of disease.\textsuperscript{27} For example, while national vaccine coverage against measles approached 95 percent in 2011 for children in kindergarten, outbreaks continue. From January 1 to May 16, 2014, 216 cases were reported in 18 states.\textsuperscript{28} Usually, there are about 60 cases a year, but 2013 saw a spike in American communities\textsuperscript{29} that has continued into 2014. In particular, California and New York City have experienced large outbreaks. From January 1-April 18, 2014, the California Department of Public Health received reports of 58 confirmed cases of measles, with patients ranging in age from 5 months to 60 years.\textsuperscript{30} From January 1-March 7, 2014, New York City announced that it had identified 16 cases (9 pediatric and 7 adult) in Northern Manhattan and the Bronx, and urged all New Yorkers to make sure they are vaccinated against measles.\textsuperscript{31}

The majority of people who got measles in 2014 were unvaccinated.\textsuperscript{32} Measles is so contagious that the vast majority of a population must be vaccinated to prevent sustained outbreaks. This means that imported cases spark outbreaks among pockets of unvaccinated people, including infants and young children. It is still a serious illness: 1 in 5 children with measles is hospitalized. Even after a person recovers from measles, in rare cases there can be long-term complications, such as neurological damage or subacute sclerosing panencephalitis (SSPE) later in life, which can result in death.\textsuperscript{33}

Strong efforts must continue to maintain high immunization coverage among children. They must also address immunization across the lifespan. Healthy People 2020 established targets to increase immunization rates for adolescents and adults. Among adolescents, national targets have been met for tetanus-diphtheria-acellular pertussis (Tdap) booster. However, national targets have not been met for effective vaccination of adolescents against meningococcal disease, varicella, and human papillomavirus (HPV).\textsuperscript{34} Routine vaccination of older adults fall far short of Healthy People 2020 targets for vaccination against shingles and pneumococcal disease for noninstitutionalized adults.\textsuperscript{35}

As set out below, IIS are a key component of U.S. strategy to maintain and achieve high immunization levels across all populations and geographic areas. To achieve maximum coverage levels for all recommended vaccinations, immunization must be emphasized every time anyone, at any age, receives health care services. This means that providers must have access to a complete and accurate immunization history for each patient to ensure timely and appropriate vaccination throughout the lifespan. Additionally, health departments and others need population data to assess state and local coverage, monitor trends, and implement effective vaccine strategies.

\textbf{D. Benefits of IIS}

Children, parents, adult patients, health care providers, health plans, schools, and communities benefit from IIS. To maximize benefits, an IIS must be fully operational and contain complete and reliable immunization data.

\begin{enumerate}
\item IIS consolidate immunization information from multiple sources into one record.
\end{enumerate}
IIS consolidate immunizations from all health care providers into one record, thus providing an accurate and reliable immunization history for an individual. Studies show that 22 percent of U.S. children see two immunization providers in the first two years of life and an additional 3 percent see three or more providers. Adults receive services from an array of providers in a variety of settings over their lifespan. As a result, paper records may be scattered and incomplete. Immunization cards may be lost, forgotten, or not kept up to date. IIS help vaccine providers, recipients and families by consolidating immunization information into one reliable source that provides accurate records for child care, school or camp entry or travel requirements. Some IIS can also exchange information with IIS in other states, or provide access to providers in border states, providing immunization history even when families move out-of-state or receive health care from out-of-state providers.

2. **IIS make certain that vaccination is complete, timely, and appropriate.**

IIS provide reliable and accurate immunization history to the health care provider at the point of service for new and continuing patients, minimizing missed opportunities for immunization and ensuring patients do not get duplicative vaccinations. IIS help providers check a child's immunization history through a centralized database, without depending on the individual or parents for a paper record or basing vaccination decisions on their memories, which are not often reliable. For children, studies show that both parents and providers overestimate vaccination. At the same time, 21 percent of 19-35 month old children have received unnecessary (duplicative) immunizations. IIS are also used to generate “reminders” to families, individuals, and providers that a child is due for an immunization and “recalls” when an immunization is missed. Reminder-recall systems are an evidence-based strategy to improve vaccine uptake. Depending on the IIS system, health departments and/or providers may deliver the reminders and recalls.

IIS are also a useful tool to administer complex vaccination schedules, ensuring that children and adults get all indicated vaccines while protecting them from under-vaccination and over-vaccination. In the early 1980s, the immunization schedule for children in the United States provided protection against seven infectious diseases, and included 11 total doses of vaccine during infancy, childhood, and adolescence. The childhood immunization schedule in 2014 includes vaccines that provide protection against 16 different infectious diseases. This protection results from the administration of 30 to 40 doses of vaccine between birth and 18 years. An IIS may have an automated function that compares an individual’s immunization history to date with current recommendations of the Advisory Committee on Immunization Practices (ACIP). The IIS identifies to the provider the vaccines that are due, past due, or coming due at the point of care. This automated function is especially valuable for increasing vaccination rates among adults since health care providers are less familiar with recommended vaccines for this age group.

3. **IIS provide convenience for adult vaccine recipients, parents, health care providers, schools, child care providers, health departments, and others.**

IIS benefit vaccine recipients, parents, health care providers, schools, and others by providing a convenient “one stop shop” for complete and accurate vaccination information. By combining immunization information from different sources into a single record, IIS can generate official certificates of immunization that parents can present to school, camp, day care, or wherever else needed. Parents and adult patients can take this immunization record to a provider in another state if the family moves to or receives health care in another state. IIS provide official vaccination reports in other circumstances where needed, such as employment in the health care field, admission to a health facility or for travel. IIS enable schools, child care facilities, school-based early childhood programs, and others with access to ensure that children have immunization documentation for enrollment. For schools, IIS reduce the time that school nurses and administrative staff have to spend checking the immunization status of all students, every year, at every school, in grades K-12. IIS also help ease the administrative burden placed on health care providers when parents ask for verification of pediatric immunizations for school enrollment purposes.

4. **Health care providers and health plans benefit from IIS.**

IIS make medical practices and clinics more efficient and keep patients healthier. IIS simplify immunization record keeping, provide quicker access to immunization records, and help keep track of a patient's immunization status. They
supply ready access to the current recommendations and information on new vaccines, vaccine combinations, and changes in the vaccine schedule. IIS can easily find immunizations for new patients and reduce paperwork by providing required school, camp, or child care immunization records.

Immunization providers are able to extract data that provide statistics on individual immunization coverage rates. A Healthy People 2020 goal is to increase to 50 percent the proportion of immunization providers in the U.S. who have measured the vaccination coverage levels among children in their practice populations.44 IIS help providers assure and improve quality by pinpointing where their practices are under-immunizing and over-immunizing, facilitating provider review and improvement of immunization practices.

IIS also generate coverage reports for managed care and other organizations. They reduce or eliminate chart pulls needed for coverage assessment and Healthcare Effectiveness Data and Information Set (HEDIS) reports for managed care organizations.45 HEDIS is a tool created by the National Committee for Quality Assurance (NCQA) to collect data about the quality of care and services provided by the health plans.46 It is used by more than 90 percent of U.S. health plans to measure performance on selected criteria of care and services, including immunizations. HEDIS reports have increased immunization rates for managed care organizations by identifying unimmunized children.47

While new vaccines offer the opportunity for increased disease prevention, these additions impact ordering and inventory systems and place a greater burden on current disease surveillance and delivery systems. IIS can help manage vaccines inventories. Most IIS have a vaccine inventory management system that helps providers account for the vaccines they’ve purchased, stored and used. That function is essential to providers who participate in the federal Vaccines for Children program because the program requires a high level of accountability for vaccines administered.48

5. **IIS protect the community against vaccine preventable diseases.**

Ultimately, the purpose of all immunization activities – including IIS – is to ensure the appropriate delivery of immunization services to all members of a population. Vaccines protect more than the vaccinated individual. They also protect society. When vaccination levels in a community are high, the few who cannot be vaccinated—such as young children, those who are immunocompromised (e.g., cancer patients) and persons with contraindications to vaccination—are indirectly protected because of group immunity.

IIS help ensure high immunization coverage at both the provider and population level. Many studies show an improvement in immunization rates when IIS are used. Oregon improved its coverage rates from 32 percent to 36 percent as a result of having more accurate, up-to-date immunization data. Minnesota from 88.2 percent to 95.7 percent within one year of implementation of its IIS, and Arizona from 45 percent to 90 percent through a combination of better records and additional immunizations.49

IIS provide data at the population level, aggregating data on vaccinations at the state and community level for use in surveillance and program operations. This data guides public health action to improve vaccination rates and reduce vaccine preventable diseases. In this regard, IIS help immunization programs identify populations at high risk for vaccine-preventable diseases and target interventions and resources efficiently. An IIS can be used to assess specific vaccines and produces reports that monitor new vaccine uptake. Some IIS have geographic information systems (GIS) that can report immunization rates by small geographic areas, such as blocks or census tracts, which help target outreach to under-immunized populations to prevent and control a disease outbreak.

6. **IIS promote vaccine safety.**

IIS promote vaccine safety in both public and private health care settings. They increase vaccine safety by recording any complications or side effects from a vaccination. IIS advise providers on recognized contraindications, and alert providers of any safety concern.50 The detailed data in IIS can provide data for post-licensure vaccine studies51 and greatly streamline the process of reporting to the Vaccine Adverse Events Reporting System (VAERS).52

Although it is rare, occasionally a problem is identified with a specific manufacturer or lot of vaccine. Such problems may include the administration of a vaccine too weak to confer protective immunity, requiring re-immunization; or association of...
a specific vaccine with adverse outcomes. In either case, the detailed administration records in an IIS can greatly facilitate identifying all recipients of that vaccine so proper follow-up can be initiated. For example, in 2007, the New York City Bureau of Immunization used its IIS to quickly notify providers that Merck had issued a voluntary recall of certain lots of its conjugate Hib vaccine due to potential contamination. The health department was then able to monitor the success of the recall by examining the number of recalled doses administered and reported to its IIS before and after the recall. In this recall, there was no danger to patients in receiving the affected vaccine, but in a different and unwelcome scenario where the vaccine might be ineffective or harmful, the IIS could have helped identify the individuals who received the affected vaccine, and facilitate appropriate action, if necessary.

7. IIS improve response to a vaccine shortage.

IIS are used to manage vaccine shortages. When Merck voluntarily recalled certain lots of its conjugate Hib vaccine, the recall affected more than 1 million doses of Hib vaccine, causing a nationwide shortage that lasted more than a year. To maintain adequate protection against Hib, public health officials changed the vaccine's administration schedule based on CDC recommendations and released national cache. During the shortage, 46 percent of immunization program managers used their IIS to monitor provider compliance with recommendations regarding Hib vaccine use, and of these, nearly 60 percent reported success in monitoring provider compliance with recommendations compared with 35 percent who did not use their IIS in this way.

Used in this way, IIS provide accountability and enable immunization programs to reach out to providers who may not adhere to revised administration guidance. IIS can then be used to identify and recall patients whose immunization was deferred due to vaccine shortages after the shortage has been resolved.

8. IIS support effective response to public health and other emergencies.

Successful use of IIS to respond to shortages of routine vaccines can inform preparation for larger-scale public health emergencies that may require mass distribution of vaccines or other medical countermeasures. In 2009, IIS were used in many states to record administration of H1N1 influenza vaccine. IIS enable health departments to monitor provider compliance with temporary shortage recommendations or other directives like priority group guidance or change in vaccination schedule recommendations.

IIS can also provide needed immunization data during a disaster. IIS enable providers to recover information about their patients should their own records be destroyed or unavailable in a flood or other event. Use of the Louisiana Immunization Network for Kids Statewide (LINKS) during the aftermath of Hurricane Katrina saved parents and immunization providers' time, money, and the inconvenience of having to unnecessarily revaccinate children displaced both inside and outside Louisiana. LINKS contained immunization records for approximately 1.5 million people of all ages at the time of the hurricane. This immunization information system remained online via a backup system following the hurricane, thereby making immunization history data available to queries from healthcare providers caring for displaced persons both within Louisiana and throughout the United States.

Some key informants noted that IIS have helped their states during less acute emergencies. For example, as a result of the natural gas boom in the northwestern part of North Dakota, people are flooding into the area for jobs. The North Dakota Immunization Information System (NDIIS) has helped to ensure that children are able to receive appropriate immunizations, whether they are born in the state or visit a provider at some later point.

9. IIS save money.

IIS bring many benefits to the bottom line:

- IIS save money by preventing over-vaccination. Administering at least one unneeded shot to 21 percent of 19-35 month old children adds up to an estimated cost of $15 million (without considering administration costs). Virginia estimates that it would save $97,500 per year by eliminating duplicate Hep B vaccines.
• IIS save money and improve administrative efficiency, eliminating costs of manual record pulls and entry and storage of immunization data. According to one report, manual record pull and review for 22 percent of American children who see two or more immunization providers in their first two years of life would cost approximately $16 million annually.\(^{61}\)

• IIS save money by automating state public health agency tasks. For example, IIS can automatically calculate and produce required public vaccine inventory reports. Absent IIS, public health departments must manually review and aggregate reports submitted by users to account for public vaccine. Annual cost savings to state public health agencies was calculated at $11,740 for Utah and $146,750 for Virginia.\(^{62}\)

• Vaccine inventory management can reduce vaccine waste. For example, health departments can identify and redistribute vaccines among sites for use before they expire.\(^{63}\)

• By increasing immunization rates, IIS reduce financial costs that are associated with diagnosing and treating vaccine-preventable diseases. Vaccines are among the most cost-effective preventive services. Healthy People 2020 reports that childhood immunization programs provide a very high return on investment.\(^{64}\) For example, for each birth cohort vaccinated with the routine immunization schedule (this includes DTap, Td, Hib, Polio, MMR, Hep B, and varicella vaccines), society:
  - Saves 33,000 lives.
  - Prevents 14 million cases of disease.
  - Reduces direct health care costs by $9.9 billion.
  - Saves $33.4 billion in indirect costs.

• By increasing immunization rates, IIS reduce costs to the public associated with the investigation and control of outbreaks. For example, a public health response to measles in Salt Lake County, Utah, from March 2011 to April 2011, involved nine measles cases but required officials to track down thousands of individuals who had contact with the measles cases (contacts), review immunization records of hospital workers and teachers, give post-exposure prophylaxis to nearly 400 people, and isolate 200 others. The estimated cost of this response was $300,000.\(^{65}\)

• As discussed above, LINKS saved parents and immunization providers' time, money, and inconvenience during the aftermath of Hurricane Katrina. LINKS successfully responded to over 21,000 electronic immunization queries from virtually all states regarding children and adolescents displaced outside Louisiana state boundaries. Savings in revaccination expenses are estimated at more than $4.6 million.\(^{66}\)

E. Development of and Support for IIS

Today’s high vaccination coverage of children is due to a comprehensive vaccine strategy that has developed over many years with federal support and intensive and extensive efforts by communities and states. These efforts include development and adoption of IIS for children and, more recently, adults across the lifespan.

1. Historical Development of IIS

In the late 1970s-early 1980s, immunization efforts were aimed at school-aged children. States enacted laws that required children to be immunized prior to school entry. This resulted in immunization levels of over 95 percent in 5-6 year-old children beginning in the early 1980s.\(^{67}\) In contrast, for preschool children, immunization levels remained low. For example, in some urban areas, only 20 percent of 2-year old children were immunized, resulting in outbreaks of measles and other diseases.\(^{68}\) In the late 1980s, an epidemic of 55,000 cases of measles resulted in 11,000 hospitalizations, 120 deaths, and $100 million in direct medical care costs.\(^{69}\) The measles resurgence was attributed to low immunization rates in preschoolers as well as inadequate access to care, missed opportunities for administering vaccines, and inaccurate (high) estimates of protections on the part of both parents and providers.\(^{70}\)
While work began in the late 1970s to develop pilot immunization information systems, organized nation-wide efforts began in the early 1990s when the measles outbreaks called attention to low immunization coverage levels. The Robert Wood Johnson Foundation launched the All Kids Count Childhood Immunization Initiative in 1991 that provided funding to establish immunization monitoring and follow-up systems. These systems – when combined with other local, state and federal immunization efforts – would increase immunization rates among preschool children. Other organizations and community coalitions were also established. One such organization, Every Child By Two (ECBT), was founded in 1991 by Former First Lady of the United States Rosalynn Carter and Former First Lady of Arkansas Betty Bumpers to raise parent awareness of the need for timely immunizations and develop a systematic method of vaccinating all of America’s children using IIS.

In 1993, the federal government launched the Childhood Immunization Initiative (CII) that promoted the development of IIS. CII sought to comprehensively address barriers that prevented infants and young children in the United States from receiving needed immunizations by: (1) improving the quality and quantity of vaccination delivery services; (2) reducing the cost of vaccines for parents; (3) increasing awareness of infants immunization, enhancing community participation, and expanding private-public partnerships; (4) improving the systems for measuring vaccination coverage and disease surveillance; and (5) increasing the emphasis on the development of new, safer, and more effective vaccine.

Three community-based strategies, widely implemented through the CII, were particularly effective in improving immunization levels: the use of reminder/recall systems, assessment of immunization levels (with feedback and corrective action), and linkages between immunization programs and WIC (Special Supplemental Nutrition Program for Women, Infants, and Children) to ensure that a child’s immunization status is accessed at every WIC visit. IIS could better provide for reminder/recall, provider assessment, and WIC linkages than resource-intensive, paper-based systems.

An important goal of the CII was to build a sustainable system to maintain high immunization coverage. To accomplish this goal, President Clinton directed the Secretary of Health and Human Services to “start working with the states on an integrated immunization registry system.” As a result, in 1997, the National Vaccine Advisory Committee (NVAC) launched its Initiative on Immunization Registries. A workgroup was formed to develop a plan to facilitate and coordinate a nationwide network of community-state based immunization registries. Over the next year, the workgroup convened public meetings and received testimony from over one hundred experts and stakeholders. In addition, to ensure input from a cross-section of parents, twenty parent focus groups were conducted around the country.

The NVAC issued its report, Development of Community- and State-Based Immunization Registries, on January 12, 1999. The report outlined policy directions and major steps needed to establish a nationwide network of community/state population-based registries that are capable of sharing information while maintaining privacy and confidentiality.

The report recommended that the initial target group for inclusion in IIS should be children birth through 5 years. It recognized, however, that “[i]mmunization registries can also be used to enhance adult immunization services and coverage.” Thus, “many registries will want to continue the registry beyond school entry and/or include other age groups (e.g., adolescents, older adults).”

The NVAC identified the following four primary objectives with recommendations and action steps for each objective:

- Ensure appropriate protections of privacy and confidentiality for individuals and security for information included in the registry.
- Ensure participation of all immunization providers and recipients.
- Ensure appropriate functioning of registries.
- Ensure sustainable funding for registries.

“It’s easy to ensure coverage of school-age children because they must provide vaccination records to enter school. How do you find and immunize all the 2-year olds without a registry? Without a comprehensive registry it’s difficult for health providers to check which shots a child may already have, so some are overimmunized for some diseases and underimmunized for others.”

-- Rosalynn Carter, Co-Founder Every Child By Two
Since issuing its report in 1999, the NVAC has periodically evaluated progress in meeting its objectives to promote IIS in the four areas described above: privacy and security, provider and recipient participation, functionality, and funding. In its most recent report, issued in February 2007, NVAC found considerable progress in each area. In particular, IIS have demonstrated their effectiveness in:

- Improving immunization services and coverage
- Addressing vaccine shortages
- Coping with disasters
- Expanding IIS to persons of all ages

Still, NVAC concluded that challenges remain. These include sustainable IIS funding and communication between IIS and other information systems, including electronic medical records and health information exchanges.

2. IIS Today

Healthy People established its first objectives for IIS in 1999, to cover children, with “[p]opulation-based registries [to] be a cornerstone of the Nation’s immunization system by 2010.” Today, Healthy People sets objectives for participation in IIS of adolescents, as well as children, establishing the following national targets by 2020:

- **Children.** Increase to 95 percent the number of children (birth through age 5) whose immunization records are in a fully operational population-based IIS.
- **Adolescents.** Increase the number of States that have 80 percent of adolescents with two or more age-appropriate immunizations recorded in an IIS among adolescents aged 11 to 18 years to 40 states, including the District of Columbia.

Healthy People has not established targets for inclusion of adult immunizations in IIS. The NVAC, however, recognizes IIS participation as a key strategy for increasing immunization rates for adults, as well as adolescents. To increase immunizations for these age groups, NVAC recommends that venues for vaccine administration be identified beyond the traditional health care providers, including schools and colleges, pharmacies, retail locations, as well as other settings. This means that IIS participation of all immunization providers and recipients is vital to ensure accurate determination of vaccinations received and needed for these age groups at the point of care.

Each year, the CDC determines IIS participation nationally of children, adolescents, and adults from data submitted to it by states and other jurisdictions that receive federal funds toward their IIS. According to CDC’s most recent data, Healthy People national targets have not been met for participation of children or adolescents in IIS and adult participation is low.

- Nationally, 19.5 million children (86%) under age 6 participated in an IIS in 2012, as defined as having two or more vaccinations documented in an IIS. While the national target (95%) has not been met, IIS participation of children has steadily increased from 48 percent in 2004 to 86 percent in 2012.
- For 2012, only 8 states met the Healthy People goal for adolescents (80% of adolescents with two or more age-appropriate immunizations recorded in an IIS). The national coverage rate was 54 percent.

All states, except Connecticut, Rhode Island, and New Hampshire (which does not operate an IIS), collect immunization information on adults. Nationally, in 2012, 57.8 million U.S. adults aged ≥ 19 years (25%) participated in IIS, which is defined as having one or more vaccinations administered documented in an IIS. Participation for state IIS ranged from 0.7 percent (Texas) to 85 percent (Minnesota).

In comparison, participation rates in the Minnesota Immunization Information Connection (MIIC) have exceeded national averages. Minnesota has met the Healthy People goal for children; almost all children under age 6 have two or more vaccinations documented in MIIC. Although it did not meet the Healthy People 80 percent goal for adolescents (72 percent of adolescents aged 11 through 17 years have 2 or more age-appropriate immunizations recorded in the MIIC), it substantially exceeded the national coverage rate of 54 percent. As indicated above, Minnesota reported the highest percentage of adult IIS participation in the country, with 85 percent participating in the MIIC.
Regardless of the age group, IIS are most successful with active use by all public and private immunization providers. Public providers include public health departments, public hospitals, and other government-based clinics, such as WIC or community health centers. Private providers are funded privately or indirectly by a government (e.g. Medicaid) and include private practice offices, pharmacies, private for-profit and nonprofit hospitals, and other private health facilities.

As more immunization providers enroll and enter information in IIS, immunization information will be entered for more individuals with more complete immunization data on these individuals, thus increasing further the benefits of IIS. In September 2008, the NVAC endorsed a set of principles and recommendations for increasing provider and patient participation in IIS as another strategy for increasing immunization coverage for all age groups. In addition to regulatory or policy approaches, NVAC recommended educating providers about the benefits of IIS to both their practices and their patients, improving functionality to better serve providers, and providing financial incentives, better tools and technical support to providers who use IIS.

F. Federal Recommendations for Operation of IIS

Section 317(b) of the Public Health Service Act ("Section 317"), administered by CDC, provides key support for immunization activities, including IIS. Currently, Section 317 funding is made available for 50 states, 6 cities and 8 U. S. Territories. CDC has established functional standards for IIS through a consensus process, which have been approved by NVAC. Although they are not required, these standards are intended to improve vaccine delivery and guide the development of IIS by Section 317 grantees to realize its full potential. Grantees address functional standards in their IIS Annual Reports, which they submit to CDC. These reports enable CDC to monitor progress toward achieving IIS program goals.

The functional standards include storage of core data regarding each individual who is immunized, timeliness for establishing an immunization record, capability to produce an official immunization record, and automated functions for clinical decision support, and reminder and recall. Most recent standards recognize the growing importance of IIS to the broader health information technology landscape, to include the goal that IIS be able to operate with other health information systems. In this regard, the Health Information Technology for Economic and Clinical Health Act (HITECH), part of the American Recovery and Reinvestment Act of 2009, provides financial incentives to eligible healthcare providers that implement and meaningfully use certified electronic health record technology. To demonstrate meaningful use, eligible providers select among a menu set of objectives and measures, which must include at least one public health objective. Submission of electronic data to public health IIS is one means of satisfying the first stage of meaningful uses requirements. To qualify for stage 1 incentives participating providers and facilities must meet one of three public health criteria. One available criterion is to test, and if successful, establish a connection from the EHR to the IIS in the provider’s jurisdiction.

The CDC has also established IIS Functional Standards for privacy and security. These standards help preserve the integrity, security, availability and privacy of all personally-identifiable health and demographic data in the IIS. They require:

- The IIS program has written confidentiality and privacy practices and policies based on applicable law or regulation that protect all individuals whose data are contained in the system.
- The IIS has user access controls and logging, including distinct credentials for each user, least-privilege access, and routine maintenance of access privileges.
- The IIS is operated or hosted on secure hardware and software in accordance with industry standards for protected health information, including standards for security/encryption, uptime and disaster recovery.

Many states have laws to protect the information in the IIS. Some of these laws include:

- Penalties for improper disclosure of information;
- Provisions defining with whom immunization information can be shared (for example, providers, schools, health department); and
- Provisions allowing parents to opt out or limit access to immunization registry information.
All states report having written privacy and security policies and procedures in place and implemented consistent with applicable state, local, and federal law. These include administrative and technical practices and physical safeguards to protect health care information.\textsuperscript{103}

**G. Public Attitudes and IIS**

Generally, parents support their child’s participation in IIS, but may be concerned about privacy and the opportunity to choose whether to participate.

As part of its Initiative on Immunization Registries, in 1998 the NVAC sought input from parents regarding IIS. At that time, IIS were in their infancy and few states had developed them. Even so, most parents had a positive reaction to IIS and would support inclusion of their children. However, they were concerned about privacy and a possible breach of confidentiality. Most parents believed that parents should have a choice about participation. Generally, parents favored express consent over opt-out, but some acknowledged the risk that children would be excluded because their parents failed to read, sign, and return consent.\textsuperscript{104} On the other hand, providers generally favored opt-out approaches, which they felt would pose less of an administrative burden than opt-in approaches.\textsuperscript{105}

More recently, a 2006 study assessed the attitudes of parents of vaccinated and unvaccinated school-aged children toward IIS in four states. At the time of the survey, three of the states (Colorado, Missouri, and Washington) were opt-out states while the fourth state (Massachusetts) was opt-in. While support for IIS was relatively high for both groups, less than 10 percent of parents were aware of IIS in their communities. Even in the two states (Missouri and Washington) with more than 75 percent of children enrolled in an IIS, parents were largely unaware of IIS.\textsuperscript{106} Nearly a third of parents of vaccinated and exempt children did not indicate a preference for opt-in versus opt-out, suggesting that this difference may not be important to many parents. The study’s investigators suggested that opt-out might be a preferred strategy to opt-in given overall parental support for registries and the general efficiency of opt-in versus opt-out.\textsuperscript{107}

**1. Privacy and Security of IIS**

As noted above, parents are primarily concerned about the privacy of identifiable information contained in IIS. Because of this, the 1999 NVAC report on the development of IIS recommended developing stringent specifications to protect information.\textsuperscript{108} Developers have had to demonstrate from the inception of IIS, that the privacy and confidentiality of children and families can be maintained.\textsuperscript{109} IIS have technical, physical and administrative safeguards to prevent inappropriate disclosure of information or inappropriate access by unauthorized persons or organizations.

**2. Choice and Participation in an IIS**

Some individuals and organizations do not want or trust the government to receive and manage information about themselves or their children, even when the information is intended to protect and improve the health of individuals and communities. They may oppose any public health collection of and use of information about them, absent their explicit consent.\textsuperscript{110}

Nonetheless, to protect the community against vaccine-preventable diseases, policy decisions about IIS consent models require consideration of many factors, including ease of implementation, effectiveness, and cost. As discussed below, with three exceptions, states have chosen “opt-out” consent models or mandatory participation in IIS.

Public health agencies are entrusted with access to private and sensitive information about individuals; they must be good stewards of the information. In addition to privacy and security protections, public health agencies must be transparent about information that they maintain, who has access to the information, and for what purposes.
II. STATE OF IMMUNIZATION INFORMATION SYSTEMS ACROSS THE NATION

A. General Statistics Regarding State Laws and IIS

For the most part, IIS are established and maintained by state governments. Forty-nine states, the District of Columbia, and three cities (New York, Philadelphia, and San Antonio) currently operate an IIS. Although New Hampshire is not accepting immunization data at this time, it is in the process of establishing an IIS that is expected to accept data by early 2015. The New Hampshire Division of Public Health Services is working with healthcare providers, hospitals, and others to receive standardized immunization data from health care providers. That way, health care providers in the state can demonstrate “meaningful use” through electronic exchange of immunization data from a certified EHR system to an immunization registry.

State IIS-related laws vary in both the types of provisions and terms. Three surveys of state IIS laws – conducted in 2000, 2011, and 2012 – show trends and variations among states regarding child immunization data on notification, choice, access and disclosure, and data retention. For the 2012 survey, the Public Health Informatics Institute, on behalf of CDC, studied IIS state legislation for both child and adult immunization data. This survey covered the 53 jurisdictions that currently operate an IIS.

The CDC has posted its findings regarding specific IIS authorization, reporting requirements for immunization providers, and consent provisions for including a child’s or adult’s immunization data in the IIS. The information summarized in this section, and section B below, for the 2012 survey is based on data posted by CDC on its website on March 20, 2014 and a published summary of these results. CDC warns that it has not finalized this data, so it is subject to change.

For the 53 jurisdictions that operate an IIS that collects information on children:

- Thirty-four states and two cities collect immunization data on the basis of laws that specifically authorize IIS.
- Five states (including Minnesota) and the District of Columbia collect immunization data on the basis of laws that specifically authorize sharing of immunization, but do not specifically mention IIS.
- One state collects immunization data on the basis of laws allowing the sharing of general health information.
- Nine states and one city collect immunization data based on general public health authority.

With regard to adults, for the 51 jurisdictions that operate an IIS that collects information on adults:

- Twenty-five states and two cities collect immunization data on the basis of laws that specifically authorize IIS.
- Seven states (including Minnesota) and the District of Columbia collect immunization data on the basis of laws that authorize sharing of immunization, but do not specifically mention IIS.
- Three states collect immunization data on the basis of laws allowing the sharing of general health information.
- Twelve states and one city collect immunization data based on general public health authority.

In over half of the jurisdictions (31), some or all providers are mandated to report required vaccinations to the state health department. Twenty-two jurisdictions had no mandate to report. Required reporting has increased. In 2000, only 12 states mandated reporting. Depending on the state, mandatory reporting may be limited to certain age groups (e.g. children), certain vaccines (e.g. publically funded vaccines), or certain types of providers (e.g. all immunization providers, public health providers, Vaccines for Children providers, or pharmacies/pharmacists).

B. State Law Regarding Consent to Inclusion in IIS

For the most part, consent for including an individual’s immunization information in an IIS is based on state law. According to CDC survey data across the United States, there are three models for including an individual’s immunization data in an IIS:
• **Mandatory participation.** For this model, information is automatically included in the IIS without consent of the individual or parent. No option is provided for the individual or parent to exclude their immunization data.

• **Opt-out, also known as voluntary exclusion.** This model is based on implied consent. Information is automatically included in the IIS without the express consent of the individual or parent. The individual or parent may choose to exclude themselves or their children from participating in an IIS by “opting-out.”

• **Opt-in, also known as voluntary inclusion.** This model is based on express consent. Immunization information is included only if the parent or individual provides express consent.

With the exception of four states (Arkansas, Arizona, New Jersey and New York), the consent model for children and adults are the same. Arkansas, New Jersey, and New York provide either opt-out or mandatory participation systems for children and opt-in systems for adults. Arizona provides an opt-out system for children and adults who are vaccinated by pharmacists; express consent for inclusion in the IIS is required for adults who are vaccinated by other providers.

According to the CDC’s 2012 survey, for children:

• Forty-seven states (counting the District of Columbia) automatically include immunization information in their IIS without the parent’s explicit authorization:
  
  o For 11 states, participation is mandatory and parent cannot opt out
  o For the remaining 36 states (including Minnesota), the parent may opt-out or restrict access to information.
  o New Hampshire law provides for an opt-out model, but it was not included in total states in the CDC survey because it was not operating an IIS

• Only three states (Kansas, Montana, and Texas) employed an opt-in procedure for children, requiring explicit consent before a child’s information is included. Kansas and Texas require that the parent consent to IIS inclusion in writing. Montana accepts either written or verbal consent.

Opt-in states for children have declined substantially over the last decade. In 2000, of the 49 states that had adopted a consent model, 14 states required explicit consent from parents to include information for their children\(^{119}\) compared to three in 2012. Correspondingly, states that automatically include immunization information (mandatory participation or “opt-out”) grew from 35 in 2000 to 47 in 2012. Table 1 below summarizes the trend in states shifting from opt-in to either opt-out or mandatory participation in IIS over the twelve years.

<table>
<thead>
<tr>
<th></th>
<th>Opt-In</th>
<th>Automatic Inclusion (Opt-Out + Mandatory Participation)</th>
<th>Opt-Out</th>
<th>Mandatory Participation</th>
<th>Total states a</th>
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<tbody>
<tr>
<td>2000 Survey(^{120})</td>
<td>14 states (CA, HI, ID, IL, IN, KS, LA, MA, ND, NJ, NM, NY, TX, VA)</td>
<td>35 states</td>
<td>23 states (AZ, CT, FL, GA, IA, KY, ME, MD, MI, MN, MT, NE, NH, NV, OH, OK, OR, RI, SD, TN, UT, WI, WA)</td>
<td>12 states (AL, AR, CO, DC, DE, MO, MS, NC, PA, SC, VT, WV)</td>
<td>49b</td>
</tr>
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</table>
Opt-In Automatic Inclusion (Opt-Out + Mandatory Participation) Opt-Out Mandatory Participation Total states a

| 2012 Survey121 | 3 states (KS, MT, TX) | 47 states | 36 states (AK, AL, AR, AZ, CA, CO, CT, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, c ME, MD, MI, MN, NE, NJ, NM, NV, OH, OK, PA, RI, c SD, TN, UT, VA, WI, WA, WY) | 11 states (DC, DE, MO, MS, NC, ND, NY, OR, d SC, VT, WV) | 50° |

a. For purposes of this summary, the District of Columbia is counted as a state.
b. Two states (AK, WY) had not adopted a consent model at the time of this survey.
c. In these states, providers are required to report immunization information. However, parent can “opt out” of having this information available to IIS users.
d. CDC has classified Oregon as a mandatory participation state because its right to opt out is very restricted.
e. New Hampshire has had a law since 1999 establishing an opt out model; however, it has not operated an IIS so its data was not included in the 2012 CDC survey.

Table 1. Comparison of change in states with opt-in, opt-out, and mandatory participation models for children’s participation in IIS from 2000 to 2012.

C. Federal Law Regarding Consent to Inclusion in IIS

Two federal laws establish national standards for the disclosure of identifiable information: the federal Privacy Rule,122 adopted by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA)123 and the Family Educational Rights and Privacy Act (FERPA).124 However, neither law should impact the reporting by a health care provider of immunization information to an IIS.

1. HIPAA Privacy Rule

The HIPAA Privacy Rule sets a minimum national standard for protecting the privacy and security of individually identifiable health information ("protected health information" or "PHI"). HIPAA prohibits disclosure of an individual’s PHI unless the individual authorizes the disclosure or an exception applies. HIPAA allows health care providers to disclose immunization information, without the patient’s consent, for purposes of treatment, as required by state law, and as authorized to a public health agency for the purpose of preventing or controlling disease, injury or disability including but not limited to public health surveillance, investigation, and intervention.125 Under one or more of these exceptions; health care providers are authorized to submit patient information about immunization to an IIS without the patient’s consent.

IIS are commonly recognized as Public Health entities and may not be strictly covered under HIPAA. Regardless, the responsibility for strict confidentiality, privacy and security remain fundamental to IIS operations.126 Moreover, most states, like Minnesota, have strict laws protecting private health information.127 Whether or not HIPAA standards apply to public
health agencies, health care providers are required by HIPAA to ensure that electronic health information is transmitted to other entities and stored in a secure manner. They may not contribute data to IIS absent assurance that public health agencies maintain their IIS in compliance with HIPAA regulations. The HIPAA Security Rule represents security best practice, covering administrative, physical, technical safeguards for electronic data, addressing for example, data backup, disaster recovery and emergency operations. As such, they ensure compliance with IIS Functional Standards for implementation by CDC-funded Immunization programs. The American Registry Association (AIRA) has issued a resource document regarding compliance with HIPAA security standards.  

2. FERPA

The Family Educational Rights and Privacy Act (FERPA) applies to information about students maintained in school records. It prohibits schools from disclosing identifiable information about a student unless his or her parent consents or an exception applies. FERPA does not prohibit schools from accessing information in IIS. Depending on state law, schools may receive immunization data to monitor students’ compliance with mandatory student immunization laws. However, FERPA limits information that schools may disclose about students to public health agencies and others, absent the parent’s consent. In the event of a public health or safety emergency, FERPA would allow disclosure of necessary information without a parent’s consent. FERPA also allows schools to disclose certain directory information about its students, which includes a student’s name, address, telephone number, email address, date and place of birth, dates of attendance, most previous school attended and grade level. This means, absent objection by the parent, public health departments are able to obtain directory information to update their records about children they serve. For example, schools might provide updated addresses for children to immunization programs that send reminders to parents that their child is due for a vaccine.

III. MINNESOTA IMMUNIZATION INFORMATION CONNECTION

The Minnesota Immunization Information Connection (MIIC) is a network of regional immunization service providers coordinated by the Minnesota Department of Health. MIIC provides a confidential, computerized information system that contains shared immunization records in order to provide authorized users with secure, accurate, complete, and up-to-date immunization data, no matter where the shots were given. MIIC contains immunization records for over six million persons of various ages. Nearly 4000 organizations, including health care providers, public health agencies, hospitals, health plans, pharmacies, nursing homes, child care facilities, and schools use MIIC. Minnesota has many stakeholders whose input must be considered when determining laws and policies related to immunization, IIS, and consent practices for IIS.

Collection of and access to immunization data in Minnesota is governed by several statutes. These laws operate in the context of the general authority of the Department of Health to collect and analyze data. Together, they provide the legal authority for MIIC.

A. Minnesota Immunization Data Sharing Law

Minnesota’s Immunization Data Sharing Law defines immunization data and sets forth the persons who may share immunization data without first obtaining consent.

Under the law, “immunization data” includes:

(1) Information about the patient
   • the patient’s name,
   • address,
   • date of birth,
• gender,
• parent or guardian’s name;

(2) Information about the immunization
• date vaccine was received,
• vaccine type,
• lot number and manufacturer of all immunizations received by the patient,
• whether there is a contraindication or an adverse reaction indication.

The Immunization Data Sharing Law authorizes providers, group purchasers, elementary or secondary schools or child care facilities, public or private postsecondary educational institutions, boards of health, community action agencies, and the commissioner of health to share immunization data with one another without obtaining the patient’s consent, if the person requesting access to the data provides services on behalf of the patient.

B. Minnesota Department of Health and Health Data Generally

The Commissioner of Health has the duty to develop and maintain programs to protect, maintain, and improve the health of the state’s citizens. This includes the authority to collect and analyze health and vital data. The legislature further charged the Department of Health to:

(1) prevent the waste or unnecessary spending of public money;

(3) coordinate the department’s activities wherever appropriate with the activities of other governmental agencies;

(4) use technology where appropriate to increase agency productivity, improve customer service, increase public access to information about government, and increase public participation in the business of government;

(7) recommend to the legislature appropriate changes in law necessary to carry out the mission and improve the performance of the department.

At the same time, the commissioner is required to "make and preserve all records necessary to a full and accurate knowledge of [his or her] official activities." The commissioner has a duty to "establish and maintain an active, continuing program for the economical and efficient management of the records of the agency."

Together with the Immunization Data Sharing Law, the Commissioner’s duty to protect health, authority to collect and analyze health data, and mission to coordinate activities with other government agencies, use technology to improve performance of departmental duties, and prevent wasteful expenditures of public funds provide the parameters of the legal authority, goals, and methods for MIIC.

C. Minnesota Government Data Practices Act

In general, the Minnesota Government Data Practices Act governs the actions of state agencies with respect to information. The Data Practices Act regulates the collection, creation, storage, maintenance, dissemination, and access to government data in government entities. It establishes a presumption that government data are public unless there is federal law, a state statute (including one within the Data Practice Act itself), or a temporary classification that provides that certain data are not public.

The Data Practices Act defines health data as "data on individuals created, collected, received, or maintained by the Department of Health, political subdivisions, or statewide systems relating to the identification, description, prevention, and control of disease or as part of an epidemiologic investigation the commissioner designates as necessary to analyze, describe, or protect the public health." Because health data are private data on individuals, the data may not be disclosed unless authorized by law. For example, health data may be disclosed to assist the commissioner to locate or identify a case, carrier, or suspect case, to alert persons who may be threatened by illness as evidenced by epidemiologic
data, to control or prevent the spread of serious disease, or to diminish an imminent threat to the public health.\textsuperscript{152} The Immunization Data Sharing Law also authorizes disclosure of health data in certain circumstances.

**D. Minnesota Health Records Act**

Another law in Minnesota that addresses access to health information is Minnesota’s Health Records Act, which governs patients’ access to their own health data, as well as release of that data to providers and other persons.\textsuperscript{153} It also addresses unauthorized access to a person’s health records.\textsuperscript{154} However, as with the Data Practices Act, some aspects of this provision are superseded by the specific authorization in the Immunization Data Sharing Law.

**E. Minnesota School Immunization Law**

Government power to require vaccinations as a condition to the right of admission to the public schools has been recognized in Minnesota at least since 1902.\textsuperscript{155} The state has had a school immunization law since 1967. Today, the law consists of Minn. Stat. § 121A.15 and Minnesota Rules Ch. 4604. It provides that, with certain exceptions, no person over two months old may be allowed to enroll or remain enrolled in any elementary or secondary school or child care facility or school-based early childhood program until the person has submitted appropriate immunization documentation to the school, child care facility, or early childhood program.\textsuperscript{156} Consistent with state and federal law, schools may read student immunization records in MIIC in order to determine compliance with the School Immunization Law.\textsuperscript{157} In general, however, schools must obtain consent before sharing immunization information, other than directory information. Use of MIIC by schools and child care facilities helps them to efficiently meet their record-keeping and reporting obligations under the law.

**F. Minnesota College Immunization Law**

Minnesota’s College Immunization Law provides that, with certain exceptions, no student may remain enrolled in a public or private postsecondary educational institution unless the student has submitted to the administrator a statement or immunization record showing that the student has received certain immunizations.\textsuperscript{158} The institution must maintain immunization records for each student for at least one year from the time of original filing. Such records are subject to inspection by MDH and the local board of health of the jurisdiction in which the college or university is located.\textsuperscript{159}

**IV. IIS CONSENT MODELS IN DEPTH—BENEFITS AND COSTS**

As discussed above, IIS benefit children, parents, adult patients, health care professionals, health plans, schools, and health departments. The Community Preventive Services Task Force found strong evidence that IIS are effective in increasing vaccination rates and reducing vaccine-preventable disease based on 71 published papers and 123 conference abstracts.\textsuperscript{160} While information abounds about the benefits of IIS, information about the relative merits of opt-in and opt-out consent models is scarce.

**A. Impact of Opt-out vs. Opt-in Consent Models on Immunization Rates**

We located an older study that correlated opt-out systems with higher vaccination rates. This study utilized 2002 data from the CDC and survey data collected from state immunization programs, showing that the implementation of opt-out state registries and state-mandated participation in reminder/recall and assessment systems are associated with higher early childhood (19 to 35 months) immunization rates across states, controlling for other factors.\textsuperscript{161}

According to that study,

States with opt-out state registries have a two-percentages point increase in coverage relative to states without opt-out registries for the 4DTP [diphtheria, tetanus, and pertussis] series, but there is no statistically significant relationship between opt-out registry states and coverage for the 4:3:1:3 series [which includes four doses of DTP, three doses of poliovirus and at least one dose of any measles-containing virus].\textsuperscript{162}
New studies comparing vaccination rates under the three consent models would be helpful.


In 1999, during the infancy of IIS, NVAC recommended that states inform parents about IIS and its purposes, and parents be allowed to opt-out. In communities where opt-in is most consistent with community values, NVAC recommended that this option be offered. State trends indicate that opt-out is the preferred model. As states have switched from opt-in to opt-out systems, participation in IIS has also increased. According to CDC data, participation of children less than 6 years in IIS has steadily increased from 21 percent in 1999 to 86 percent in 2012. (Figure 1)

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However, we could locate no study analyzing to what extent this increase is related to states’ movement toward opt-out systems. Several factors may contribute to increased participation in IIS between 1999 and 2011. The most obvious is the growth in number and maturity of IIS. Another variable – participation of immunization providers in IIS – directly impacts participation of children and adults. The CDC, American Academy of Pediatrics, American Immunization Registry Association (AIRA), and others are engaging multiple efforts to improve functionality and promote IIS’ benefits to increase participation of immunization providers.

Opt-out registries are recommended because they are more efficient as it is easier to enter information at birth and then give parents the choice to remove the data rather than depending on an active response by parents.

## C. Economic Impact of Opt-in vs. Opt-out Consent Models

Opt-in consent models for IIS are much more costly than opt-out models. Researchers conducted a cost analysis of Texas’ IIS, ImmTrac, which requires explicit consent for inclusion of immunization information. ImmTrac is an established IIS that has been used statewide since 1978. Researchers estimated costs to hospitals, medical providers offices, and the state of Texas for 2005 with operating an opt-in IIS and compared them to estimated costs associated with a hypothetical opt-out system. Time study analyses were used to determine staff time associated with ImmTrac consent collection in both public and private birth hospitals and providers’ offices. Direct expenses and time costs associated with obtaining and documenting consent by ImmTrac offices were included. The cost analysis compared a consent process with an estimated 90% opting in and the cost of a consent process with an estimated 10% opting out.

According to one journal article, in an opt-in system, all parents must be approached and consent procedures must be completed to facilitate the inclusion of 90 percent or more of children. Conversely, in an opt-out system, all parents are informed of their child’s automatic participation in the IIS and exclusion procedures are completed for the less than 10 percent who chose to decline participation. As discussed below, key informants from several states indicated that the percentage choosing to opt out or failing to opt in is generally far lower than 10 percent.

Even with the relatively high assumption of 10 percent opting out or failing to opt in, the cost analysis for Texas demonstrated that the proposed opt-out costs were substantially less than the actual opt-in model currently utilized.

- The cost of operating its current opt-in system was estimated at $2.24 per child, with an annual cost of $1,389,805. Costs per child were calculated as an average of staff costs for obtaining opt-in consent in hospitals as part of the birth registration process and in provider offices form children without prior consent.
- The cost of operating an alternative, opt-out system was estimated at $0.29 per child, with an annual cost of $110,714.
- An opt-out would mean a costs savings of $1,279,091 annually.
This is the first study of economic impact published for a state. Thus, it is unlikely that legislatures considered associated costs in the past in enacting IIS legislation. Because the proposed opt-out costs were demonstrated in this study to be substantially less than the actual opt-in model currently utilized, changing to an opt-out IIS might free up healthcare funding for more critical areas such as vaccine purchasing, administration, and education or other health care initiatives.

D. Impact of Opt-in vs. Opt-out Consent Models on Quality of Care and Administrative Efficiency

In 2012, the Immunization Partnership engaged Texas immunization stakeholders in statewide meetings and a web-based survey to build support for positive immunization policy change. The Immunization Partnership (TIP) is a nonprofit organization in Texas that works to eradicate vaccine-preventable diseases by educating the community, advocating evidence-based public policy, and promoting immunization best practices.

Survey respondents included ImmTrac users, health care providers, state agency personnel, and representatives from hospitals, foundations, medical associations, local public health authorities, and nonprofit organizations. Stakeholders identified Texas’ opt-in consent process as a primary barrier affecting the use of ImmTrac. Ninety-three percent of immunization stakeholders who took the survey believe that the current process hinders the ability of health care providers to access immunization information and provide quality care. The majority of respondents indicated that the opt-in process makes it difficult to determine a child’s immunization status, contributing to unnecessary vaccines. Many felt that the current opt-in system increases paperwork, is costly, and is an unnecessary use of staff time and resources. As a result of the administrative burden, stakeholders felt that providers are less likely to participate in ImmTrac. Other stakeholders communicated the importance of moving to an opt-out system to accommodate the increasing demand of electronic medical records and interoperability needed between IIS and other health information systems, especially those used for Medicaid and Medicare. Because the costs of an opt-out system are substantially lower than the current opt-in system, changing to an opt-out process would mean that critical dollars could then be used to improve the ImmTrac system to enhance functionality and encourage provider use.

V. National Trends in Implementation of IIS

This report now turns to an examination of trends in how other states across the country are addressing collection and sharing of immunization information, with special attention to consent practices in those states. A number of clear trends were observed in the literature and in the key informant interviews and are noted below. A discussion of IIS implementation in Minnesota follows in Section VI.

A. Adoption of Explicit Statutory or Administrative Authority for IIS

Many states that developed IIS originally relied upon general grants of legal authority to their state department of health. Increasingly, however, states have adopted explicit statutory authority to create and maintain an IIS. One source reports that in 1995, 13 states or other CDC grantees had specific laws authorizing IIS, and by 2010, 37 states or other CDC grantees had specific laws authorizing IIS. Examples of states that have adopted or amended explicit authority for IIS in recent years include Colorado, Iowa, and Oregon. Thus, Minnesota is among a minority of states without explicit statutory authorization for its IIS. Among key informant interviews, at least one state noted that the lack of explicit statutory authority was sometimes problematic in operation of the IIS, even though other provisions in state law made reference to the IIS.

B. Level of Opt-in is High; Level of Opt-out is Low

Based on the key informant interviews, in states with an opt-in system, the percentage of parents, guardians, and patients who opt in is typically well over ninety percent. Similarly, interviewees in states with an opt-out system reported that the number of patients, guardians, and parents who opt out is well under ten percent.
Indeed, a key informant from Idaho reported that the extremely high rate of persons opting in under the previous system (reportedly about 90% at birth and about 98% by age two) was an important factor in the state department of health and welfare's recommendation, adopted by the state legislature, to transition to an opt out system. He reported that about 200 people have actively opted out since adoption of an opt-out system, out of a population of about 1.1 million. 

A key informant from Colorado reported that about 1252 people have opted out, compared to a total of 3.8 to 3.9 million people in the registry. A key informant in Iowa reported that a total of 15 people—from three or four families—have opted out of the state IIS.

C. Adoption of Implied Consent Model

One article reported that over half of states or other CDC grantees changed consent practices between 2000 and 2010. A number of states that initially developed an opt-in IIS have transitioned to an opt-out model based upon implied consent.

Idaho has had an immunization registry (IRIS) since 1999. It was explicitly an opt-in registry, until a statutory change in 2010. One key informant observed that the opt-out approach preserves the rights of parents, they simply must exercise the rights by action rather than inaction.

Montana is an exception. It operates a lifespan registry as an opt-in model. The use of an opt-in model was a policy decision based upon a legal memorandum written in 2010. The participation rate for Montana’s children in IIS is 98.1 percent, though many children began participating in IIS prior to adoption of the 2010 legal opinion, and thus this participation rate may be higher than, and not a true reflection of, a pure opt-in system. Despite the reportedly lower than 3 percent of persons affirmatively declining to opt in, key informants did not identify any advantages to the opt-in model. Some modifications have been made. Initially, the Department required a written consent. This proved challenging, as when school nurses sought to report consent over the phone; the Department now allows verbal consent, provided it is recorded as such in the IIS. One practical difficulty for providers using Electronic Health Records arises because most states operate an opt-out IIS and do not require a consent field, so providers must work with software vendors to create a consent field. A legislative initiative to adopt an opt-out model in Montana was unsuccessful in 2013, though a similar bill will likely be introduced in the next legislative session, in 2015.

D. Expansion of IIS to Cover the Lifespan

Many states initially adopted an IIS geared toward childhood immunizations. Increasingly, IIS collect immunization for adults as well. Some states reported that they have always had a lifespan registry. Minnesota operates a lifespan registry.

At least two states have faced challenges in legislative efforts to adopt statutory authority for a lifespan IIS. In Idaho, there was opposition to a 2013 legislative initiative to change the word “child” to “individual” in the IIS statute, which follows an opt-out model. Resistance might have been motivated by opposition to immunization and IIS as a whole. The bill did not pass. North Dakota has a lifespan registry, but a recent bill to require mandatory reporting of adult immunization information to the state IIS never reached the floor, despite a lack of active opposition.

Another factor likely to further advance this trend is the Affordable Care Act (ACA), which will require health plans to cover preventive services, including vaccines, without charging a deductible, copayment, or coinsurance. This should increase immunizations against vaccine preventable diseases across the lifespan. In addition to increasing the number of immunizations for adults and senior citizens, the ACA is likely to also increase the number of settings where immunizations are given — including pharmacies, retail clinics, providers and clinics that serve adults and elderly. This makes it even more important to increase provider and patient participation in IIS, in order to capture the financial and other benefits of IIS with respect to immunizations of adults, as well as to avoid under- and over-vaccination.

E. Use of Vital Records to Create a Population-based IIS
Many states use vital records, specifically data from birth certificates, to populate their IIS. There is variation in the source of legal authority for this practice, whether a specific statute or regulation, or internal policy consistent with the health department’s general public health authority. Use of vital records facilitates development of a comprehensive, population-based registry, and enables states to determine more accurate percentages of the population who have received a specific immunization.

Despite operating on an opt-in basis, Montana uses birth records from vital statistics in order to create a population-based IIS. In Montana’s system, entries may be made, but they will not be visible to authorized users until consent has been obtained.

F. Differing Practices to Provide Notice of IIS and of Opt-In or Opt-out

States differ in their practices to provide notice to parents and adults regarding the existence of IIS and of their right to opt out, if any. Some states rely primarily upon their websites to provide notice of IIS and the right to opt out. Kansas provides a brief description of IIS on the birth certificate. Other states engage in affirmative efforts to provide notice. For example, Colorado requires providers to notify patients about IIS by describing the Colorado IIS, including opt out, in a poster in the waiting room. Colorado providers are encouraged to pair the poster with a fact sheet describing IIS, explaining its benefits, and the process to opt out. Rhode Island has a limited opt out for its IIS, but it has a three-part system for informing parents about collection of immunization data and other children’s health information—through obstetricians, birthing hospitals, and mailings following birth or a first medical appointment in the state.

G. Differing Criteria to Exercise Right to Opt Out from an IIS

Most states do not require patients or parents to state a reason to opt out of their IIS. However, mandatory participation states have no statutory or administrative provision to allow persons to opt out. Oregon allows opt out of the IIS only upon demonstration of a threat to health or to safety (for example, danger of violence or kidnapping by a non-custodial parent) if the person were included.

H. Differing Practices with Respect to Implementation of Opt Out in an IIS

States differ in their practices to implement a patient’s or parent’s decision to opt-out. One approach is for an IIS to retain all information but block access for most authorized users. Another approach is to retain only demographic information, accompanied by a note that the person has opted out of including immunization data in the IIS. Keeping demographic data in the system helps ensure that a new record won’t be created. A third approach is to remove all information from the IIS when a person opts out. As a consequence, IIS vary on whether a provider attempting to add a new immunization record is notified that a patient has opted out, and whether the IIS permits the provider to enter the new immunization event.

In Massachusetts, individuals are automatically enrolled in the IIS. A patient or patient’s guardian may opt out of data sharing by signing a waiver. The data remains accessible by the provider who entered it and by the state health department, but is not accessible by anyone else.

In Iowa, administrative rules address implementation of the opt-out. When a person opts out, the record is “locked” and a message appears that there is a potential match and suggests contacting the help desk. The information of a person who has opted out is not viewable or searchable by authorized users, but remains accessible to the state department of public health.

In Colorado, when a person opts out, all immunization data is purged from the system. High level demographic data, such as name, date of birth, and ZIP code are retained. The record is flagged in order to indicate that the person has opted out and to prevent authorized users from either entering or accessing additional information.

Idaho law provides that, “Upon the written request of a parent or guardian, the department of health and welfare shall: (a) cause all information relating to the child to be removed from the registry and any databases or files of other entities or persons to which information in the database has been disclosed.” The practice at the Department had been to delete
all immunization information but to retain demographic information. This departure from the literal statutory language became controversial, and a 2013 legislative initiative to amend the provision to refer to removal of all “medical” information failed. Thus, the Department began in 2013 to remove all information for persons who opt out. The Department advised persons who opt to have all of their information removed that it would remove the information one time, but that the Department would not engage in ongoing monitoring. Rather, the Department advised parents it would be their responsibility to prevent or monitor future entries in the IIS. The Department also began to offer two opt-out options: (1) Remove all information from the registry or (2) remove all medical information from the registry and retain demographic data.

Sample opt-out forms collected in March, 2014 from a number of state websites are attached in Appendix B. The forms reflect the different approaches toward implementing opt-out. To some extent, they may also reflect differences in political, legal, and administrative culture in the various states. States vary in how they explain the benefits of immunization and of IIS, how prominently they display information about opt-out procedures, and how they explain and implement their opt-out process, if any.

I. Mandated Provider Participation

A growing number of states require some or all providers to record immunizations in IIS. In 2008, the North Dakota state legislature added consequences for failure to report child immunizations in NDIIS within four weeks of vaccination. The consequences include a prohibition on further receipt of vaccines from the North Dakota Immunization Program until all required reports are submitted and filing a report by the state department of health with the provider’s occupational licensing entity. The Department has generally sought to encourage compliance before invoking the statutory enforcement mechanisms.

As a practical matter, the evidence suggests that increased participation by providers in IIS may have a greater impact upon overall participation than changes in consent practices for patients. This is because over 95 percent of children “participate” to some extent in most state IIS, regardless of whether the state utilizes express or implied consent. But the completeness of IIS records depends to a large extent upon provider participation.

New York state law provides that all providers must report immunizations within 14 days. About 50 to 55 percent of immunizations are reported within that window. In Massachusetts, all providers are mandated to report all immunizations to the IIS. Oregon enacted a Vaccine Stewardship Law in 2011 which requires any provider who receives public vaccine to report all vaccinations. Idaho is a universal vaccine state. It is a program requirement for providers who participate in Idaho’s program to use IIS for inventory management, including accounting for doses administered. In Iowa, Vaccines for Children program providers are required to use IIS. However, an accommodation is made for providers unable to use IIS.

Iowa and Kansas both enacted laws to require pharmacists to report immunizations in IIS. Ironically, Kansas does not have a specific law authorizing its IIS.

J. Transitions in Software or Technology Platform Used

A number of states reported recent transitions in the technology platform used for their IIS. These states included Colorado and Iowa. Transitions frequently involved migrating data from a previous IIS, as well as developing strategies to address consent-related issues, such as “flagging” or “locking” access to records of persons who have opted out. States with an opt-in system reported some challenges in adapting the platform to the need for consent prior to entry of, or user access to, immunization data.

K. Role of Community Partners and Champions

Several key informants commented on the role of community champions for immunization generally and IIS specifically. Champions included professional associations, such as groups for pediatricians and family physicians, as well as parent
and citizen groups. These champions may take the lead in advocating for statutory changes, since many government employees face limitations in their communications with legislators.

L. Expanded Use of IIS for Child Health Profiles

Some key informants reported that their states were exploring use of IIS for child health profiles, that is, for data reflecting a broad range of aspects of children’s health. Colorado is one of these states.212

VI. Implications for Minnesota’s Administration of MIIC

The overall legal, economic, and political climate at both the national and state level favor IIS that rely upon implied consent, as demonstrated by the rapid growth in opt-out and mandatory IIS over the past decade. Minnesota is addressing many of the same key implementation issues addressed in the key informant interviews and identified as trends in other states.

A. Consent Practices and Procedures

As discussed above, Minnesota’s Immunization Data Sharing Law and the duties assigned to the Commissioner of Health provide authority for the Department to collect immunization data without first obtaining a patient’s consent and to share it with certain identified parties. Granted this authority by the state legislature, Minnesota has adopted an opt-out IIS.

The Commissioner’s authority under the Immunization Data Sharing Law, his duty to collect and analyze health and vital data in order to protect, maintain, and improve the health of Minnesotans, and the duty to do so in a cost effective manner all argue against an opt-in system. An opt-in system would expend substantial state resources to secure consent that the state legislature has already indicated need not be obtained prior to sharing immunization data.

The national trend is for states to move away from opt-in models for their IIS. In adopting an opt-out IIS, the Minnesota Department of Health has chosen a middle ground. Some states have gone farther, and have mandatory inclusion, or extremely limited grounds to opt out of their IIS. In many of these states, this approach is explicit in their statutes.213 Neither the Immunization Data Sharing Law nor the Commissioner’s general grant of authority requires MIIC to allow patients, parents, and guardians to elect not to participate in MIIC, but neither does it mandate participation. As a matter of policy, MDH allows them to opt out from MIIC. This recognizes the privacy and autonomy interests of patients and parents who seek not to participate, yet places the burden on them to act in order to avoid participation. It achieves high participation at a lower cost than an opt-in system.

1. Notice Requirements Related to Disclosure of Immunization Information and the Right to Opt out

Notice related to MIIC is provided at the birthing hospital, with a confirmation letter sent afterward.214 The User Agreement for participating in MIIC requires that authorized users agree to “Prominently display and/or distribute informational materials about MIIC that notify individuals of their option to not participate.”215 These requirements arise out of MDH policy.

2. Implementation of Decision to Opt out

Appendix B provides samples of the opt-out forms collected from the websites of a number of states in March, 2014. Review of these forms assisted the MIIC program in evaluating its approach with respect to implementation of decisions by patients or their parents to opt out of MIIC. The Association of Immunization Managers or the American Immunization Registry Association may also provide a forum for discussion of best practices for states to implement decisions to opt-out.

The Immunization Data Sharing Law sets forth a two-part definition of “immunization data,” that includes information about the patient and information about the immunization. This statutory definition provides MIIC with flexibility in implementing
decisions by patients or their parents to opt out. It explicitly acknowledges a distinction between patient demographic data and immunization information.

As the authors of this report understood practices in Minnesota, the MIIC program locked the records of people who opted out, but did not delete the data.216 This practice was generally aligned with the interests of those seeking to opt out, because the presence of a locked record provides notice to the provider or other authorized user not to create a new record and enter additional immunization data. Of course, this meant that MDH (specifically MIIC staff) still had access to the data.

MIIC has recently created guidance for patients and parents on how they may limit access to their MIIC records, based upon their preferences.217 As this report is being finalized, MIIC offers three options to patients and their parents who choose to limit access to their records. Such persons may (1) decline to receive immunization reminders, (2) allow access to their MIIC records to only their current healthcare provider, or (3) opt out of participating in MIIC. For those who elect to opt out of MIIC, they may choose to either retain demographic data in MIIC for the purpose of preventing subsequent entries, or to have their entire records including both immunization information and demographic information “sealed” so that they may not be accessed by MIIC users.

Retaining demographic information about the patient contributes to the ability of MIIC to evaluate progress in immunization at the population level by using an accurate denominator. That is, when calculating the percentage of Minnesotans of a certain age who have received a specified immunization, it is important to have as accurate a count of all Minnesotans of that age as possible.218

B. Use of Vital Records to Populate MIIC with Information from Birth Certificates

The Minnesota Office of Vital Records is housed within the Minnesota Department of Health. In general, information contained in vital records such as birth certificates is public information (Minn. Stat. § 144.225, subd. 1.) and may be shared with MIIC. Populating MIIC with data from birth certificates fosters creation of a more comprehensive, population-based immunization information system.

MIIC currently uses vital records to populate MIIC. This practice is based upon general authority possessed by MDH.219 MDH has an Internal Data Use Agreement which governs sharing data among different programs within the Department. Because of the Internal Data Use Agreement and the Immunization Data Sharing Law, the data sharing is able to occur automatically. The ability to avoid individual processing for each record is one part of the cost savings of an implied consent system which benefits Minnesota.

The current statutory treatment of children born to unmarried women may benefit from modernization.220 Under current Minnesota law, data related to the birth of a child to an unmarried woman is confidential.

C. Child Health Profiles

Minnesota is not currently contemplating use of MIIC for additional purposes, such as storing data related to newborn screening, lead testing, WIC, or body mass index, nor is it considering expanding MIIC to provide a child health profile.221

D. Mandatory Provider Participation

As noted above, states are increasingly requiring provider participation, especially for immunizations for children, immunizations paid for with public funds, required immunizations, and emerging providers, such as pharmacists. Implied consent for patients is only part of the equation needed to maximize the use and benefits of IIS. Increased provider participation is another important part of the equation. Minnesota may want to explore whether key stakeholders, including professional associations, would support mandatory provider participation.

One way to increase provider participation in the absence of a statutory requirement is dedicated outreach. Minnesota’s Child and Teen Checkups program provides Medical Assistance administrative funding to support MIIC for children and teens enrolled in Medical Assistance and MinnesotaCare as one element of early and periodic screening, diagnosis, and
treatment (EPSDT).\textsuperscript{222} The funds help enable the regional IIS that participate in MIIC to recruit and maintain provider participation, promote the benefits of the registry to providers and the public, and assist with reminder and recall activities and notifications. All of the data are centralized in one location through MIIC.

VII. Conclusions
IIS provide considerable public health benefits, and do so at a relatively low cost when based upon implied consent to participation by patients, including the parents of patients who are children. As states shift to IIS based upon implied consent beginning at birth and continuing throughout the lifespan, implementation practices are shifting to provide efficient and effective notice and implementation of opt-out procedures. Minnesota’s use of an implied consent system through MIIC appears to be consistent with the legal, political, and economic climate of the state. Some states are just beginning to explore mandatory participation for health care providers and use of IIS for child health profiles, though by and large, Minnesota has not.

Endnotes

\* Denise Chrysler is the director of the Mid-States Region of the Network for Public Health Law. Jill Krueger is the director of the Northern Region of the Network for Public Health Law. The authors gratefully acknowledge the research assistance of Jennifer Bernstein, senior staff attorney in the Mid-States region of the Network, and Neil Pederson, research assistant in the Northern Region and third year law student at William Mitchell College of Law.


5 45 C.F.R. Parts 160 and 164.


8 What is the Minnesota Immunization Information Connection?, www.health.state.mn.us/immunize.

9 What is the Minnesota Immunization Information Connection?, www.health.state.mn.us/immunize.

10 Minn. Stat. § 144.3351.

11 Including physicians, physician assistants, acupuncture practitioners, respiratory care providers, traditional midwives, chiropractors, nurses, speech language pathologists and audiologists, optometrists, dietitians and nutritionists, occupational therapists and occupational therapist assistants, physical therapists, athletic trainers, psychologists, certified doulas, marriage and family therapists, alcohol and drug counselors, provisionally-licensed social workers, dentists, dental therapists, advanced dental therapists, dental hygienists, licensed dental assistants, faculty dentists, resident dentists, dental technicians, pharmacists, podiatrists, dispenser of hearing instruments, home care providers, and health care facilities. Minn. Stat. § 144.291, subd. 2.

12 Including health insurance companies, health maintenance organizations, nonprofit health service plan corporations, and other health plan companies; employee health plans offered by self-insured employers; trusts established in a collective bargaining agreement; community integrated service networks; the Minnesota Comprehensive Health Association; group health coverage offered by fraternal organizations, professional associations, or other organizations; state and federal health care programs; state and local public employee health plans; workers’ compensation plans; and the medical component of automobile insurance coverage. Minn. Stat. § 62J.03, subd. 6.

13 Including public, nonpublic, and home schools. Minn. Stat. § 121A.15, subd. 9.

14 Including colleges, universities, community colleges, technical colleges, professional and graduate institutions. Minn. Stat. § 135A.14, subd. 1.

15 Minn. Stat. § 145A.02, subd. 2.

16 Minn. Stat. § 256E.31, subd. 1.

17 Minn. Stat. § 144.05 subd.1.


27 For example, for children 19-35 months, the 2011 National Immunization Survey estimates that hepB birth dose coverage ranged from 23.1 percent in Vermont to 83.4 percent in Indiana and North Dakota and 82 doses of hepA coverage ranged from 29.3 percent in South Dakota to 69.2 percent in Nebraska. CDC, National, State and Local Area Vaccination Coverage Among Children Aged 19-35 Months – United States, 2011, CDC, Morbidity and Mortality Weekly Report (MMWR), September 7, 2012 / 61(35):689-696. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6135a1.htm?s_cid:mm6135a1_e0%0d%0a. Accessed February 24, 2014.


58 Interview with Molly Howell, North Dakota, Aug. 9, 2013; An FAQ from the local public health unit addressed the challenges for adults whose immunizations were not recorded in NDIIS, see http://www.ndhu.org/cgi-bin/programs.pl?display&pid=209.


Adolescent Vaccinations: Recommendations from the National Vaccine Advisory Committee (NVAC)


Historic Dates and Events Related to Vaccines Website supported in part by a cooperative agreement from the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention (CDC). Available at http://www.immunize.org/timeline/, Accessed March 31, 2014.


In 1999, Healthy People set a national objective to increase to 95 percent the number of children enrolled in fully functional population-based immunization registry (birth through age 5). Healthy People 2010: Objectives for Improving Health, 14 Immunization and Infectious Diseases, p. 14-41-42. Available at http://www.healthypeople.gov/2010/document/word/volume1/14immunization.doc, Accessed February 24, 2014. Healthy People 2020 has continued this objective.


93 Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)).


97 Health Information Technology for Economic and Clinical Health Act, also known as the HITECH Act, Pub. L. 111-5, 42 U.S.C. 300jj et seq.; 17901 et seq.


122 45 C.F.R. Parts 160 and 164.


125 45 CFR 164 CFR §§164.506, 164.512(a), 164.512(b).


127 The Minnesota Department of Health has posted a legal analysis regarding application of HIPAA to MIIC at http://www.health.state.mn.us/divs/idepc/immunize/hippadata.html. The legal memo was originally drafted in 2003, but has been updated recently.


130 34 C.F.R. §99.36.

131 34 C.F.R. §99.37.

What is the Minnesota Immunization Information Connection?, www.health.state.mn.us/immunize.


Minn. Stat. § 144.3351.

Including physicians, physician assistants, acupuncture practitioners, respiratory care providers, traditional midwives, chiropractors, nurses, speech language pathologists and audiologists, optometrists, dietitians and nutritionists, occupational therapists and occupational therapist assistants, physical therapists, athletic trainers, psychologists, certified doulas, marriage and family therapists, alcohol and drug counselors, provisionally-licensed social workers, dentists, dental therapists, advanced dental therapists, dental hygienists, licensed dental assistants, faculty dentists, resident dentists, dental technicians, pharmacists, podiatrists, dispenser of hearing instruments, home care providers, and health care facilities. Minn. Stat. § 144.291, subd. 2.

Including health insurance companies, health maintenance organizations, nonprofit health service plan corporations, and other health plans; employee health plans offered by self-insured employers; trusts established in a collective bargaining agreement; community integrated service networks; the Minnesota Comprehensive Health Association; group health coverage offered by fraternal organizations, professional associations, or other organizations; state and federal health care programs; state and local public employee health plans; workers’ compensation plans; and the medical component of automobile insurance coverage. Minn. Stat. § 62J.03, subd. 6.

Including public, nonpublic, and home schools. Minn. Stat. § 121A.15, subd. 9.

Including colleges, universities, community colleges, technical colleges, professional and graduate institutions. Minn. Stat. § 135A.14, subd. 1.

Minn. Stat. § 145A.02, subd. 2.

Minn. Stat. § 256E.31, subd. 1.

Minn. Stat. § 144.05 subd.1.

Minn. Stat. § 144.05 subd. 2 (emphasis added).

Minn. Stat. § 15.17 subd. 1.

Minn. Stat. § 38.17 subd. 7.


Minn. Stat. § 13.01.

Minn. Stat. § 13.01.


Minn. Stat. § 13.3805 subd. 1(b)(3).

Minn. Stat. §§ 144.291 to 144.298.


State ex. rel Freeman v. Zimmerman, 90 N.W. 783 (Minn. 1902).

Minn. Stat. § 121A.15 subd. 1 and Minn. R. 4604.0200.


Minn. Stat. § 135A.14 subd. 2 and Minn. Rules Ch. 4604.

Minn. Stat. § 135A.14 subd. 4.


See page 34.


181 Interview with Deb Warren, Kansas, Sept. 6, 2013.

182 Interview with Mitch Scoggins, Idaho, Aug. 9, 2013.

183 Interview with Mitch Scoggins, Idaho, Aug. 9, 2013.


185 Interview with Kim Tichy, Iowa, Aug. 21, 2013.


Interview with Lisa Underwood and Lisa Rasmussen, Montana, Aug. 12, 2013.

Interview with Kim Tichy, Iowa, Aug. 21, 2013.

Interview with Mitch Scoggins, Idaho, Aug. 9, 2013.

Interview with Kim Tichy, Iowa, Aug. 21, 2013; Interview with Deb Warren, Kansas, Sept. 6, 2013.


Interview with Kim Tichy, Iowa, Aug. 21, 2013; Interview with Deb Warren, Kansas, Sept. 6, 2013.

Interview with Mitch Scoggins, Idaho, Aug. 9, 2013.

Interview with Kim Tichy, Iowa, Aug. 21, 2013; Interview with Deb Warren, Kansas, Sept. 6, 2013.

Interview with Kim Tichy, Iowa, Aug. 21, 2013; Interview with Deb Warren, Kansas, Sept. 6, 2013.

Interview with Deb Warren, Kansas, Sept. 6, 2013.

Interview with Heather Shull, Colorado, Aug. 19, 2013. CDC has made some funds available for pilot projects in this area.

States with this type of approach include North Dakota and Oregon.

Interview with Emily Emerson on August 27, 2013.


Phone interview with Emily Emerson, MIIC Manager, August 27, 2013.


Interview with Patti Segal Freeman, Minnesota, Aug. 28, 2013.

Minn. Stat. § 144.05 subd.1.

Minn. Stat. § 144.225, subd. 2.

Interview with Emily Emerson on August 27, 2013.

2013 Immunization Registry Grant Contract and Funding Request, Minnesota Department of Human Services Bulletin (August 14, 2012).
### Appendix A

**List of Key Informants**

<table>
<thead>
<tr>
<th>State or City</th>
<th>Key Informants</th>
<th>Title/Position</th>
<th>Date Interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC</td>
<td>Gary Urquhart</td>
<td>Chief, IIS Support Branch</td>
<td>Multiple Occasions</td>
</tr>
<tr>
<td>Colorado</td>
<td>Heather Shull</td>
<td>Interim Program Manager</td>
<td>August 19, 2013</td>
</tr>
<tr>
<td>Idaho</td>
<td>Mitch Scoggins</td>
<td>Imm. Program Manager</td>
<td>August 9, 2013</td>
</tr>
<tr>
<td>Indiana</td>
<td>Cameron Minich</td>
<td>IIS Manager</td>
<td>May 7, 2013</td>
</tr>
<tr>
<td>Iowa</td>
<td>Kim Tichy</td>
<td>IRIS Coordinator</td>
<td>August 21, 2013</td>
</tr>
<tr>
<td>Kansas</td>
<td>Deb Warren</td>
<td>Project Manager</td>
<td>September 6, 2013</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Pejman Talebian</td>
<td>Director Imm. Programs</td>
<td>September 4, 2013</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Emily Emerson</td>
<td>Assistant Director</td>
<td>Multiple Occasions</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Patti Segal Freeman</td>
<td>Policy Analyst/Legal Counsel</td>
<td>Multiple Occasions</td>
</tr>
<tr>
<td>Montana</td>
<td>Lisa Underwood</td>
<td>Imm. Section Supervisor</td>
<td>August 12, 2014</td>
</tr>
<tr>
<td>Montana</td>
<td>Lisa Rasmussen</td>
<td>imMTrax Manager</td>
<td>August 12, 2014</td>
</tr>
<tr>
<td>New York</td>
<td>Dina Hoefer</td>
<td>NYSIIS Program Manager</td>
<td>August 22, 2013</td>
</tr>
<tr>
<td>New York City</td>
<td>Dr. Jane Zucker</td>
<td>Assistant Commissioner</td>
<td>September 10, 2013</td>
</tr>
<tr>
<td>New York City</td>
<td>Amy Metroka</td>
<td>Director, Imm. Registry</td>
<td>September 10, 2013</td>
</tr>
<tr>
<td>North Dakota</td>
<td>Molly Howell</td>
<td>Immunization Program Manager</td>
<td>August 9, 2013</td>
</tr>
<tr>
<td>Oregon</td>
<td>Lorraine Duncan</td>
<td></td>
<td>August 13, 2013</td>
</tr>
<tr>
<td>Oregon</td>
<td>Lydia Emer</td>
<td>Immunization Program Manager</td>
<td>August 13, 2013</td>
</tr>
<tr>
<td>Oregon</td>
<td>Mary Beth Kurilo</td>
<td>Director, Oregon ALERT IIS</td>
<td>August 13, 2013</td>
</tr>
</tbody>
</table>
Appendix B

Sample State Forms and Explanations of Opt-Out Policies

As noted in the report, states differ in their practices to implement a patient's or parent's decision to opt-out. In addition to conducting key informant interviews, we visited a number of state immunization program and IIS websites to see if we could get a sense of how IIS that allow opt-out in an implied consent environment operationalize their approaches. Based upon our legal research, the key informant interviews, and publicly-available information on IIS websites, we developed the following typology of approaches:

Sealing the record from external access [Approach 1]: All immunization and demographic information is kept on file and will continue to be reported and updated. However, information is not released to authorized users outside the IIS program.

Removal of all information except demographic information [Approach 2]: Demographic information is retained, but immunization information about the individual is removed. Systems frequently “flag” the entries, or otherwise block entry of additional immunization information for individuals who have opted out.

Removal of all information including demographic information [Approach 3]: All immunization data regarding the individual is removed, and all demographic information is also removed. In general, this approach does not prevent subsequent entry of data related to the individual. For this reason, states such as Idaho provide persons choosing to opt-out the option to have demographic data retained in the system.

This appendix includes several samples of state opt-out forms, many of them from states in which key informant interviews were conducted. The state department of health websites where the forms were found during February and March of 2014 are on record with the authors.

The sample forms are not intended to provide a comprehensive representation of the forms in use in all 50 states, but we believe they reflect the major approaches in use among states that allow an opt-out from an implied consent process. A few states, like Iowa, do not appear to have forms, but simply encourage persons interested in opting out to contact the IIS program. A few states, such as Idaho and Oregon, may utilize more than one approach, depending upon the circumstances.

<table>
<thead>
<tr>
<th>State</th>
<th>All information retained; locked record</th>
<th>Immunization data deleted, demographic data retained</th>
<th>All data removed, including immunization and demographic data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Georgia</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Idaho</td>
<td>X</td>
<td>X*</td>
<td></td>
</tr>
<tr>
<td>Illinois</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Massachusetts</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oregon</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Texas</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virginia</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Option to retain demographic data provided.

The sample forms reviewed for this report are included in this appendix in alphabetical order, by state.
Colorado Immunization Information System

Opt-Out Form

(Please Print) First Name                     Middle Name                     Last Name                     Date of Birth

Mailing Address: Street

Mailing Address: City                     State                     Zip Code

Name of Doctor or Clinic                     Address of Doctor or Clinic

The Colorado Immunization Information System (CIIS) is a confidential, computerized, population-based system that collects and consolidates vaccination data for Coloradans of all ages and provides tools for designing and sustaining effective immunization strategies to prevent disease and reduce healthcare costs. By accessing the secure CIIS web application, your healthcare provider will be able to see the immunizations that you/your child has received even if you forget to bring the records to the clinic. Your healthcare provider will also be able to print immunization forms needed for child care, school and camp enrollment directly from the CIIS web application with the touch of a button.

Information in the Colorado Immunization Information System can be released only to:

- the individual or the individual’s parent/legal guardian
- the individual’s physician or healthcare provider
- a school, child care center or university where the individual is enrolled
- a managed care organization or health insurer where the individual is enrolled if the organization or health insurer pays for immunizations
- hospitals, persons or entities who have contracted with the State of Colorado for immunizations
- the Department of Health Care Policy and Financing for individuals enrolled in Medicaid

Anyone who releases information in CIIS to anyone who is not permitted to have the information commits a crime and can be punished. Under Colorado law, you have the right to exclude your/your child’s immunization information from CIIS at any time. If you change your mind you can have your healthcare provider resubmit your/your child’s immunization records at a later time. If you choose not to participate in CIIS, you are responsible for keeping your/your child’s immunization records.

By signing this Opt-Out Form, I confirm that I am the individual or parent/legal guardian of the individual listed above. I choose to have immunization information for myself/my child excluded from CIIS at this time. I understand that I can continue to receive vaccines for myself/my child from my healthcare provider even if the immunization information is excluded from CIIS.

(Please Print) Individual or Parent/Legal Guardian First Name                     Last Name

Signature of Individual or Parent/Legal Guardian

Date

It is your responsibility to mail or fax this form to:

Colorado Immunization Information System Program

Colorado Department of Public Health and Environment

DCEED-IMM-A3

4300 Cherry Creek Dr. S.

Denver, CO 80246-1530

Fax          303-758-3640

If you have questions call: 1-888-611-9918

July 2013
# Opt-Out of Registry Form

Note: This form is required to allow an individual to request that a person’s immunization history be removed from the registry and no further immunization data be accepted into the registry.

<table>
<thead>
<tr>
<th>Name of Client: __________________</th>
<th>__________________</th>
<th>__________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last</td>
<td>First</td>
<td>Middle</td>
</tr>
</tbody>
</table>

| Date of Birth: _____________     | Sex: _______________ | Race: ________     |
| MM/DD/YYYY                      | M/F or Unknown       |

<table>
<thead>
<tr>
<th>Name of Parent or Guardian: __________________</th>
<th>__________________</th>
<th>__________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last</td>
<td>First</td>
<td>Middle</td>
</tr>
</tbody>
</table>

| Relation: _______________ | Mother’s Maiden Name: ____________________ |

<table>
<thead>
<tr>
<th>Telephone Number: ___________________________</th>
<th>Area Code</th>
<th>Number</th>
</tr>
</thead>
</table>

| Street Address: ____________________________________________________________________________ |

| City: ___________________________________________ | State: ______ | ZIP: ____________________________ |

I request this person be removed from the Georgia Registry of Immunization Transaction and Services (GRITS). I understand the state will remove all immunization data on this person from the registry as a result of this action. The registry will retain only core demographic information necessary to identify the client has chosen to opt out of the registry. This information is necessary to enable the registry to filter and refuse entry of immunization information for the client. Additionally, any prior immunization records associated with the client will also be deleted from the registry.

The Opt-Out Form will be maintained at the Georgia Immunization Office where it is available for review in accordance with OCGA sec. 31-12-3.1 and the Department of Public Health (DPH), Infectious Disease and Immunization Program (IDI) rules and regulations.

No immunization information may be added to the registry for this client until the Georgia Immunization Office receives a notification from the parent or legal guardian indicating their desire to opt back into the registry. An Opt-In Form is available from the service provider through the GRITS online system. The Georgia Immunization Office must receive a completed Opt-In Form signed by a responsible person to allow the entering of immunization information on this client.

_____________________________   __________________
Signature of Parent or Guardian   Date

Action to delete a person from the registry can occur only after receipt and processing of this signed form. This form must be mailed to the following address:

**GRITS OPT–OUT**
DPH Immunization Office
2 Peachtree Street NW
13th Floor, Room 274
Atlanta, GA 30303-3142

FORM OUT–GRITS9-2013
Idaho’s Immunization Reminder Information System (IRIS)
Opt – out Request Form

Idaho’s Immunization Reminder Information System (IRIS) is a secure health information system containing the names and immunization history of people who have received vaccinations in Idaho. This information is available only to authorized health care providers, child care providers, and schools. Participation in IRIS is voluntary and you may opt out at any time by contacting the Idaho Immunization Program at (208)334-5931 and requesting an opt-out form, or by completing the opt-out form on our website www.immunizeidaho.com.

People may opt out of IRIS in one of two ways (please choose only one):

☐ I wish to opt out of IRIS for myself, my minor child (under the age of 18 years), or person for whom I am a legal guardian. Please remove only immunization-related information. I give permission for my/his/her demographic information including name, address, phone number, mother’s maiden name, date of birth and gender to be retained in IRIS. This retained demographic information will not be viewable by medical providers, schools or childcare staff. I understand that allowing demographic information to be retained in IRIS will reduce the chance of accidental or intentional re-entry of vaccination information about me/him/her.

OR

☐ I wish to opt out of IRIS for myself, my minor child (under the age of 18 years), or person for whom I am a legal guardian. Please remove all information from IRIS: both immunization and demographic. By making this selection, I understand that at any time, information regarding myself, my child, or person for whom I am a legal guardian, may be re-entered by a health care provider. I understand that I must work with my health care provider(s) to ensure this information is not re-entered into IRIS.

Regardless of the Opt-out method you’ve selected, please complete the following information about the person opting out (all fields must be completed to ensure the correct person is deleted from IRIS):

Name of Patient: ________________________ ____________________________ ____________________________
Last First Middle Initial

Date of Birth: ________________________ Gender: ________________________
MM/DD/YYYY (M/F/Unknown)

Person Requesting Patient Opt-Out: ________________________ Relationship to Patient: Self/Parent/Guardian
(Please Circle one)

Patient’s Mother’s Maiden Name: ________________________
Patient Address: _____________________________________________________________

City: ___________________________  State: ___________  Zip Code: ___________________________

Patient Telephone Number: ______________________________________________________

(Area Code)  Number

Information about the person completing the opt-out request (this information will be used to contact you if this form is incomplete or unclear, to send you a letter once your request has been completed, and will be filed as legal documentation of the opt-out request).

☐ Same as above  (If not, please complete additional information below):

Name of Person Requesting Patient Opt-Out: __________________________________________

Relationship to Patient:  Self/Parent/Guardian  (please circle one)

Address:  _________________________________________________________________

City: ___________________________  State: ___________  Zip Code: ___________________________

Telephone Number:  ___________________________  Email Address:  ___________________________

I understand that my request to opt-out of IRIS for myself, my minor child, or person for whom I am a legal guardian means that the record being deleted will not be available to authorized health care providers, child care providers, or school officials through IRIS.

Please remember that if you opt to have information about yourself, your minor child, or person whom you are a legal guardian be removed from IRIS, then you must maintain the individual’s immunization (shot) records. Verification of immunization status is a requirement for entry to schools (including some secondary schools and colleges), summer or day camps, employment in certain industries, participation in certain volunteer activities, and other situations.

______________________________  ___________________________
Signature  Date

By signing [or digitally signing] this form, I verify the information above is accurate and represents my request to have information about myself, my minor child, or person for whom I am a legal guardian, deleted from IRIS. I am certifying that I have the legal authority to make decisions for the person listed on this form.
Illinois’ Immunization Registry
Opt Out of Registry Form

This form is required to allow an individual to request that a person’s immunization history be removed from the registry, and no further immunization data be accepted into the registry. Please print.

Name of Client: ____________________________  ____________________________  ____________________________
  Last   First    Middle

Date of Birth: ____________________________  Sex: ____________________________
  MM/DD/YYYY         Male or Female

Name of Parent or Guardian: ________________________________  ____________________________
  Last      First   Middle

Relation: ____________________________  Telephone Number ____________________________

Street Address: ____________________________________________________________

City: ____________________________  State: ____________________________  ZIP: ____________________________

I request this person be removed from the Illinois Immunization Registry. I understand the state will not share immunization data on this person from the registry as a result of this action. The registry will retain core demographic information necessary to identify the client has chosen to opt out of the registry. This information is necessary to enable the registry to filter and refuse entry of immunization information for the client. Additionally, any prior immunization records associated with the client will not be shared from the registry.

The completed opt out form will be maintained at the provider’s office in the patient file.

No immunization information will be added to the registry for this client until the Illinois Immunization Program receives notification the individual, parent or legal guardian wishes to opt back into the registry. To opt back in, check the box below and date. The provider is responsible for keeping this form as well as opting the patient back into the Illinois Immunization Registry.

___________________________________________ __________________ ______________________
  Signature of Parent or Guardian      Date

You have the right to change this decision at any time. If you refuse today, you can decide later if you would like to participate by checking the box at the left. Please initial and date after box is checked.

Please place a copy in the patient’s medical chart, provide a copy to the parent.
SHARING YOUR IMMUNIZATION INFORMATION
Objection (or Withdrawal of Objection) Form

The Massachusetts Immunization Information System (MIIS) keeps track of all immunizations which doctors and health care providers give to patients in Massachusetts. The system has been created according to state law (M.G.L c. 111, Section 24M), and is operated by the Massachusetts Department of Public Health (MDPH). All information in the MIIS is kept confidential.

The law requires that immunizations be reported to the MDPH through the MIIS. It allows for the information to be shared among doctors and nurses providing your care, school nurses, local boards of health, and staff at state agencies involved with immunization (including the WIC Program). The MIIS enables a new health care provider to check what shots you or your child have received in the past from other providers. Your records will only be available to those involved in your care, who have a reason to know about them. You have the right to limit who else may see your or your child’s information in the MIIS. If you prefer that your or your child’s immunization history not be shared in this way, you need to Object to sharing your or your child’s immunization information. If you have changed your mind or if you change your mind in the future and decide to share the information with more healthcare providers, you will need to Withdraw your previous objection to sharing your or your child’s immunization information.

What it means to Object to the sharing of your or your child’s immunization information:
- Your or your child’s immunization history will not be seen by all healthcare providers in the MIIS.
- Your or your child’s immunization information will still be in the MIIS, but only the provider(s) who gives you shots and the Department of Public Health will be able to see it.
- Please note: you will need to keep track of your or your child’s immunization records in the event that you change doctors or get immunizations from other health care providers.
- How to Object to the sharing of your or your child’s immunization information:
  - Check the box next to “I OBJECT” on the other side of this form and complete the information requested.
  - Give the completed form to your healthcare provider, or send by fax or mail to the Department of Public Health at the contact information provided on the other side of this form.

What it means to Withdraw a previous objection to sharing your or your child’s immunization information:
- You have changed your mind and decide to share your or your child’s information with all of your or your child’s healthcare providers who are using the MIIS.
- Once the Withdrawal has been processed your records will be made available to individuals involved in your care, who have a reason to know about them.
- How to Withdraw a previous objection:
  - Check “I WITHDRAW MY PREVIOUS OBJECTION” on the other side of this form and complete the information requested.
  - Give the completed form to your healthcare provider or send by fax or mail to the Department of Public Health at the contact information provided on the other side of this form.
SHARING YOUR IMMUNIZATION INFORMATION
Objection (or Withdrawal of Objection) Form

Name of Patient: _________________________________________________________

I OBJECT to the sharing of information in the MIIS about me or my child. I understand that this will keep my or my child’s doctor or other health care provider from being able to check the MIIS for immunization information that comes from other health providers. I further understand that this objection will not prevent my child or me from receiving immunizations.

I WITHDRAW MY PREVIOUS OBJECTION to the sharing of immunization information in the MIIS about me or my child. I understand that by signing and submitting this form, the MIIS will be able to share immunization information with my or my child’s doctor(s) or other health care providers and other persons allowed by law to view this information.

Patient’s Information (this information is necessary to properly identify the patient):

<table>
<thead>
<tr>
<th>Name:__________________________</th>
<th>Date of Birth: / / MM/DD/YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last</td>
<td>First</td>
</tr>
<tr>
<td>MI</td>
<td>MI</td>
</tr>
<tr>
<td>Mother’s Maiden Name:___________</td>
<td>For child younger than 18 yrs of age</td>
</tr>
<tr>
<td>Gender: ________________________</td>
<td>_____________________________</td>
</tr>
<tr>
<td>Address: _______________________</td>
<td>Phone#: (<strong><strong>)</strong></strong>____________</td>
</tr>
<tr>
<td>City: _________________________</td>
<td>State: _______________________</td>
</tr>
</tbody>
</table>

Parent/Guardian Information (required if form is completed for a child younger than 18 years of age):

<table>
<thead>
<tr>
<th>Name:__________________________</th>
<th>Date of Birth: / / MM/DD/YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last</td>
<td>First</td>
</tr>
<tr>
<td>MI</td>
<td>MI</td>
</tr>
<tr>
<td>Relationship to Patient: ________</td>
<td>CHECK IF ADDRESS &amp; PHONE # ARE SAME AS PATIENT’S</td>
</tr>
<tr>
<td>Address: _______________________</td>
<td>Phone#: (<strong><strong>)</strong></strong>____________</td>
</tr>
<tr>
<td>City: _________________________</td>
<td>State: _______________________</td>
</tr>
</tbody>
</table>

Signature of Patient, or Parent/Guardian (if child is younger than 18 years of age):

| Signature:_______________________| Date:__________________________|

Health Care Provider Use Only – please enter your contact information, mail or fax a copy of the form to MDPH, and keep the original for the patient’s record:

☐ CHECK TO CONFIRM THE DATA SHARING STATUS WAS CHANGED IN THE MIIS FOR THE ABOVE PATIENT. If an objection, change the patient’s data sharing status to No. If a withdrawal, change patient’s data sharing status to Yes.

Staff Member’s Name:__________________________________________________________
Facility or Practice Name:_____________________________________________________
Vaccine PIN#: ______________________ Staff Phone#: (____)____________ext:________

Please submit this form by mail or fax to the Massachusetts Department of Public Health:

Mailing Address: Massachusetts Immunization Information System (MIIS) Immunization Program Massachusetts Department of Public Health 305 South Street Jamaica Plain, MA 02130
Fax: 617-983-4301
What is ALERT IIS and why does it keep immunization records?

ALERT IIS is Oregon’s statewide immunization information system (IIS). ALERT IIS assists medical providers and their patients by consolidating all immunizations into one record, regardless of where the immunization was given. This allows patients to have a lifetime immunization record in a centralized place, which prevents the need to repeat immunizations because of missing documentation. Documentation of immunizations is often required for attending school, traveling and in some occupations.

What if I don’t want my child’s record shared?

While Oregon law allows adults over 18 years of age to request that their record be removed from ALERT IIS, children’s records may be sealed only in specific circumstances as specified by Oregon law. Parents or legal guardians must provide documentation of their child’s circumstances. Upon approval, the record will be sealed until the child reaches 18 years of age. At that point, the adult may request that their record be unsealed or with no action, the record will continue to be sealed.

Under what circumstances can a child’s record be sealed?

Oregon law allows a child’s record to be sealed when:

1. The child has a disease or condition that precludes administration of some or all vaccines; or,
2. When concern exists that a third party could use the information in the record to locate the child, or other family members who reside with the child, and the parent or legal guardian reasonably believes there is a risk of harm if they are located.

The law requires that the request for sealing the child’s record be accompanied by a statement and evidence that supports the request. This evidence may include: 1) copies of police reports, restraining orders or other legal documents pertaining to the need for physical protection; or, 2) a licensed physician’s statement indicating a specific medical diagnosis that precludes immunization with some or all vaccine antigens.
Why do you need a copy of my photo ID?

We need to verify the identity of the adult requesting to have their child’s record sealed. We will send a notice to the address that is on the identification once we have executed the request, within 30 days of receiving the completed paperwork.

Can I get a copy of my minor child’s record?

To receive a copy of your minor child’s unsealed record, call ALERT IIS Help Desk at 1-800-980-9431. Once a record is sealed it cannot be released, even to authorized users.
In accordance with Oregon Revised Statute 433.100 and Oregon Administrative Rule 333-049-0080, immunization records for children under the age of 18 years may be sealed in cases where the child has a medical condition that precludes immunization or where there is a risk of harm to the child, or family, if they are located.

Parent’s or Guardian’s Name: ____________________________________________
Address: ________________ City: __________ State: _____ Zip: __________
Relationship to Child: ____________________________________________
Child’s Name: ____________________________________________
Child’s Date of Birth: ____________________________________________
Mother’s Maiden Name: ____________________________________________
(used for verification purposes)
Signature: ____________________________________________
Copy of photo ID with current address:
☐ Driver’s License ☐ State Issued ID Card ☐ Passport * ☐ U.S. Military ID Card
*If using a passport, please include a piece of mail with your current address.

Submit completed form and a photocopy of both sides of your photo ID by mail to:
Oregon Immunization ALERT
Attn: Records Retention
800 NE Oregon St, Ste. 370, Portland, OR 97232
ALERT Immunization Information System (IIS)
Request for Sealing of Adult Record / Purging of Adult Record

What is ALERT IIS?

ALERT IIS is Oregon's statewide immunization information system. ALERT assists medical providers and their patients by consolidating all immunizations into one record, regardless of where the immunization was given. This allows patients to have a lifetime immunization record in a centralized place, which prevents the need to repeat immunizations because of missing documentation. Documentation of immunizations is often required for attending school, traveling and in some occupations.

Who can see my record?

Access to ALERT IIS is strictly controlled by Oregon statute. Authorized users include medical clinics, local health departments, the Division of Medical Assistance Programs, insurance companies, colleges, schools and child care centers. Authorized users are restricted to accessing information only for their own patients or students, assured by requiring detailed demographic information to conduct a patient search.

What if I don’t want my record shared?

Adults over 18 years of age have the right to request that their record be either sealed, so authorized users cannot access it, or purged from the information system altogether. Adults can request this by completing the following form and mailing it, along with a photocopy of a driver’s license, state ID card, passport or U.S. Military ID Card. Please use an ID that has your current address on it.

Why do you need a copy of my photo ID?

We need to verify the identity of the adult requesting to have their record sealed or purged. We will send a notice to the address that is on the identification once we have executed the request, within 30 days of receiving the completed paperwork.

Can I get a copy of my record?

To receive a copy of your unsealed record, call ALERT customer service line at 1-800-980-9431. Once a record is locked it cannot be released, even to authorized users. A sealed record can be unsealed only by the adult who sealed the record by sending in a request with a copy of photo ID. Purged records have been deleted and cannot be recovered.
ALERT Immunization Information System (IIS)
Request for Sealing of Adult Record / Purging of Adult Record

Note – This form may be used only for adults age 18 years and over. Requests for sealing of children’s records must be submitted on form DHS AL521.

In accordance with Oregon Revised Statute 433.098 and Oregon Administrative Rule 333-049-120, adults over the age of 18 years have the right to have their immunization record in the Immunization Information System (IIS) either purged or sealed at their discretion.

PLEASE SELECT HOW THE RECORD SHOULD BE HANDLED (choose one option only):

☐ SEALING – When a record is sealed, all immunization and demographic information is kept on file. If additional information is reported, the record will continue to be updated. However, the information will not be released to any authorized user without a signed release of information form from the patient. In a declared public health emergency, information about a patient may be released to public health officials responding to the emergency.

☐ PURGING – When a record is purged, all immunization information is deleted from the record and no information will be released to any authorized user, for any reason. However, certain pieces of demographic information must be kept on file in order to assure that any additional immunization information reported be deleted as soon as possible. Information from a purged record cannot be recovered.

Name: ______________________________
Address: ___________________________ City: ___________ State: _____ Zip: _________
Date of Birth: _______________________
Mother’s Maiden Name: __________________ (used for verification purposes)
Copy of photo ID with current address:
☐ Driver’s License ☐ State Issued ID Card ☐ Passport* ☐ U.S. Military ID Card
* If using a passport, please include a piece of mail with current mailing address.

Signature: ____________________________

Submit completed form and a photocopy of both sides of your photo ID by mail to:
ALERT IIS
Attn: Record Update
800 NE Oregon St, Ste. 370, Portland, OR 97232

DHS form AL520
Revised May 2010
Withdrawal of Consent and Confirmation Form

Please type or print clearly.

Last Name __________________________ First Name __________________________

Middle Name __________________________ Date of Birth __________________________

Gender: ☐ Male ☐ Female Requestor’s Daytime Telephone __________________________

Address __________________________ Apartment # __________________________

City __________________________ State __________________________ Zip Code __________________________ County __________________________

Optional information regarding the individual: This information is used for ImmTrac record search purposes only and will not be retained.

Birth City __________________________ Birth State __________________________ Previous Address __________________________

Nickname (Aliases and/or Other Last Name(s) used) __________________________

Mother’s First Name __________________________ Mother’s Maiden Name __________________________

Please mark the box ☐ to indicate your intent:

☐ I withdraw consent for participation and inclusion in ImmTrac for the individual named above. Please delete all information for this individual from ImmTrac and any related files.

Individual or Individual’s Legally Authorized Representative: __________________________

Printed Name __________________________ Date __________________________

Signature __________________________

Send this completed form to:

Mail: Texas Department of State Health Services · ImmTrac Group, MC1946 · PO Box 149347 · Austin, TX 78714-9347

Fax: (512) 458-7790

PRIVACY NOTIFICATION: With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See http://www.dshs.state.tx.us for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003 and 559.004)

Questions? (800) 252-9152 · (512) 458-7284 · www.ImmunizeTexas.com

Information Below for ImmTrac Staff Use Only

Confirmation of Delete: Upon processing of your Request for Withdrawal from ImmTrac, registry staff will mark the appropriate box below and return this form to you.

☐ NO RECORD Found: No matching records were found in ImmTrac for the individual named above.

☐ Record DELETED: All information for the individual named above has been deleted from ImmTrac and any related files.

ImmTrac, the Texas immunization registry, has been designated as the disaster-related reporting and tracking system for immunizations, antivirals, and other medications administered to individuals in preparation for, or in response to, a disaster or public health emergency. From the time the event is declared over, ImmTrac will retain disaster-related information received from health care providers for a period of 5 years. At the end of the 5 year retention period, disaster-related information will be removed from the registry unless consent is granted to retain the information in ImmTrac beyond the 5 year retention period.

ImmTrac will not retain documentation of your request for withdrawal of consent.

Date request processed: ___________ Staff Initials: ___________
Retiro de Consentimiento y Confirmación

Escriba claramente a máquina o con letra de molde.

Apellido Nombre

Segundo nombre

Fecha de nacimiento

Genero: ☐ Masculino ☐ Femenino

Teléfono durante el día

Dirección Apartamento #

Ciudad Estado Código postal Condado

Información opcional: Esta información sólo será usada con el propósito de buscar en el registro de vacunas ImmTrac y no se conservará.

Ciudad de nacimiento Estado de nacimiento Dirección anterior

Apodo (Aliases u otros apellidos que ha usado)

Nombre de la madre Apellido de soltera de la madre

Favor de marcar el cuadro ☑ para indicar sus intenciones

☐ Retiro mi consentimiento para que el individuo antes nombrado participe y esté incluido en ImmTrac. Favor de borrar de ImmTrac y de cualquier archivo relacionado toda información sobre este individuo.

Individuo o representante legalmente autorizado: Escriba su nombre con letra de molde

Fecha Firma

Complete y envíe esta forma a:

Correo: Texas Department of State Health Services · ImmTrac Group, MC1946 · PO Box 149347 · Austin, TX 78714-9347

Fax: (512) 458-7790

NOTIFICACIÓN SOBRE PRIVACIDAD: Tan solo por unas cuantas excepciones, usted tiene el derecho de solicitar y de ser informado sobre la información que el Estado de Texas reúne sobre usted. A usted se le debe conceder el derecho de recibir y revisar la información al requerirla. Usted también tiene el derecho de pedir que la agencia estatal corrija cualquier información que se ha determinado sea incorrecta. Diríjase a http://www.dshs.state.tx.us para más información sobre la Notificación sobre privacidad. (Referencia: Government Code, sección 552.021, 552.023, 559.003 y 559.004)

¿Tiene preguntas? (800) 252-9152 · (512) 458-7284 · www.ImmunizeTexas.com

Sólo para uso del personal del ImmTrac

Confirme de que se borró la información: Al tramitar su Solicitud de Retiro de ImmTrac, el personal del ImmTrac marcará el cuadro adecuado a continuación y le devolverá esta forma.

☐ No se localizó el record de vacunas: No se encontró el record de vacunas en ImmTrac del individuo antes nombrado.

☐ El record de vacunas de ImmTrac se BORRÓ: Toda la información sobre el individuo antes nombrado ha sido borrada de ImmTrac y de cualquier archivo relacionado.

* ImmTrac, el registro de vacunas de Texas, ha sido designado como el sistema de informes y seguimiento relacionados con desastres para vacunas, antivirales y otros medicamentos administrados a individuos en preparación para, o en respuesta a, un desastre o una emergencia de salud pública. A partir del momento en que se declare finalizado el evento, ImmTrac conservará la información relacionada con el desastre recibida de profesionales de salud por un periodo de 5 años. Al final del periodo de retención de 5 años, la información específica del cliente relacionada con el desastre se removerá del registro a menos que se dé el consentimiento para conservar la información en ImmTrac después del periodo de conservación de retención 5 años.

ImmTrac no conservará esta forma solicitud de retiro del consentimiento.

Fecha de tramitación de la solicitud: _____________ Iniciales del personal: _____________
Virginia Immunization Information System (VIIS)
Opt-Out of VIIS form

This form is required to request that a person’s immunization history be removed from VIIS and that no further immunization data be accepted into VIIS.

Name of Client: _______________________     ______________________  ____________________________
LAST                                                  FIRST                                        MIDDLE

Date of Birth:   ______________________  Sex:  __________________  Race:  __________________
MM/DD/YYYY                     M/F or Unknown

Name of Parent or Guardian: __________________   ____________________   ________________________
LAST                                FIRST                                     MIDDLE

Relation: ________________________________  Telephone Number: ____________  ___________________________
PARENT OR GUARDIAN                                       AREA CODE         NUMBER

Street Address: ______________________________________________________________________________

City:  __________________________________________  State:  __________  ZIP:  ___________________

I request this person be removed from the Virginia Immunization Information System (VIIS). I understand the state will remove all immunization data on this person from VIIS as a result of this action. VIIS will retain only core demographic information necessary to identify the client chose to opt out of VIIS. This information is necessary to enable VIIS to filter and refuse entry of immunization information for the client. Additionally, any prior immunization records associated with the client will be deleted from VIIS. I understand that if I choose to have my child re-entered into VIIS, I can do so at any time.

This Opt-Out form will be maintained in the Virginia Department of Health, Division of Immunization Program’s office. The Virginia Department of Health, Division of Immunization Program must receive a completed Opt-Out form before the client is removed from VIIS.

SIGNATURE OF PARENT OR GUARDIAN                        DATE (MM/DD/YYYY)

THIS FORM MUST BE COMPLETED AND MAILED TO THE FOLLOWING ADDRESS.

VIIS-Opt-Out
Virginia Department of Health
Division of Immunization
109 Governor Street, Room 314W
Richmond, Virginia 23219
**Virginia Immunization Information System (VIIS)**

**Opt-In to VIIS form**

This form is required to allow a person who has previously opted-out of VIIS to opt back into VIIS thereby allowing collection of immunization data on the person.

| Name of Client: _______________________     ______________________  ____________________________ |
|-----------------------------------------|------------------------|------------------------|
| LAST                                                  FIRST                                        MIDDLE |

<table>
<thead>
<tr>
<th>Date of Birth: ______________________</th>
<th>Sex: ____________________</th>
<th>Race: ____________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>MM/DD/YYYY                     M/F or Unknown</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Name of Parent or Guardian: __________________   ____________________   ________________________ |
|-----------------------------------------------|------------------------|------------------------|
| LAST                                FIRST                                     MIDDLE |

<table>
<thead>
<tr>
<th>Relation: _________________________</th>
<th>Telephone Number: ____________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARENT OR GUARDIAN                     AREA CODE         NUMBER</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Street Address:______________________________________________________________________________</th>
</tr>
</thead>
</table>

I request this person be reinstated into the Virginia Immunization Information System (VIIS). I understand this action will allow the state to add all immunization data on this person from participating providers in VIIS. VIIS will be the official source of immunization history for this person.

This Opt-In form will be maintained in the Virginia Department of Health, Division of Immunization Program’s office. The Virginia Department of Health, Division of Immunization Program must receive a completed Opt-In form before action is taken to add the person into VIIS.

<table>
<thead>
<tr>
<th>SIGNATURE OF PARENT OR GUARDIAN</th>
<th>DATE (MM/DD/YYYY)</th>
</tr>
</thead>
</table>

THIS FORM MUST BE COMPLETED AND MAILED TO THE FOLLOWING ADDRESS.

VIIS-Opt-In
Virginia Department of Health
Division of Immunization
109 Governor Street, Room 314W
Richmond, Virginia 23219

Virginia Department of Health
Division of Immunization
(800) 568-1929