Childhood Immunization Information System **Exchange with Payers: State and Federal Policies**

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Summary

Federal passage of the HITECH Act in 2009 encourages use of Electronic Health Records, which now includes submission of Immunization Information Systems (IIS) records. IIS were developed to improve health care quality and reduce infectious diseases, health disparities, and costs. These advantages are available to all IIS users, which may include public and/or private payers. Laws that govern IIS data exchange are developed at the state-level, and may interact with federal policies, and impact utility for all those with a stake in maintaining appropriate immunization levels. This study examines IIS and immunization records laws in 56 Grantees (50 states, five cities and Washington D.C. that receive public health funds) that specify payer information exchange. Of the 56 Grantees, 31 (55.4 percent) have payer exchange provisions (private or public), 20 of which allow direct access by payers for quality assurance, reimbursement, or evaluation purposes. The laws vary by type of exchange and allowable purpose for exchange. HIPAA is applicable when grantee law does not specify exchange. IIS can be used to facilitate measurement and immunization program evaluation, including for public and private payers. All stakeholders, including payers, should be involved in the policy making process, to improve efficiencies intended by IIS and furthered in the HITECH Act.

Key points

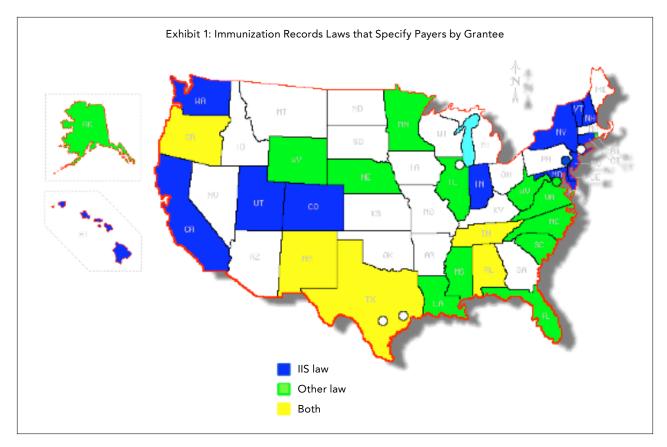
- HIPAA allows state law to require reporting for public health and health plan quality review purposes.
- Over half of the Grantees have laws that specify immunization data exchange with payers, 20 allow payer access.
- Grantees laws that allow two-way exchange may be better placed leverage payer data for improved IIS value and IIS data for payer HEDIS reporting and cost savings.

Introduction

IMMUNIZATION INFORMATION SYSTEMS (IIS) are "confidential, computerized information systems that collect and consolidate vaccination data from multiple health-care providers..." which are maintained by health departments at the state and city levels. IIS can assist clinicians and health plans track individual immunizations and ensure appropriate and timely administration, and enhance public health surveillance of immunization levels and disparities. IIS participation was deemed "a public health imperative" to improve quality of care, promote efficiency, ease burden and lessen health disparities.²

Recognizing the potential of IIS, the government has encouraged use of IIS through funding and legal channels. Beginning in 1993 with implementation of the federal Vaccines for Children (VFC) program, the National Immunization Program of the CDC supported immunization registry development through the 317b Public Health Service Act grant process.3 This funding mechanism allowed autonomy to allot funding specific to registries as each "Grantee" deemed necessary.3 CDC grants for IIS have varied in purpose (for example development or capacity building) and amount from year to year with funding estimates ranging from a high of \$42.5 million in 1996 to \$1.04 million in 2010.³⁻⁷

IIS could serve as "building blocks" to a more broad national health information system.8 At the federal level, passage of the Health Information Technology for Economic and Clinical Health (HI-TECH) Act in 2009 encourages use of Electronic

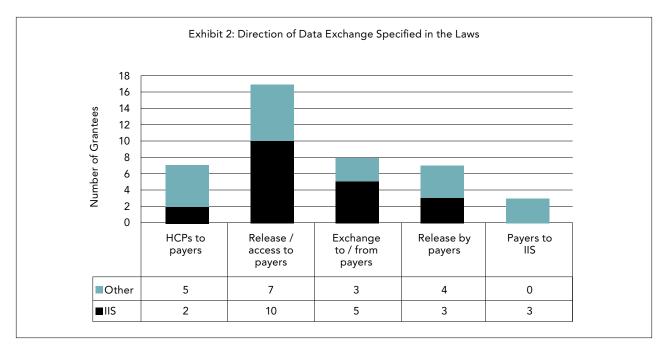


Health Records (EHRs) to: improve quality, coordination of care and public health activities; reduce costs; guide medical decisions; facilitate research; promote competition and improved outcomes; and reduce disparities.9 The Act specifies that EHRs should be used in a "meaningful" manner to improve quality care and measures. 10 The U.S. Department of Health and Human Services developed Meaningful Use (MU) guidelines that offer health care providers with explicit instruction for the development and application of EHRs, including submission of EHRs to IISs. As a part of what is termed "Stage 1," the Centers for Medicare & Medicaid Services offer incentive payments to eligible professionals who test the ability to submit EHRs to an IIS, if the test is successful.¹¹

Using the World Health Organization Working Group definition, it can be argued that IIS is a "public good."12 In other words, its social value (or the "positive externalities" of overall quality of care improvement, and reduction in infectious diseases, health disparities, and costs) far exceeds private individual stakeholder value. However, in order to achieve this wide-ranging value for everyone in society, both public and private participation is a must. And not only must IIS be "used" by all, but each stakeholder should be an active participant in populating IIS.

From the individual stakeholder perspective, most providers and administrators know, over immunization can waste vaccine and administrative resources and under immunization may produce the need for expensive treatment of disease. IIS can prevent or reduce these costs,14-16 including cost savings to managed care organizations (MCOs) for production of their Healthcare Effectiveness Data and Information Set (HEDIS) reports.^{4,17} HEDIS measures are developed by the National Committee for Quality Assurance and used by 90 percent of U.S. health plans, allowing consumers and employers to compare quality across health plans and health plans to identify areas for quality improvement.¹⁸ Based on the 2010 HEDIS Childhood Immunization Status (CIS) measures include percentage of: "children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV); one measles, mumps and rubella (MMR); two H influenza type B (HiB); three hepatitis B (HepB), one chicken pox (VZV); four pneumococcal conjugate (PCV); two hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines."19

IIS offers administrative efficiencies for outreach efforts and more efficient use of health care dollars for taxpayers (Medicaid) and employers purchasing coverage. At least one health plan showed that use of IIS as its data source for HEDIS compliance can re-



duce the administrative burden of chart reviews and realize a benefit-to-cost ratio of 8.06.17 To realize this potential, participation in IIS must be high and data exchange with MCOs must be permitted. Present IIS participation is currently at 75 percent of all U.S. children aged <6 years. 20 Healthy People 2010 and 2020 set the goal of 95 percent. 21,22 As new immunizations are added to the HEDIS CIS and cost savings are measured,23 IIS is one possible source that may provide even greater savings.

In the United States, public health laws are generally the province of the state laws and local health ordinances.²⁴ State legislatures can enact statutes, state regulatory bodies can enact regulations or rules, and local health bodies can pass city ordinances (all henceforth referred to as "laws"). Laws which relate to many aspects of IIS have been passed in states and cities, which are Grantees of the Public Health Services Act, which relate to many aspects of IIS. These laws governing IIS are complex, may interact with federal policies, and impact utility of IIS for all stakeholders.

The information presented here is part of a study identifying and cataloging Grantee IIS laws. The objective of this component is to identify and describe elements of laws for immunization information data exchange with payers. The results can inform payers of allowable exchange, and inform all stakeholders of the complexity and need for better policy options for improving the value and utility of IIS.

Methods

The study population is 56 U.S. "Grantees" (50 states, five cities and Washington, D.C.) receiving

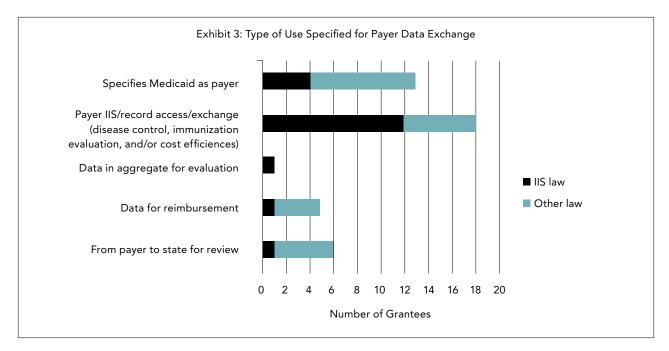
funds under section 317b of the Public Health Service Act. IIS relevant statutes and regulations were identified for each of the Grantees via legal databases and systematically reviewed for content. For those Grantees without IIS or immunization record laws, general health or medical records laws, if available, were used as a proxy to determine allowable exchanges of data.

Content of the laws was coded into categories using a coding instrument developed for a study identifying and cataloging Grantee IIS laws. The coding categories were derived from previous IIS and public health law studies²⁵⁻²⁹ and a preliminary review of the laws. The Delphi technique was used to obtain expert input for the coding document. The 131 variable instrument received 93.7 percent agreement and a K-α of 0.791. The coding categories specific to payers were extracted from the resultant database and tabulated to determine Grantees laws that specified payer immunization data exchange or access.

The specifications within these laws is described and presented in graphic form. Possible interactions with Grantee IIS exchange laws and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule are also described.

Results

Of the 56 Grantees examined, 31 (55.4 percent) had IIS or other immunization record laws that indicate payers immunization records exchange. Laws governing exchange with payers include IIS-specific laws (those governing IIS establishment and operation) and other laws such as immunization reporting or insurance laws. Payer exchange provisions were



noted in 11 Grantee IIS laws, 15 Grantee "other" laws, and five Grantees had provisions in both IIS and "other" laws (Exhibit 1).

The payer access provisions of the laws vary by Grantee. Exhibit 2 depicts the types of information exchange indicated and the types of laws where the provision is indicated. The laws may indicate several types of data exchange, and provisions may appear in several types of laws.

Payer data exchange was described in the laws as records transfer or access with IIS, health departments, health care providers (HCPs), or health plan review committees.

Exhibit 2 also depicts the frequency of Grantees with IIS or immunization laws with different directions of exchange or access specified. The type of exchange specified in Grantee laws was not mutually exclusive. For example, a Grantee's law(s) could specify that payers may access IIS and also that they must report to the IIS. The most frequent reference relates to payer access to IIS.

The most frequent purpose of payer exchange specified was for IIS access, or exchange with an IIS, for the patients/members that they serve, which supports IIS use for HEDIS compliance. Frequency by purpose is shown in Exhibit 3. These figures are not mutually exclusive.

Laws specifying payer data exchange were classified as either 1) IIS development and implementation laws or 2) other applicable immunization records laws. Descriptions of the laws follow below.

IIS Laws

Grantees in this category have specific IIS creation

and implementation laws that reference payers. They include: California, Colorado, Delaware, Hawaii, Indiana, Maryland, New Jersey, Tennessee, Utah, and Vermont.

California's IIS law allows the State Department of Health Services to disclose immunization data to health plans covering immunization services for the patient, local health departments and the State Department of Health Services. The law specifies the purposes of health plan access are for payment and immunization assessment. Similarly, Delaware's law allows IIS data release to the patient's insurer, while New York's IIS statute allows immunization records to be available to authorized users, including payers.

IIS laws in five states (Colorado, Maryland, New Jersey, Tennessee, and Utah) mention two-way data exchange. Colorado's IIS statue allows state and local health officials to gather information for the IIS from MCOs or health insurance plans and the Department of Health Care Policy and Financing (Medicaid) for medical assistance patients. Additionally, all data sources, including health care providers and health plans, are allowed to release immunization records to each other for treatment purposes and to provide an individual with a complete immunization record. Maryland's IIS statute authorizes gathering information for the registry from payers and allows the state Secretary of the Health Department to designate payers as IIS users. New Jersey's IIS laws allow payers to collect immunization data for their members, authorize providers, payers and health officers/agencies to exchange data for IIS administration and payers to request data on their prior members for HEDIS reporting and

quality assurance or accreditation. The law also allows providers to report to the IIS through the NI Medicaid program among others. (Tennessee is covered under the section IIS and other laws, because it has both types of laws.) Utah's IIS rule references a statute allowing release of data to insurers to obtain payment, while the rule itself allows exchange of the IIS with payers and access by payers.

Hawaii's IIS statute only authorizes the health care provider to disclose immunization information to a payer for reimbursement purposes. Indiana's IIS statute allows release of IIS data to the state's Medicaid office. New Hampshire's IIS rule allows IIS data to be released in aggregate to payers, researchers and other government agencies.

Vermont mandates immunization data reporting by health care providers and insurers to the health department.

Of the five city-level Grantees, only Philadelphia's IIS regulation mentions payers as possible authorized IIS users. The other cities - Chicago, Houston, New York, and San Antonio - would follow the law of their respective state.

IIS and Other Applicable Laws

This section includes Grantees that have IIS laws as above and immunization records laws that specify payers. Four Grantees (Alabama, New Mexico, Tennessee and Oregon) have payer provisions in both IIS and other immunization records laws.

Alabama statute requires providers to supply immunization information to other providers, insurers and Medicaid, and authorizes payers as possible users of the IIS. New Mexico's IIS statute "limits access" to certain specified entities, including payers. It contains a rule mandating "reporting health plans" or those licensed in New Mexico or meeting other requirements as specified, to submit HEDIS data elements to the health department. Further, New Mexico has two Medicaid-related regulations. One that governs the state's Medicaid managed care program, states that the MCO will encourage providers to report to the IIS, but does not specify Medicaid access. The other requires the state Medicaid office to maintain the records, but states nothing specifically about exchange of the data to Medicaid.

Tennessee has two different statutes allowing payer release of immunization data to the IIS and payer access to the IIS. Tennessee also has an IIS provision in a medical records law that requires that the Medicaid fraud unit have access to the data. Texas laws require payers to report immunization data received (for those under 18, with consent) to the health department, while another law requires immunization data collection for each person receiving Medicaid.

Oregon's IIS statute allows for exchange among authorized users, including payers. Its public health emergency statute authorizes release of information to authorized users, including payers. And finally, its IIS rule authorizes exchange among authorized users and payer access to their member information.

Other Applicable Laws

The types of laws governing IIS exchange with payers under other applicable laws include Health Information Exchange (HIE), immunization reporting, medical records or insurance laws. Fifteen Grantees fall under this category; Alaska, the District of Columbia, Illinois, Florida, Louisiana, Minnesota, Mississippi, Nebraska, North Carolina, Rhoda Island, South Carolina, Virginia, Washington, West Virginia, and Wyoming.

Alaska has a HIE statute that authorizes information exchange with payers. The District of Columbia's immunization reporting law authorizes release of immunization information to a patient's insurer regarding immunization due dates, or those that were missed or are overdue.

Seven states have medical records laws that might be applied to immunization records, where no other immunization records law exists. Illinois has a medical records statute allowing immunization data release to payers for reimbursement. Florida has a health professions law that allows release of records by the state health department to the state Medicaid Fraud Control Unit upon request. An immunization records section in a Minnesota health records law allows payers to exchange information with providers and other specified entities providing services on behalf of the patient. A Rhode Island health records statute allows release of records to payers related to business operations and utilization review and release to the Medicaid fraud control unit. South Carolina's medical records statute allows physicians to release medical information to insurers, if the insurance claim authorization is on file. Virginia has a medical records statute that references HIPAA and allows the sharing of data with payers. Washington's statute allows release of medical records to payers. Another Washington regulation is related to chronic care data sharing requirements under Medicaid programs, but only specifies exchange with the Department of Social and Health Services and care contractors. Wyoming statute allows release of hospital records to payers. Wyoming also has a regulation regarding eligibility for state and federal provided vaccine program (WyVIP, VFC, and Medicaid), but with no specific mention of reporting to the Medicaid office.

Several Grantees also have insurance laws that ref-

erence medical or immunization records. Louisiana has a Medicaid Managed Care Immunization Payfor-Performance rule that requires physicians to report to the state's IIS, with the implication (not specifically stated) that the Medicaid office will access the data. Mississippi's insurance law allows release of data to review committees, while its Medicaid HMO contract rule requires the release of immunization records by payers to the Division of Medicaid. The Mississippi Division of Medicaid is also granted access to the data that providers participating in Medicaid programs are required to keep under two separate rules. Nebraska has a regulation that sets out the requirements for providers to participate in the state's Medicaid HMO Program, including IIS participation and exchange with the state Medicaid HMO. North Carolina also has an insurance statute with an immunization record provision and another immunization reporting statute that both allow for release of this information by insurers to the health department, while an immunization information rule allows the health department and physicians to release to HMOs. South Carolina's insurance statute related to external review of insurance adverse determination allows for release of information by payers. West Virginia's HMO statute authorizes payers to release data to facilitate assessment of quality of care or review grievance, pursuant to statute or court order, in event of claim or litigation, with written consent, or pursuant to contract with department of the state.

HIPAA

Health care providers and payers, as covered entities under HIPAA Privacy Rule, must follow HIPAA specifications except under certain circumstances, in which state law would apply. State law is an exception to HIPAA if it allows or requires reporting for public health surveillance, investigation, or intervention. These circumstances apply to IIS. HIPAA also allows state laws requiring a health plan to report or allow access to data for audits, program evaluation, or licensure. Immunizations are program evaluation measures under HEDIS, and therefore an exception to HIPAA.

Discussion

In order to realize the full benefits if IIS, including age-appropriate immunization administration and levels and associated cost efficiencies, all immunization stakeholders must work together to ensure completeness of records. Health care provider, organization and health plan contribution and access are key components in the process, and all have a interest in improving outcomes. In this study, half of Grantees

had laws with provisions for payer participation in IIS, although the provisions varied by Grantee.

One potential payer benefit of IIS is availability of data for HEDIS reporting. Insurers in eleven, possibly twelve, Grantee localities (Alabama, California, Colorado, Delaware, Maryland, New Jersey, New Mexico, New York, Oregon, Philadelphia, Tennessee, Utah, and potentially Alaska) are authorized to collect or receive data from IIS for this purpose. A second potential benefit for payers is reduced cost for HEDIS-related data collection compared to traditional chart reviewing. Payers in the above Grantee locales are in a position to test the benefit-to-cost of IIS-based HEDIS data collection.

Some Grantees specify one-way data transfer, but there are benefits to exchange in both directions. MU provides incentives to providers who receive funding from the Centers for Medicare and Medicaid to report to IIS. However, children may switch providers or see providers with inconsistent IIS submission practices. Data from payers in the form of reimbursement requests could contribute valuable information that improves appropriate immunization, identifies immunization disparities, and reduces costs associated with over and under immunization. Laws allowing private payer contribution to add value to the IIS would also help to eliminate the possible question of free rider use of this public good. Grantees could examine the efficiencies of reporting from multiple sources.

Payers are key stakeholders in the successful immunization process, adding value to an IIS, and can potentially benefit from IIS participation in terms of cost savings and improved quality service provision. Therefore, payers may want to collaborate with public health officials and policy makers to improve allowable access and exchange. Additionally, payers could partner with health care providers to promote participation in IIS systems to improve completeness of data and, therefore IIS utility to all users.

This study's collection and presentation of the payer provisions of Grantee IIS-related laws may provide policy makers with models that can be referenced in the development of policy that encourage IIS use among all stakeholders.

Laws that limit information to uni-directional or aggregate data or certain data elements, may not facilitate most efficient use and promote duplication and wasted resource. However, Grantees laws without mention of payers may not have an obstacle, if their law delegates to the health department how information will be collected, exchanged and stored.

Limitations

The study was designed to capture IIS and immuni-

zation record laws, and considered only Grantee IIS or immunization record-applicable insurance laws. Potentially relevant insurance law that did not explicitly note immunization records may have been missed. Further, this study focused only on childhood immunization records. Laws that specified childhood immunization or did not specify an age group were considered. Adult immunization records laws were excluded.

Conclusion

IIS is a valuable public good. In order to reach its full potential, IIS must be populated. The HITECH Act encourages use of EHRs and exchange with IIS has been one established channel, under MU. Providers of Medicare and Medicaid have incentives to report to IIS, but payers can also serve as a data source for IIS. Equally, IIS can provide a cost-efficient data source for health plan HEDIS reporting. This synergy can only be realized if all of the data are centrally located and accessible to those providing services to the patient. HIPAA allows states to require public health reporting to IIS and for health plans to report for program review. Grantees that allow payer access to, or exchanges with, IIS, provide payers with the means to implement this cost savings. Further, payers that are adding value to the system by providing information can also offset any notions of free ridership. Payers and policymakers should work together to ensure that value is added in both directions.

Biographies

Erika M. Hedden, PhD, spent the past two years researching IIS policies and assisted with other research projects at the University of the Sciences in Philadelphia. Recently, Dr. Hedden has provided communication and research services for InforMed. She received her doctorate in health policy from the University of the Sciences.

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