Redefining Meaningful Use
Achieving Interoperability with Immunization Registries

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The Centers for Medicare & Medicaid Services (CMS) has instituted substantial incentives to providers to help foster the adoption and "meaningful use" of certified electronic health records (EHRs).[1] The Meaningful Use Incentive Program, established under the Health Information Technology Economic and Clinical Health (HITECH) Act of 2009, includes three successive stages, each with certain objectives that must be met to receive incentive payments. In the program's first year (2011), more than 100,000 providers have registered,[2] and more than $2.5 billion in incentives has already been paid by CMS to eligible providers.[3]

To qualify for incentive payments during Stage 1 (2011–2013), the specific criteria to be met include a "core set" of EHR capabilities, and an additional five capabilities selected from a "menu set."[4] Successful completion of Stage 1 should lay the foundation for increasingly rigorous criteria. Implementation of Stage 2 has recently been delayed for 1 year (now scheduled for 2014–2015) to allow greater time for system development by EHR vendors and for implementation by providers using those systems.[5] This will ultimately lead to the most-stringent criteria, which will be implemented in Stage 3.

Stage 1 includes one meaningful use criterion that pertains to submitting electronic data to a state or regional immunization information system (IIS); this should be particularly relevant for pediatric primary care practices given the prominence of childhood immunizations. Sending information from EHRs to an IIS offers important benefits and permits a more complete understanding of vaccination protection for a population. It not only enables health plans and public health officials to more accurately identify populations in which children are inadequately protected with recommended vaccines, but also facilitates the sharing of this information in real time. Such sharing of immunization data from EHRs to an IIS is accomplished through the use of a standard syntax in which information can be encoded by an EHR and subsequently decoded by an IIS using a common set of rules.

To meet this Stage 1 criterion, providers are required to attest to CMS only that they have successfully sent a single test message from their EHR to an IIS. Notably, information needs to be submitted only *unidirectionally* to an IIS; no information is required to be reported back to an EHR. Although this is certainly a step in the right direction, it may be little more than a baby step—many practices already submit data electronically to their IIS through "batch" file transfers and have done so for years.

This one-way transfer of information from EHRs to IIS falls short of the benefits that could potentially be achieved if providers were enabled to receive reciprocal information from an IIS. An IIS may have vaccination doses recorded that are unknown to a provider's EHR, such as those previously administered to their patients by a health department or another provider. When data transfers are restricted to one-way data reports from EHRs, providers must take the additional time to separately look up each patient in the IIS to ensure that they have a complete immunization history; unfortunately, past experience tells us that this does not routinely happen.[6,7]

Absent a complete record of vaccinations from the IIS, providers may spend unnecessary resources to send recall notifications to patients, or may unknowingly administer unneeded vaccine doses. Instead, through *bidirectional interoperability*, a patient's complete vaccine history would automatically be available from the IIS to the sending practice's EHR. This two-way exchange not only enables an EHR to report doses to an IIS, but also permits the IIS to be queried for any additional vaccination history. Thus, all vaccine doses are recorded and available for use in both systems in real time.

Bidirectional interoperability is not far-fetched; much of the enabling technologies already exist for an EHR to automatically report vaccination doses to an IIS, as well as to make a real-time query to an IIS. Under the HITECH Act, more than $500 million has been invested by the Office of the National Coordinator on Health Information Technology (ONC) to develop and implement electronic health information exchanges (HIEs) in each state.[8] It is anticipated that these HIEs, which provide the

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necessary secure electronic environment for the movement of health information among providers, will play a crucial role in achieving a wide range of meaningful use objectives. Importantly, national standards have been established to support the structure of such exchanges; several state IISs have already demonstrated the capability for a queried IIS to respond to an EHR with a complete vaccination history and an evaluation of vaccination status (i.e., up-to-date, eligible, or overdue for specific doses).

However, things can get tricky once the information is received by the querying EHR: either the EHR can be modified to allow an image of a screen sent by the IIS, which displays the history and status evaluation in graphic format such as a screen shot, or the EHR can be programmed to independently evaluate the immunization history and make the appropriate determination regarding vaccination status. Either option is likely to require substantial customization on the part of practices, EHR vendors, and the IIS. Regardless of the method employed, bidirectional interoperability between an EHR and one state's IIS does not enable the same EHR product to have bidirectional interoperability with another state's IIS, both because of the variability of EHR products and of IIS functionality.

Other important questions pertain to the sustainability of key processes that support these exchanges. For example, national vaccination recommendations are issued by the Advisory Committee on Immunization Practices (ACIP), with frequent updates and clarifications, raising the issue of which entity should be responsible for assessing vaccination status based on current national recommendations. Should that task be left to the discretion of individual EHR vendors? That approach could very well lead to inconsistent vaccination assessments across EHR products, causing widespread confusion among providers and parents.

Problems of inconsistency could be avoided by establishing a mechanism to verify the correct interpretation of ACIP recommendations across all vendors and products. However, the cost to vendors to modify each EHR's algorithms for determining vaccination status each time the recommendations change may be substantial; these costs may be passed on to practices, thereby increasing their costs for childhood immunization delivery. Another approach would be the standardized implementation of the ACIP recommendations into a single assessment algorithm, applied centrally by the IIS and reported to all of its associated EHRs; this reflects the current approach of most state IIS programs.

Although the consistency of standardized implementation is desirable, extending this model to the use of a singular, nationally standardized ACIP assessment algorithm by all IIS programs is challenged by variations in state interpretations and in some cases, state laws. Development of open source, freely available assessment algorithms could foster greater consistency among IIS programs yet also allow the flexibility for IIS-specific modifications.

Despite the likely benefits to achieving EHR–IIS interoperability, EHR vendors currently have little motivation to address the issues necessary to make this a reality. Bidirectional interoperability with IIS is not required for Stage 1 meaningful use incentive payments, and preliminary indications suggest that it will also not be required under the more stringent Stage-2 criteria. As a consequence, a substantial investment by practices may fall far short of achieving its potential, because EHR immunization records will not be synchronized with IIS records on a real-time basis. Ultimately, this will likely cost practices time and resources and may negatively affect the quality of care provided to children in pediatric practices.

As draft Stage-2 meaningful use criteria are finalized,[9] there is an important opportunity to encourage participation by EHR vendors to achieve bidirectional interoperability with IIS. Key to this process will be constructive collaboration among technical and clinical experts from the CDC, IIS programs, and the myriad of EHR vendors. Such partnerships could be instrumental in efforts to harmonize and maintain vaccination assessment implementations that are consistent with the ongoing changes to ACIP recommendations. More fundamentally, CMS has an opportunity to align meaningful use incentives with functions that will enable real-time, seamless, bidirectional interoperability between EHRs and IIS programs.

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