AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

May 31, 2019

Dr. Don Rucker
Department of Health and Human Services,
National Coordinator for Health Information Technology
Mary E. Switzer Building, Mail Stop: 7033A
330 C St. SW
Washington, DC 20201

RE: **21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program**

Dear Dr. Rucker -

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on the Office of the National Coordinator's (ONC's) recently released notice of proposed rulemaking titled **21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.** As a member organization with more than 600 members representing 77 Public Health organizations, 12 businesses and sponsors, and 512 individuals from Immunization Information System (IIS) programs and partners, these comments represent a broad perspective on federal actions that affect immunization programs across the country, particularly as they relate to issues that impact the interoperability of immunization records.

Recognizing the growing importance of health information technology, we believe that Immunization Information Systems (IIS) are a key part of the health care infrastructure. Incentive programs like Meaningful Use (MU) and Promoting Interoperability (PI) have helped to automate IIS reporting and have improved Electronic Health Record (EHR)-IIS interoperability, thus lowering provider burden and increasing the value and broad use of IIS data. We want to ensure that the proposed rules continue to support the important role IIS play in consolidating and sharing immunization information. **To this end, we are strongly suggesting that any clear public health activities related to interoperability be excluded from this rule, and not be viewed as information blocking.**

Similarly, AIRA is supportive conceptually of a common coordinated data set (USCDI), but the language implies that all USCDI data would need to be exchanged, which would conflict with IIS and Immunization Program state laws that emphasize only sharing relevant data. **We ask that the rule be explicit about the reach of this regulation and its effect on Public Health.**

IIS, or immunization registries, are available and highly utilized in nearly every state across the US. They support provider access to the most complete, timely and accurate immunization information available. Immunization providers and other stakeholders rely on IIS to implement an increasingly complex vaccination schedule, as well as monitor vaccine safety, efficacy, and vaccine delivery. IIS play an essential role in creating a comprehensive consolidated immunization record, assisting with vaccine evaluation and forecasting, generating patient reminders, assessing vaccine uptake, providing schools and childcare providers access to consolidated records, and assisting with vaccine ordering and inventory management. This information is also heavily leveraged in population-based assessments, to support surveillance, program operations and guiding public health action. IIS serve as a vital link to responding to a vaccine-preventable disease outbreak or community or public health emergency, supporting outbreak investigation, calculating vaccine coverage estimates, and much more. One need only look to recent measles outbreaks[1] across the US to recognize the need for strong immunization surveillance and informatics tools.

Immunizations are acknowledged as one of the most effective and life-saving health interventions of modern medicine; CDC states that the vaccinations given to infants and young children in the past 20 years alone will prevent an estimated 322 million illnesses and save 732,000 lives just in the United States.[2] Similarly, an evidence-based systematic review of current literature demonstrated IIS capabilities and actions in increasing vaccination rates, contributing heavily to the overall goal of reducing vaccine-preventable disease.[3] IIS are increasingly well-populated, with childhood IIS participation increasing from 90% in 2013 to 95% in 2017, now reaching the Healthy People 2020 objective of ≥95% child IIS participation.[4] Similar growth in IIS population capture has been seen with adolescents and adults, where IIS store immunization data on 79% of 11-17 year olds and 51% of age 19 years and above of the population.[5]

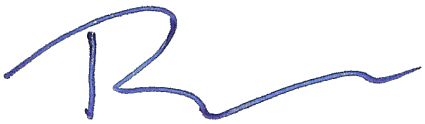
In addition to the comments above, AIRA provides suggestions on the ONC proposed rules in our detailed comments presented on the following pages, organized by page number (based on

[1] CDC Measles surveillance, 2019, accessed 4/3/2019: https://www.cdc.gov/measles/cases-outbreaks.html
[2] MMWR, 2014, accessed 5/28/2018: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm
[3] Journal of Public Health Management Practice, 2014, Accessed 5/28/18: https://www.thecommunityguide.org/sites/default/files/publications/vpd-jphpm-evrev-IIS.pdf
[4] MMWR, 2017, accessed 5/31/2018: https://www.cdc.gov/mmwr/volumes/66/wr/mm6643a4.htm
[5] CDC, 2017, IIS Annual Report Data (unpublished)

the Federal Register[6] version of the rule) and section within the report. Please contact Mary Beth Kurilo, AIRA's Policy and Planning Director, with any questions: mbkurilo@immregistries.org.

AIRA greatly appreciates the opportunity to comment on these proposed rules, and we look forward to continuing to collaborate to ensure high-value health IT interoperability with our many partners.

Sincerely,



Rebecca Coyle, MSEd, Executive Director

[6] Federal Register, 2019, accessed 4/3/19: https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf

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Comments on the ONC Proposed Rules: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

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Pg. 7429	In section VII.B.4 of the preamble, we outline our proposals to implement the Cures Act's API Condition of Certification. These proposals include new standards, new implementation specifications, a new certification criterion, as well as detailed Conditions and Maintenance of Certification requirements.	We request that the final rule explicitly clarify that FHIR API support does not replace any existing immunization interoperability standards currently called out by the Promoting Interoperability and 2015 EHR certification requirements. That is, support for Release 1.5 of the HL7 v2 immunization implementation guide (for both submission and query) is still required going forward.
Pg. 7440	We propose that the USCDI Version 1 (USCDI v1) include the newest versions of the "minimum standard" code sets included in the CCDS available at publication of a subsequent final rule. We request comment on this proposal and on whether this could result in any interoperability concerns. To note, criteria such as the 2015 Edition "family health history" criterion (§ 170.315(a)(12)), the 2015 Edition "transmission to immunization registries" criterion (§ 170.315(f)(1)), and the 2015 Edition "transmission to public health agencies—syndromic surveillance" criterion (§ 170.315(f)(2)) reference "minimum standard" code sets; however, we are considering	Public health has had little formal input to the development of USCDI. While it seeks to identify a minimum data set for interoperability transactions, USCDI data classes and data elements are not uniformly required for all public health transactions and some of the data defined should not be sent to public health. The code sets proposed for USCDI need further examination to determine whether they are correct as proposed. We recommend that the USCDI Version 1 be clarified to point more specifically to which code set is utilized. For example, 'race' is listed on the USCDI, but not the proposed code set for 'race'. Increasing the data set to include elements not previously listed (such as address and phone number) could also help with patient matching.

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	changing the certification baseline versions of the code set for these criteria from the versions adopted in the 2015 Edition final rule to ensure complete interoperability alignment. We welcome comment on whether we should adopt such an approach.	We also recommend that the CDC Core Data Elements for IIS be considered in the final set of immunization-specific elements. These can be found at: https://www.cdc.gov/vaccines/programs/iis/core-data-elements/iis-func-stds.html. Note that ONC is requesting an exemption for USCDI from The National Technology Transfer and Advancement Act (NTTAA) requirements that standards adopted by the Federal government must be developed or adopted by voluntary consensus standards bodies. We do not believe that USCDI development should receive this exemption and it has not been developed with an appropriate consensus process. At minimum, we request that the USCDI Task Force include a representative from Public Health.

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Pg. 7446	We propose to adopt a new 2015 Edition certification criterion for EHI export in § 170.315(b)(10). This criterion is intended to provide patients and health IT users with a means to efficiently export the entire electronic health record for a single patient or all patients in a computable, electronic format, and facilitate the receiving health IT system's interpretation and use of the EHI, to the extent reasonably practicable using the developer's existing technology.	AIRA supports this provision, as this may be an opportunity for public health to benefit from more standardized and comprehensive formats for EHR data export that may facilitate public health registry data import. While we are not suggesting that this data import replace routine public health registry reporting, there are some cases where a more complete patient history (or subset of a history) may be desired (e.g., most IIS only requires new vaccine administrations to be sent though retrospective vaccine histories are also desired).
Pg. 7448	For both use cases supported by this criterion, EHI export encompasses all the EHI that the health IT system produces and electronically manages for a patient or group of patients. This applies to the health IT's entire database, including but not limited to clinical, administrative, and claims/billing data. It would also include any data that may be stored in separate data warehouses that the system has access to, can produce, and electronically manages.	It is important to recognize that this is an extremely ambitious scope of work. An EHR contains a great deal of data related to clinical, administrative and billing processes that could be interpreted to be included in this scope. Some of this data may not be readily usable by another system or the patient. In the absence of a defined export format (see comment below), this scope could lead to overly complex exports which would complicate the extraction of critical data for patient and provider use.

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Pg. 7448	The proposed certification criterion does not prescribe a content standard for the EHI export. However, it requires health IT developers to provide the format, such as a data dictionary or export support file, for the exported information to assist the receiving system in processing the EHI without loss of information or its meaning to the extent reasonably practicable using the developer's existing technology.	Given the large scope of the EHI export, the lack of a prescribed content standard seems problematic, as it will lead to variance in export format by vendor. Any receiving application will not only need to understand the format for a given vendor but also be able to reconcile it with data from other EHI export formats. It may be prudent to delay this requirement until a standardized format is available or until the USCDI is expanded to reasonably include much of the data included in the EHI export scope.
Pg. 7449	Requirements on health IT developers to rollout health IT certified "EHI export" within 24 months of the effective date of a final rule for this proposed rule.	In the absence of a defined export standard, a 24 month development phase seems short.
Pg. 7450	Recovering Costs Reasonably Incurred (Section VIII.D.4) We propose that this exception would not permit the recovery of any cost that the actor incurred due to the health IT being designed or implemented in non-standard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using EHI.	In several places, the proposed rule indicates that Health IT design decisions may impact costs that can be recovered by vendors. We feel that this is problematic as a product is developed based on a variety of considerations, including those unrelated to interoperability and design decisions which may negatively impact interoperability may be necessary for other critical purposes. As well, this will penalize vendors for decisions made in the past before any of these regulations were proposed. We recommend that vendors be able to recover all reasonable implementation costs independent of design decisions.

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Pg. 7450	Multi-Factor Authentication: We propose to adopt a "multi-factor authentication" (MFA) criterion in § 170.315(d)(13) and include it in the P&S certification framework (§ 170.550(h)). We propose to make the "multi-factor authentication" certification criterion applicable to any Health IT Module currently certified to the 2015 Edition and any Health IT Module presented for certification.	As proposed in the NPRM, the discussion of multi-factor authentication tacitly presumes that the interoperability is interactive between the user and the data source, as opposed to being an automated transaction. We request that the final rule recognize more explicitly that automated transactions such as public health reporting may not readily support multi-factor authentication. In addition, requiring multi-factor authentication may add burden for IIS, EHRs and providers, extending the timelines to develop interfaces. Standards for authentication would also need to be developed to support this work.
Pg. 7458-9	This section outlines our approach to implement Section 4001(b) of the Cures Act, which requires that the Secretary make recommendations for the voluntary certification of health IT for use by pediatric health providers and to adopt certification criteria to support the voluntary certification of health IT for use by pediatric health providers to support the health care of children. … Recommendation 5: Synchronize immunization histories with registries	We support the noted alignment with the Children's EHR format and 2015 CEHRT. However, the noted alignment with Proposed New or Updated Certification Criteria does not seem appropriate: • The reference to the inclusion of pediatric vital sign data elements in the USCDI is not relevant to immunization reporting or query. • The requirement for FHIR is not currently consistent with CDC/AIRA standards or practices for immunization data submission or query/response and public health is not currently funded to provide this capability from with IIS. • The supplemental requirement for production of a school, camp or child care form from EHR data is not

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		consistent with current IIS functionality or practice where such reports are generated from the IIS when required. It is worth noting that the format of official reports tends to differ across jurisdictions and it may not be reasonable for EHR vendors to maintain reports for all jurisdictions used by their products. The IIS community should study this requirement and consider technical solutions to make these differing report formats more readily available. • It's unclear if this implies public health (specifically Immunization Information Systems) would need to support API interfaces to support the production of the reports using EHR data. At present, IIS do not support API interfaces as described in the proposed rule. • It is important to note that some states require the school report be produced from the IIS. In other places, it might be acceptable to print this information from an EHR, but it must be rendered on a school specific form designed by the state.

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Pg. 7467	We request comment as to whether certain health IT developers should be required to participate in the TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI. We would expect that such a requirement, if proposed in a subsequent rulemaking, would apply to health IT developers that have a Health IT Module(s) certified to any of the certification criteria in §§ 170.315(b)(1), (c)(1) and (c)(2), (e)(1), (f), and (g)(9) through (11); and provide services for connection to health information networks (HINs).	TEFCA, as previously described, was always purported to be a voluntary, rather than required, activity and any substantial change to that understanding would need to be done only based on a clear understanding of where TEFCA has evolved since its original draft release.

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Pg. 7467-8	The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, does not prohibit or restrict communication regarding the following subjects: • The usability of the health information technology; • The interoperability of the health information technology; • The security of the health information technology; • Relevant information regarding users' experiences when using the health information technology; • The business practices of developers of health information technology related to exchanging electronic health information; and • The manner in which a user of the health information technology has used such technology. … The [IOM] report stressed the need for health IT developers to enable the free exchange of information regarding the experience of using their health IT products, including the sharing of screenshots.	We strongly support this provision, as it may provide an opportunity for public health to speak more openly about CEHRT that does not meet public health reporting requirements well and to facilitate exchange of information between agencies about their experiences with various CEHRT products and vendors.

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Pg. 7471	We note that contractual prohibitions or restrictions on communications can, in limited circumstances, be legitimate and serve an important role in protecting proprietary information and intellectual property that are essential for health IT developers to innovate and compete. On this basis, we propose to permit certain types of prohibitions and restrictions, subject to strict conditions to ensure that they are narrowly tailored and do not restrict protected communications. These permitted prohibitions and restrictions are discussed in section VII.B.3.b.v below.	We request that the final rule explicitly clarify if the protected communication guidelines also apply to Public Health Authorities (PHAs) who interact with both Health IT developers (vendors) and users (healthcare organizations).

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Pg. 7476	Application Programming Interfaces: As a Condition of Certification (and Maintenance thereof) under the Program, the Cures Act requires health IT developers to publish APIs that allow "health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law." The Cures Act's API Condition of Certification also states that a developer must, through an API, "provide access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws."	Although we appreciate and support the embrace of APIs and FHIR as important interoperability tools moving forward, we want to ensure that HL7 V2 continues to be supported and allowed moving forward, given its broad adoption across the EHR and IIS communities. We also recognize that some ancillary public health activities, such as provision of clinical decision support (CDS) services for immunization evaluation and forecasting or determining reportable conditions may benefit from consideration of FHIR-based technologies (like CDS Hooks).
Pg. 7478	Given FHIR Release 4's public release and that the industry will begin to implement Release 4 in parallel with this rulemaking, we request comment on the following options we could pursue for a final rule.	Although the current data exchange standard for IIS is HL7 2.5.1 R1.5, the IIS community believes that FHIR Release 4 is the best future-looking standard to set. That being said, it is a risk that lack of Release 4 implementation guides (which would be required) don't currently exist, since Release 4 was just published in December. The development of appropriate documentation should be prioritized before the standard is implemented.

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Pg. 7495	Real World Testing The Cures Act requires, as a Condition and Maintenance of Certification under the Program, that health IT developers have successfully tested the real world use of the technology for interoperability in the type of setting in which such technology would be marketed.	We support the focus on real world testing; however, we strongly urge ONC and the broader IT community to engage and involve public health in designing testing processes. At minimum, ONC needs to ensure that real-world testing requirements do not create infrastructure for testing of public health transactions *without* public health involvement. This represents an opportunity for public health agencies and organizations to coordinate the real-world testing of CEHRT to ensure more consistent implementation across the country. There is also the potential for significant cost savings for both public health and CEHRT vendors in leveraging common infrastructure that might be deployed to support this testing. (NA) A further consideration related to real world testing relates to funding; If Public Health authorities are to be involved in assessing this requirement, additional funding to develop and support programs to work with Health IT vendors would be required.

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Pg. 7497	The Standards Version Advancement Process would permit health IT developers to voluntarily use in their certified Health IT Modules newer versions of adopted standards so long as certain conditions are met, not limited to but notably including successful real world testing of the Health IT Module using the new version(s).	There is risk here that vendors will be able to implement new versions of interoperability standards that public health agencies are not prepared to support. Conversely, this is also an opportunity for public health to adopt and promote newer versions of standards more quickly than current rulemaking allows. AIRA requests that ONC clarify the process for its selection of newer versions of standards that is a prerequisite for use by vendors, and that ONC explicitly indicate that public health will be actively involved in standards version selection.
Pg. 7508	The information blocking provision provides a comprehensive response to these concerns. The information blocking provision defines and creates possible penalties and disincentives for information blocking in broad terms, while working to deter the entire spectrum of practices that unnecessarily impede the flow of EHI or its use to improve health and the delivery of care.	AIRA requests that ONC clarify what public health applications (like IIS) are subject to these regulations. Suggestions for improving this section of the rule and clarifying how they affect public health agencies include: • While a state-run HIE is explicitly within the definition, Public health interface engines that are not general purpose HIEs should be excluded as a covered activities under this rule. • Delays in on-boarding provider organizations for public health reporting should not be considered information blocking under this rule (e.g., a long on-boarding queue). • Similarly, public health preference for interfacing to certain types of organizations over others should not constitute information blocking (*e.g.,* connecting larger provider

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		organizations before smaller ones, or pediatric practices over adult practices). • Obstacles (perceived or real) to primary or secondary use of data either possessed or transmitted by public health (other than those required by law) should not constitute information blocking. • Through the exclusions legal action by HHS against a government agency in relation to information blocking should not be expected or permitted. • The activities of IT vendors who fulfill contracts for products or services for public health agencies should not be subject to sanction under the rule. • Exceptions must not be used to justify failure to perform public health reporting. A final response on information blocking discussed by our community relates to a possibly unintended benefit of the rule. The presence of strong regulation prohibiting information blocking may help public health enforce reporting requirements by introducing the risk of accusation of information blocking to providers and vendors who don't report. Thus, this provision could be an incentive for routine and complete public health reporting.

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Pg. 7512-3	We propose a functional definition of "health information network" (HIN) that focuses on the role of these actors in the health information ecosystem. We believe the defining attribute of a HIN is that it enables, facilitates, or controls the movement of information between or among different individuals or entities that are unaffiliated. We propose to define a "health information exchange" (HIE) as an individual or entity that enables access, exchange, or use of EHI primarily between or among a particular class of individuals or entities or for a limited set of purposes.	We request that Public Health systems such as IIS be explicitly excluded from either of these definitions, clarifying that they are not expected to adhere to information blocking requirements.
Pg. 7553	Registries Request for Information (RFI): We seek comment on use cases where an API using FHIR Release 4 might support improved exchange between a provider and a registry.	AIRA would like to recognize and emphasize that IIS-EHR interoperability primarily uses HL7 V2 for its exchange standard. However, with respect to FHIR version, it seems appropriate for this rule to require FHIR R4 which is the first normative release. Prior releases are for trial use only and do not guarantee backward version compatibility as R4 will. There is great potential to expand the already established exchange of data between providers (EHRs) and IIS. Areas of focus may include: • Provision of patient clinical data at the time of evaluating a patient immunization history and determining personalized

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		recommendations for the patient. Often IIS lack access to the detailed clinical date (problems, medication list, occupational history, etc.) that profoundly impact the recommendation process. Harnessing the FHIR APIs could dramatically enhance the ability for IIS to determine the best possible set of recommendations for a patient. • Ordering and inventory management is a critical yet time intensive process for providers and vaccine suppliers. Enhanced interoperability in this area could reduce burden on both sides. • The exchange of bulk data between providers and IIS or between two different IIS is critical for onboarding and cross-jurisdictional data exchange. Enhanced standards in this area would be an excellent opportunity to expand interoperability. Regardless of which areas of focus are chosen, any expansion of Public Health use cases must be accompanied by fiscal support for Public Health jurisdictions to develop and implement new technology.

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Pg. 7554	Patient Matching Request for Information (RFI): We specifically seek input on the following: [Topics include: • Data elements available for matching • Unique pediatric matching requirements • Notion of involving patients themselves in matching • Metrics for measuring matching • Measures of database duplication level • Input on private sector emerging techniques, including referential matching and biometrics • Additions to or constraints on USCDI that might enable or facilitate matching]	The IIS community has significant experience addressing patient matching as a result of years of consolidating patient records from diverse clinical locations. We would welcome the opportunity to help inform ONC efforts in this area, and we encourage you to contact AIRA to collaborate and leverage public health and IIS knowledge and subject matter expertise. In addition, the following rows include specific responses to questions posed in the ONC Patient Matching RFI.
Patient Matching RFI, Pgs. 7554-5	It is a common misconception that technology alone can solve the problem of poor data quality, but even the most advanced, innovative technical approaches are unable to overcome data quality issues. Thus, we seek input on the potential effect that data collection standards may have on the quality of health data that is captured and stored and the impact that such standards may have on accurate patient matching. We also seek input on other solutions that may increase the likelihood of accurate data	The quality of data used for patient matching is indeed a difficult problem which has plagued public health registries for some time. As we described in an article published in 2017, ONC convened a Patient Matching Community of Practice in 2014-15. We wrote, "Its major focus was developing a five-level data quality maturity model to try to characterize an organization's sophistication in using different common data elements to perform patient matching functions, as well as articulating value propositions for improved matching for different

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	capture, including the implementation of technology that supports the verification and authentication of certain demographic data elements such as mailing address, as well as other efforts that support ongoing data quality improvement efforts.	stakeholder types. The project released two documents, *Developing and Testing a Data Management Model and Maturity Scale Tailored to Improving Patient Matching Accuracy* and Guidelines for Pilot Testing of Data Management Maturity℠ Model for Individual Data Matching describing its work. The Data Quality Maturity Scale, included as Appendix B, highlights how systems across the healthcare community, at least as reflected in the core data elements, are at the high levels of maturity. In practice, however, the data elements needed for levels 4 and 5 are precisely the ones that are least consistently captured." We encourage ONC to draw on these documents and resources whose development ONC funded. External validation of key data elements used for matching can also be a big help. For example, in 2017 the American Immunization Registry Association (AIRA) arranged access to SmartyStreets, a cloud-based address cleansing service, for all Immunization Information Systems (IIS) which chose to access it. By leveraging available CDC funding, for a modest amount this service is able to cover the *entire* IIS community and significantly increase

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		the level of quality in address data which is often key for proper patient matching. AIRA maintains the license, provides documentation and coordination, and sponsors a monthly user group of interested IIS projects.
Patient Matching RFI, Pgs. 7554-5	In concert with the GAO study referenced above, we seek input on what additional data elements could be defined to assist in patient matching as well as input on a required minimum set of elements that need to be collected and exchanged. We encourage stakeholders to review the Patient Demographic Record Matching section of the Interoperability Standards Advisory and comment on the standards and implementation specifications outlined. Public comments and subject matter feedback on all sections of the Interoperability Standards Advisory are accepted year round.	The Patient Demographic Record Matching Sections seems inadequate to address data elements for patient matching as it primarily focuses on IHE transactions which do not seem to focus normatively on *which* data elements might be best for matching. The Data Quality Maturity Scale, included as Appendix B in Guidelines for Pilot Testing of Data Management Maturity℠ Model for Individual Data Matching referenced above, provides detailed suggestions for data elements to be used for patient matching that were vetted through the community of practice that developed the guidelines. In addition, in January 2019 AIRA published its *IIS Functional Guide, Vol. 2: CDC Endorsed Data Elements*. This exhaustive document includes (in Appendix C) a list of data elements endorsed to fulfill the IIS functional standard of identifying, preventing and resolving duplicated and fragmented patient records using an automated process. This list is also worth consulting.

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		Research in New York City by the Citywide Immunization Registry (CIR) has demonstrated that though matching is a complex activity, and it is difficult to tease apart factors affecting successful matching, the search success rate for the CIR was higher when more search fields were sent, especially the internal ID assigned to each patient in the CIR and available to EHRs that query the system should they choose to store it. Studies such as this one should be replicated to help determine the most effective fields for searching and matching.
Patient Matching RFI, Pgs. 7554-5	Also in alignment with the GAO study, we seek input on whether and what requirements for electronic health records could be established to assure data used for patient matching is collected accurately and completely for every patient. For instance, the adopted 2015 Edition "transitions of care" certification criterion (§ 170.315(b)(1)) currently includes patient matching requirements for first name, last name, previous name, middle name, suffix, date of birth, address, phone number, and sex. These requirement also include format constraints for some of the data.	Requiring specific data quality for is admirable but may not be practical, since in many (if not most) cases an EHR can only contain data as good as what is provided by the patient. To the degree that data formats can be enforced (like data formats for date of birth), or standard value sets maintained (like sex, race, and ethnicity), the quality of the data will naturally improve.
Patient Matching RFI, Pgs. 7554-5	There are unique matching issues related to pediatrics and we seek comment on innovative and effective technical or non-technical approaches that could support	The IIS community has worked in this domain specifically for more than twenty years. There are a number of specific patient matching issues that

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	accurate pediatric record matching.	affect pediatric records, including: • Birth records that do not contain a true first name (but rather are populated with "baby boy" or "baby girl" as a first name was not available) can become difficult to match to future records. • Multiple births can sometimes present confusing matching problems, especially when first names are close or even identical. • Children do not usually have records in referential matching databases that are primarily drawn from financial/credit data sources (see below). • Though not unique to children, some data sources may include a patient's middle name embedded in the patient's first name field. • Children may lack common identifiers that adults typically possess that may be used as primary or secondary matching fields (*e.g.,* driver's license number, social security number, cell phone number, e-mail address, unique Medicaid ID [which may be a family ID]). • On the other hand, children are often associated with parents/guardians and parent/guardian data can be used to supplement primary data for matching. There are no simple answers to addressing these issues; technology developers need to be sensitive to them

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		when crafting solutions to pediatric matching challenges.
Patient Matching RFI, Pgs. 7554-5	Recent research suggests that involving patients in patient matching may be a viable and effective solution to increase the accuracy of matching, and giving patients access to their own clinical information empowers engagements and improved health outcomes. We seek comment on potential solutions that include patients through a variety of methods and technical platforms in the capture, update and maintenance of their own demographic and health data, including privacy criteria and the role of providers as educators and advocates.	Public health registries are only just beginning to provide direct access to patients; IIS are probably leading the way given the broad usefulness of an up-to-date immunization history and forecast for school/child care/camp admission and preventive care. Many IIS also perform automated or semi-automated outreach services to encourage patients to complete missing immunizations ("Reminder") or to warn them of upcoming immunization needs ("Recall"). These services will often use text messages or e-mails to contact patients directly, yet IIS often do not have complete cell phone or e-mail records for their patients. Most IIS projects are somewhat reluctant to accept patient contact information (which could then also be available for matching) directly as opposed to soliciting this information from healthcare providers when they submit immunization records *to* the IIS. We do feel there is some potential for augmenting IIS contact information with patient-supplied data once patient access to IIS data becomes more prevalent.

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Patient Matching RFI, Pgs. 7554-5	In addition, we seek input on standardized metrics for the performance evaluation of available patient matching algorithms. Health IT developers are each relying on a number of patient matching algorithms, however, without the adoption of agreed upon metrics for the evaluation of algorithm performance across the industry, existing matching approaches cannot be accurately evaluated or compared across systems or over time.	This has always been a difficult topic and we do not see any easy answers ahead. In 2017 ONC sponsored the Patient Matching Algorithm Challenge (PMAC) whose was to allow vendors to compete for the highest performance metrics for their matching algorithms by testing their software against a large set of test data provided by ONC. Cash prizes were awarded in a number of categories, and the winning vendors were featured in the discussion on the webinar. One of the main purposes of the challenge was to promote the use of standard metrics to evaluate algorithm products. We were a little concerned that the winners by their own admission "analyzed patterns in the data." This seems to call into question the applicability of their results to the "real world" where you don't get to see the data set; you have to adjudicate them as they come in. That means that these particular test runs were "tuned" for the data set and the measurable results might not hold up for other data sets. Over the years, several public health initiatives have attempted to provide comparative measures of matching algorithm performance or quality and have had less than successful results.
Patient Matching	There are a number of emerging private-sector led approaches in	In an article published in 2017, the

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RFI, Pgs. 7554-5	patient matching that may prove to be effective, and we seek input on these approaches, in general. A number of matching services that leverage referential matching technology have emerged in the market recently, yet evaluations of this type of approach has either not been conducted or has not been made public. Other innovative technical approaches such as biometrics, machine learning and artificial intelligence, or locally developed unique identifier efforts, when used in combination with non-technical approaches such as patient engagement, supportive policies, data governance, and ongoing data quality improvement efforts may enhance capacity for matching.	authors identified a set of distinct strategies for matching that seemed to be in play and the lack of any real consensus around any of them: 1. A "traditional" approach which leverages either deterministic and/or probabilistic techniques that continue to struggle with the lack of standardized data for input as discussed elsewhere in this response; 2. A unique identifier approach, either government sponsored or managed by the private sector, though this would likely be insufficient without corroborating data in a population as large and diverse as the US; 3. Health record banks which put the patient at the center of the problem but which have failed to gain any traction in the marketplace; 4. Biometrics, which still suffer from some limitations as well as privacy concerns; 5. Newer, innovative approaches such as referential matching which still have limitations in some segments of the population (like children) We believe that the public and private sectors need to get together to discuss and pilot various approaches and to encourage Congress to reexamine its current position on a national unique patient identifier.

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Patient Matching RFI, Pgs. 7554-5	Finally, ONC seeks input on new data that could be added to the United States Core Data for Interoperability (USCDI) or further constrained within it in order to support patient matching.	We recommend that ONC refer to the Data Quality Maturity Scale, included as Appendix B in Guidelines for Pilot Testing of Data Management Maturity℠ Model for Individual Data Matching reference above, provides detailed suggestions for data elements to be used for patient matching that were vetted through the community of practice that developed the guidelines.