June 22, 2018

Seema Verma
Administrator, Centers for Medicare and Medicaid Services.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1694–P
P.O. Box 8011
Baltimore, MD 21244–1850

RE: Medicare and Medicaid Programs; IPPS and Promoting Interoperability Proposed Rules, Request for Comments

Dear Administrator Verma -

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on The Centers for Medicare and Medicaid's (CMS's) ***Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims.*** 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.

AIRA and the IIS community are pleased to see that the important activities of immunization registry submission and query continue to appear as a measure in the proposed rules. We also support renaming the EHR incentive programs to "promoting interoperability", which clearly and directly communicates the goals of these programs. 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

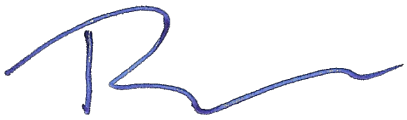
an estimated 322 million illnesses and save 732,000 lives just in the United States.[1] Similarly, an evidence-based systematic review demonstrated IIS capabilities and actions in increasing vaccination rates, contributing heavily to the overall goal of reducing vaccine-preventable disease.[2] IIS are increasingly well-populated, with childhood IIS participation increasing from 90% in 2013 to 94% in 2016, which approaches the Healthy People 2020 objective of ≥95% child IIS participation.[3]

However, we have significant concerns that the immunization registry reporting measure is now one of five public health measures which may be optionally selected, and that the proposal reduces the number of public health measures from three to two (syndromic surveillance plus one other from a list). This de-prioritization of immunization registry interoperability is troubling, and a clear reason for it is not substantiated in the draft rules themselves. We are also concerned about the stated intent in the rules to remove public health measures altogether in CY2022 and beyond. These measures have incentivized a substantial growth of the use of public health data in clinical medicine, and it would be a mistake to remove them before the full benefit of interoperability can be realized and stabilized.

We offer some suggestions in our detailed comments presented on the following pages, organized by page number and section within the Proposed Rule. 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 CMS proposed rules, and we look forward to supporting our members and promoting stronger interoperability with our EHR partners.

Sincerely,



Rebecca Coyle, MSEd, Executive Director

[1] MMWR, 2014, accessed 5/28/2018: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm
[2] Journal of Public Health Management Practice, 2014, Accessed 5/28/18: https://www.thecommunityguide.org/sites/default/files/publications/vpd-jphpm-evrev-IIS.pdf
[3] MMWR, 2017, accessed 5/31/2018: https://www.cdc.gov/mmwr/volumes/66/wr/mm6643a4.htm

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Comments on the Medicare and Medicaid Programs; IPPS and Promoting Interoperability Proposed Rules

Section, Page Number	Excerpt	Comment
Page 20521	"We understand that some hospitals may not be able to report the Syndromic Surveillance Reporting measure or may not be able to report some of the other measures under this objective. Therefore, we are proposing to maintain the current exclusions for these measures that were finalized in previous rulemaking. If an eligible hospital or CAH claims an exclusion for one or both measures required for this objective, we are proposing the 10 points for this objective would be redistributed to the Provide Patients Electronic Access to their Health Information measure under the proposed Provider to Patient Exchange objective, making that measure worth 50 points in 2019 and 45 points beginning in 2020."	This proposed language is confusing, but it seems to indicate that if an EH or CAH is able to claim an exclusion to any public health measure, then they would have their points redistributed. If that is the case, we strongly disagree with this approach. **We recommend that CMS allow EH and CAH to get credit for the work that they have done, even if they are not able to meet <u>all</u> of the measures in this area. AIRA recommends changes to the EH and CAH exclusion wording for the Public Health and Clinical Data Exchange objective consistent with those submitted by the Council of State and Territorial Epidemiologists (CSTE): CMS should use exclusion wording similar to the Public Health and Clinical Data Registry Reporting objective in the Meaningful Use Stage 3 rule, where if EHs or CAHs claim an exclusion for a public health measure, they can substitute it with one or more of the remaining public health measures to obtain the 10 points for the objective.** EHs and CAHs should work with their state public health agencies to identify which of the six reporting measures the agency is ready to receive data for. Only if three or more measures cannot be met may an EH or CAH claim an exclusion.

Section, Page Number	Excerpt	Comment
Page 20521	"…Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, Electronic Reportable Laboratory Result Reporting."	**We recommend renaming the Immunization Registry Reporting measure to Immunization Registry Data Exchange,** since this measure includes both submission to and query from an immunization registry, or immunization information system (IIS).
Page 20525	"Finally, we are proposing to rename the Public Health and Clinical Data Registry Reporting objective to the Public Health and Clinical Data Exchange objective…"	**We support renaming this objective, as "Public Health and Clinical Data Exchange" is more representative of the dynamic nature of EHR-IIS interfaces than "registry reporting."** As mentioned above, most IIS now respond to provider queries, as well as submissions, so "exchange" is a more accurate term.

Section, Page Number	Excerpt	Comment
Page 20521-20523	Proposed Performance-Based Scoring Methodology for EHR Reporting Periods in 2019: e-Prescribing – 10 points Bonus: Query of Prescription Drug Monitoring Program (PDMP) – 5 points bonus Bonus: Verify Opioid Treatment Agreement – 5 points bonus Support Electronic Referral Loops by Sending Health Information - 20 points. Support Electronic Referral Loops by Receiving and Incorporating Health Information - 20 points Provide Patients Electronic Access to Their Health Information – 40 points Syndromic Surveillance Reporting (Required) and one or more additional: Immunization Registry Reporting. Electronic Case Reporting. Public Health Registry Reporting. Clinical Data Registry Reporting. Electronic Reportable Laboratory Result Reporting – 10 points	Based on the scoring in the proposed rule, it appears that an eligible hospital or CAH could completely ignore the Public Health and Clinical Data Exchange objective, and would still potentially compile enough points to pass with the other three objectives alone. **AIRA strongly recommends that this objective be amended to require EHs and CAHs to attest to three of the six proposed public health measures of Syndromic Surveillance Reporting, Immunization Registry Reporting, Clinical Data Registry Reporting, Electronic Case Reporting, Public health Registry Reporting, and Electronic Reportable Laboratory Result Reporting.** An EH or CAH should exhaust all available measures to ensure all possible efforts are made to meet this objective and only if a public health agency is unable to support three objectives may the EH or CAH claim an exclusion.

Section, Page Number	Excerpt	Comment
Pages 20535-20536	"...we are proposing that eligible hospitals and CAHs would be required to attest to the Syndromic Surveillance Reporting measure and at least one additional measure from the following options: Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting."	We are concerned that the NPRM proposes to reduce the public health measures from three to two, Syndromic Surveillance (SS) plus one other from a list. It is not clear why Syndromic Surveillance is now being required. It is also not clear why other public health measures are being deprioritized. There is great public health benefit in maintaining high population-based immunization rates, and Immunization Registry Reporting is an excellent and evidence-based successful tool to support these high immunization rates. **We strongly recommend that immunization registry reporting be reconsidered as a required measure, given the high value of immunization data at the point of care, and the positive health impact of high immunization rates, and that this measure and at least two additional measures be selected to meet this objective. In lieu of that requirement, we recommend that three public health measures be required, allowing hospitals to select the measures they prefer.**

Section, Page Number	Excerpt	Comment
Page 20536	"We are seeking public comment on the role that each of the public health and clinical data registries should have in the future of the Promoting Interoperability Programs and whether the submission of this data should still be required when the incentive payments for meaningful use of CEHRT will end in 2021."	We have seen great strides in EHR-IIS Interoperability following the introduction of Meaningful Use and MACRA/MIPS. The number of IIS receiving HL7 2.5.1 production data from EHRs has grown from 19.7% (9 IIS) in 2011[4] to 94.5% in 2016, with 67% (37) IIS capable of bidirectional (or query and response) messaging.[5] In addition, a presentation from Epic EHR at the 2018 National Immunization Conference (NIC) detailed the millions of queries that are sent by EHRs to IIS from just a subset of interfaces from this single vendor[6]; these queries support clinical decisions and avoid over-immunization, protecting individuals from vaccine preventable disease while also ensuring funds are used appropriately. **We have seen substantial success in the development of EHR-IIS interfaces, and we strongly recommend that requirements and incentives for reporting continue to ensure greater progress in this area.**

[4] MMWR, 2013, accessed 5/31/2018: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6249a4.htm
[5] MMWR, 2017, accessed 5/31/2018: https://www.cdc.gov/mmwr/volumes/66/wr/mm6643a4.htm
[6] NIC 2018 abstracts, accessed 5/31/2018: http://www.cvent.com/events/48th-national-immunization-conference/agenda-8b963918dc5b4dc3bb548786b087b96f.aspx

Section, Page Number	Excerpt	Comment
Page 20536	"In addition, we intend to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022, and are seeking public comment on whether hospitals will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective and measures are removed, as well as other policy levers outside of the Promoting Interoperability Program that could be adopted for continued reporting to public health and clinical data registries, if necessary."	**We are deeply concerned about CMS's stated intent to remove public health measures altogether for CY2022 and beyond, and we recommend against this removal.** The incentive programs have been very successful at promoting interoperability across clinical medicine and public health. We don't believe that switching to a new and/or separate policy intervention would bring the same benefits as a well-established incentive program and could have other unintended consequences. The benefits of IIS, as supported by the current incentive program, are well-established. A 2016 presentation by Kaiser Permanente's Vaccine Safety Datalink project compared data on adolescents in Kaiser's EHR with data in local IIS, and found the IIS contained an additional 8.3% of immunization data over what was captured in the EHR for consistently enrolled adolescents; this number jumped to 18% for adolescents with enrollment gaps.[7] IIS add benefit through the consolidation of longitudinal patient records; these benefits will decline if data sharing declines.

[7] Kaiser Permanente presentation, 2016, accessed 5/31/2018: http://repository.immregistries.org/resource/track-d-partners-and-stakeholders/

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Page 20537	"...we also request public comment on whether we should modify the objectives and measures for eligible professionals (EPs) in the Medicaid Promoting Interoperability Program in order to encourage greater interoperability for Medicaid EPs."	**We advocate for stronger measures for public health generally, and immunization registry submission and query, specifically, for eligible professionals (EPs).** There is great clinical and public health benefit in providers accessing the consolidated record and forecast at the point of care, and this protocol represents the current standard of practice for providers. If these rules are strengthened to prioritize immunization registry data exchange, there may be some benefit in consistency of rules across EH, CAH, and EPs.

Section, Page Number	Excerpt	Comment
Page 20537	"For example, we are seeking public comment on whether participation in the Trusted Exchange Framework and Common Agreement (TEFCA) should be considered a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective."	While we support the approach to create a nationwide framework with TEFCA, there are many areas where the intent and outcome of TEFCA are not yet clear or detailed, so this area is difficult to comment on. Also, there are additional areas where the proposed TEFCA rules do not meet the needs of public health. For example, in not including a push use case, TEFCA as written leaves out the primary method for immunization submission, which will keep the majority of immunization reporting outside of TEFCA's proposed activities. **If participation in TEFCA is considered an incentivized health IT activity, we ask that the scope of TEFCA be expanded to include the needs of public health, while also leveraging the strengths of public health data.**

Section, Page Number	Excerpt	Comment
Page 20538	"HHS could develop a health IT activity under which an eligible hospital or CAH would participate in a pilot, and eventually implement in production, use of an API based on the emerging update to the FHIR standard which would allow population level data access through an API in lieu of reporting on measures under the Public Health and Clinical Data Exchange objective."	We are concerned that this would weaken the public health reporting requirements, as it provides a separate option for anyone willing to pilot emerging standards. IIS have demonstrated success through creating standardized, automated interfaces with a majority proportion of the hospitals and providers in their jurisdictions. **We do not support that pilots for emerging standards should be allowed to substitute for measures under the Public Health and Clinical Data Exchange objective. However, we support incentivizing innovation and use of emerging standards elsewhere, and would welcome the opportunity to support pilots that were NOT drawing participation away from the Public Health and Clinical Data Exchange objective."**

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Page 20544	"Therefore, we are proposing to amend § 495.322 to provide that the 90 percent FFP for Medicaid Promoting Interoperability Program administration would no longer be available for most State expenditures incurred after September 30, 2022."	We are concerned about the complete phase-out of the 90/10 program by 9/30/2022. Our members have greatly benefitted from the receipt of 90/10 matched dollars. These programs provide a substantial amount of support for public health programs, and it is this support that is helping to implement and expand EHR-IIS interoperability. In the absence of this support, IIS will not be able to standardize their systems at the same pace with more well-resourced hospitals, providers and EHRs. **We strongly advocate for the continuation of 90/10 matching funds, and encourage the exploration of additional funds to adequately support the important work of IIS, and the continued development of invaluable EHR-IIS interfaces.**