



June 3, 2019

The Honorable Seema Verma Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P Submitted electronically <http://www.regulations.gov>

Re: Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers

Dear Administrator Verma:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input this proposed rule.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers and public health experts who bring meaning to data, manage information and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

AMIA strongly supports CMS in its effort to provide beneficiaries improved access to health plan data through modern application programming interface (API) standards and policies to enable beneficiary access without special effort. We view these data as important components to better define the picture of patient/beneficiary care, and we appreciate CMS efforts to align standards in this proposed rule to those proposed for adoption in ONC's 21st Century Cures Act proposed rule,¹ known as the US Core Data for Interoperability (USCDI), as well as aligning with existing HIPAA transaction and NCPDP SCRIPT standards.

This alignment is foundational to accomplish the goals espoused by CMS "to move the health care ecosystem in the direction of interoperability," and "to improve access to, and the quality of, information that Americans need to make informed health care decisions, including data about health care prices and outcomes, while minimizing reporting burdens on affected plans, health care providers, or payers." However, we encourage CMS to consider additional aspects necessary to fulfillment of these intended policy impacts.

¹ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. April 23, 2019. 84 FR 16834. <https://www.federalregister.gov/documents/2019/04/23/2019-08178/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>

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Namely, we caution CMS that despite the existence of standards there is inconsistent adoption and use of such standards by various stakeholders, especially for laboratory results, drug benefit data, pharmacy directory information and formulary data. This will undoubtedly complicate the exchange and use of these data, so we recommend CMS work closely with plans and the information system vendors upon which they rely. The development of specific version and implementation guidance may be necessary to ensure that adoption and uses of specific standards is harmonized across plans. Should this be insufficient, CMS may need to consider whether specific certification criteria are needed as data diversity and payloads grow over time.

Establish a phased approach to require health plan data be made available via open API

In considering CMS's proposed timelines for adoption and deployment, AMIA recommends a phased approach for specific data proposed to be made available through open APIs. Specifically, we understand that HIPAA transaction standards, such as patient claims and encounter data, are more uniformly adopted across regulated industry. And there is promising work underway to develop implementation guides for a set of resources that payers can display health data to consumers via a FHIR API.² We anticipate that plans could more easily adopt these standards when compared to USCDI data and the NCPDP standards.

While we support the inclusion of USCDI into these proposals, we note that the USCDI FHIR version and content/vocabulary have not yet been finalized by HHS. While AMIA has recommended ONC finalize FHIR Release 4 and include the "unstructured document" template as part of the USCDI's Clinical Notes data class,³ formal implementation guides from HL7 will not be available for plans until later in 2019 (or possibly 2020). For this reason, AMIA recommends CMS require the availability of USCDI data via "open API" as part of phase 2, likely not before 2021.

As part of phase 2, or more likely as part of phase 3, AMIA recommends CMS establish requirements for plans to make available drug benefit data, including pharmacy directory information and formulary or preferred drug list data, through the APIs. These standards are well-established, but they are not consistently adopted and used. The information systems that exchange and use eRx transactions can be variable because not all stakeholders use certified EHR technology (CEHRT) to generate those data. Further, pharmacy directory, and formulary data is often incomplete and non-standard, which complicates access, exchange, and use.

AMIA strongly recommends that CMS commence with such a phased approach no sooner than July 2020, to give plans time to adopt and adhere to the proposed requirements for open APIs. We also

² CARIN Alliance Blue Button 2.0 Framework and Common Payer Consumer Data Set (CPCDS), <https://build.fhir.org/ig/HL7/carin-bb/>

³ AMIA Response to ONC 21st Century Cures Act NPRM (84 FR 16834). May 23, 2019. Available at: <https://www.amia.org/sites/default/files/AMIA-Response-to%20ONC-Cures-NPRM.pdf>

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recommend that CMS finalize its proposals to give State Medicaid and CHIP agencies additional time to adopt these standards, given their resource limitations.

Proceed with limited scope on eNotification Medicare Conditions of Participation (CoP) requirements

In comments submitted to CMS in June 2018 as part of the IPPS NPRM we recommend that CMS garner experience and insights under the Information Blocking rule, once finalized, before deciding to modify COP/CfC/RFPs. We also recommended that “Should CMS endeavor in this direction, we recommend considering Admission, Discharge, Transfer (ADT) feeds as potential candidates for incorporation into CoPs/CfCs/RFPs updates.”⁴

Given CMS is pursuing these changes, we recommend that CMS proceed with the strategy articulated in this NPRM to require hospitals that possess certified EHRs to demonstrate that its system sends notifications that include the minimum patient health information (1) patient name, (2) treating practitioner name, (3) sending institution name, and, if not prohibited by other applicable law, (4) patient diagnosis. We recommend that hospitals demonstrate this capacity for both scenarios described in this NPRM (at admission and at discharge) for a single patient during FY 2020. Rather than requiring eNotifications for all admissions or discharges, a single patient will ensure basic capability over the near-term and allow CMS to monitor industry compliance with HHS’s Information Blocking provision. As with other programs administered by CMS, a single patient requirement should be seen as a steppingstone towards fuller requirements in subsequent payment years.

Further, we recommend that CMS not specify a specific standard for these transactions at this time, but compile stakeholder feedback over the next payment year to better understand which standards and technical approaches are preferred by industry.

Enhance application requirements for all CMMI models to optimize the use of health informatics and improve interoperability, fund Clinical Informatics fellowships through new funding models

In response to the 2017 Request for Information (RFI) on “CMS Innovation Center New Directions,” AMIA urged CMMI to place a “greater emphasis on the interdependency of payment and delivery reforms, supported by health IT and health informatics.”⁵ We are heartened by the

⁴ AMIA Response to CMS 2019 IPPS NPRM. June 2018. Available at:

<https://www.amia.org/sites/default/files/AMIA-Response-to-CMS-2019-IPPS-NPRM.pdf>

⁵ AMIA Response to CMS Innovation Center ‘New Directions’ RFI. November 20, 2017. Available at:

<https://www.amia.org/sites/default/files/AMIA-Response-to-CMS-Innovation-Center-New-Direction-RFI.pdf>

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inclusion of this RFI seeking additional input on Advancing Interoperability in Innovative Models and appreciate the opportunity to continue the conversation.

We understand that CMMI has limited authority to establish specific pilots / models for purposes of testing new uses of technology. However, CMMI has wide latitude to develop service delivery models that preference applications that promote interoperability and advance health IT. The Accountable Health Communities Model is a good example where CMMI has included specific goals to improve collection of social determinants of health (SDOH) data as part of the model.⁶ To this end, AMIA strongly recommends CMMI evaluate application requirements across models to ensure they convey how health informatics and IT will be leveraged to improve care and advance interoperability. Informatics tools and methods will be central to the success of many, if not all, new models established by CMMI, and this will require that applicants describe their clinical informatics infrastructure and capacity. Application enhancement should also identify key personnel – including nurses, physicians, and other clinical staff – with health informatics and health IT responsibilities.

Beyond application enhancements, AMIA recommends CMMI explore ways to foster the growth of advanced clinical informatics professionals – specifically, Board-certified Clinical Informaticians.⁷ The future of medicine and healthcare requires trained clinicians with expertise in the systematic collection, analysis, and application of data. Board-certified Clinical Informaticians provide such expertise in leveraging health IT and health data for patient care and quality improvement. However, the health and growth of this new and promising medical subspecialty – and its effect on care delivery – are threatened by outdated and inconsistent funding models that fail to support the education and professional growth of Clinical Informaticians when compared to other clinical specialties.⁸

Structural and specified funding mechanisms for the training of Clinical Informatics fellows is necessary for CMS to attain stated goals for improved interoperability and use of data for patient care. AMIA calls on policymakers and federal funders to create direct support for ACGME-accredited Clinical Informatics fellowships through new funding models at CMMI.

CMS, not ONC, should establish industry adoption timelines for health IT

Finally, we strongly recommend CMS re-assert its jurisdictional purview to establish industry adoption timelines for health IT, rather than cede this responsibility to ONC. In the recently

⁶ <https://innovation.cms.gov/initiatives/ahcm/>

⁷ Lehmann CU, Gundlapalli AV, Williamson JJ, Fridsma DB, Hersh WR, Krousel-Wood M, Ondrula CJ, Munger B. Five Years of Clinical Informatics Board Certification for Physicians in the United States of America. *Yearb Med Inform.* 2018 Apr 22. doi: 10.1055/s-0038-1641198.

⁸ Lehmann CU, Longhurst CA, Hersh W, Mohan V, Levy BP, Embi PJ, Finnell JT, Turner AM, Martin R, Williamson J, Munger B. Clinical Informatics Fellowship Programs: In Search of a Viable Financial Model: An open letter to the Centers for Medicare and Medicaid Services. *Appl Clin Inform.* 2015 Apr 15;6(2):267-70. doi: 10.4338/ACI-2015-03-IE-0030.

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proposed rule from ONC, several provisions dictate both development and deployment timelines for certified health IT. To our knowledge, ONC's proposals represent the first instance where the Office assumed both roles: dictating development timeline and provider deployment timeline requirements. In comments submitted to ONC we urged them to establish development timelines only, and leave adoption requirements for hospitals and clinicians to other HHS agencies, namely to CMS in the case of certified health IT.⁹

We again urge ONC and CMS to work collaboratively in setting requirements for development and adoption of certified health IT. Further, we encourage CMS to leverage certification when appropriate to better ensure that providers who are required to adopt IT for specified functionality have what they need to fulfill the requirement.

We appreciate CMS's work in this important area, and we are eager to bring the expertise of health informatics professionals to this national priority. Thank you for considering our comments. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continued partnership and dialogue.

Sincerely,



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FACMI
President and CEO
AMIA



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(Enclosed: Detailed AMIA Recommendations to ONC Cures Act NPRM)

⁹ AMIA Response to ONC 21st Century Cures Act NPRM (84 FR 16834). May 23, 2019. Available at: <https://www.amia.org/sites/default/files/AMIA-Response-to%20-ONC-Cures-NPRM.pdf>

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CMS proposes that the regulated entity (that is, the MA organization, the State Medicaid or CHIP agency, the Medicaid managed care plan, the CHIP managed care entity or the QHP in an FFE, as applicable) would be required to implement and maintain an open API that permits third-party applications to retrieve, with the approval and at the direction of the individual beneficiary, data through the use of common technologies and without special effort from the beneficiary.

AMIA Response: AMIA enthusiastically supports the goals espoused by CMS to improve patient access to their health information maintained by MA organization, the State Medicaid or CHIP agency, the Medicaid managed care plan, the CHIP managed care entity or the QHP in an FFE, (regulated entities). Further, we support efforts to align with and reference standards used by ONC in [insert regulation citation]. Specifically, we agree with CMS proposals to reference content, vocabulary, and transport standards required at 45 CFR 170.213 and we are encouraged by CMS proposals to adopt similar – if not the same – policies as ONC’s API conditions at § 170.404 to ensure APIs are “open.” It will be important that CMS compel plans to make APIs open not just from a technical perspective, but from policy and practical perspectives as well. We recommend CMS finalize efforts to align standards for “open” APIs as proposed.

* * *

CMS requests comment on the data proposed to be made available as detailed in the subsections below, the appropriateness of the proposed timeframes, and suggestions for alternative timeframes that consider the utility to the beneficiary, as well as challenges that the proposed timeframe may create for the entities that would have to comply. CMS proposes that MA organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs, permit third-party applications to retrieve, with the approval of an enrollee, certain specific data, including:

- (1) Patient Claims and Encounter Data
- (2) Provider Directory Data
- (3) Clinical Data including Laboratory Results
- (4) Drug Benefit Data, including Pharmacy Directory, and Formulary Data

AMIA Response: AMIA supports these proposed data to be made available via API. However, we caution that much more than simply referencing standards will be necessary to achieve CMS’s stated goals. We note that CMS is requiring delivery of standard data elements through non-standard APIs using technology that is not tested to be conformant and/or interoperable with those specified standards.

Despite reliance on specific standards maintained at 45 CFR 170.213, 45 CFR 170.215, 45 CFR 162 and 42 CFR 423.160, we are unclear how CMS proposes to ensure that APIs deliver such data consistently and uniformly for beneficiaries. For example, our members indicated that eRx transactions are variable because some stakeholders use CEHRT, while many others in the data production/management chain do not. Members also experience drug benefit data, pharmacy directory and formulary data that is often incomplete and non-standard.

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While this may not ultimately factor into the success of beneficiaries having access to these data, we anticipate that regulated entities will need additional guidance, at a minimum, to ensure their adoption and use of specific standards is harmonized with others adopting and using the same standard. CMS may need to consider whether specific certification criteria are needed as data diversity and payloads grow over time.

[d. Documentation Requirements for APIs](#)

CMS is proposing that the specific business and technical documentation necessary to interact with the proposed APIs be made freely and publicly accessible. Specifically, at 42 CFR 422.119(d), 431.60(d), 457.730(d), and 45 CFR 156.221(d), CMS proposes virtually identical text to require publication of complete accompanying documentation regarding the API by posting this documentation directly on the applicable entity's website or via a publicly accessible hyperlink.

CMS proposes that the publicly accessible documentation would be required to include, at a minimum, the following information:

- API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.
- The software components and configurations an application must use in order to successfully interact with the API (for example, to connect and receive data through the API) and process its response(s).
- All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

AMIA Response: We support the spirit of these requirements, but question how CMS will hold regulated entities accountable for these requirements. Further, CMS will need to consider how to determine if the publicly accessible documentation is sufficient for some apps or all apps to connect as the policy intends.

[e. Routine Testing and Monitoring of Open APIs](#)

CMS is proposing that the API be routinely tested and monitored to ensure it is functioning properly.

AMIA Response: AMIA is concerned generally with this proposed approach to “routine testing and monitoring.” As we understand it, CMS would require regulated plans to “establish and maintain processes to routinely test and monitor the open APIs to ensure they are functioning properly, especially with respect to their privacy and security features,” which would require plans

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“to implement, properly maintain, update (as appropriate), and routinely test authentication features that will be used to verify the identity of individual enrollees who seek to access their claims and encounter data and other PHI through the API,” as well as “ensure an individual enrollee or their personal representative can only access claims and encounter data or other PHI that belongs to that enrollee.” While these requirements seem reasonable, we are concerned they greatly underspecify plans’ responsibilities and will likely not result in the routine testing and monitoring sought.

We recommend CMS consider a series of questions as part of this proposal’s finalization, such as:

- How often is routine?
- How would CMS verify that such testing has been performed (e.g. what documentation would satisfy compliance concerns)?
- What sort of reporting expectation would plans have to demonstrate compliance?

[j. Applicability and Timing](#)

For MA organizations, under 42 CFR 422.119(h), CMS proposes that the requirements would be effective beginning January 1, 2020. For Medicaid FFS at 42 CFR 431.60, CHIP agencies that operate FFS systems at 42 CFR 457.730, Medicaid managed care plans at 42 CFR 438.242(b)(6), and CHIP managed care entities at 42 CFR 457.1233(d)(2), CMS is proposing that the API requirements would be effective beginning July 1, 2020, regardless of when the managed care contract started. CMS requests feedback about this proposed timing from the industry. In particular, CMS is interested in information and request comment from MA organizations about their current capability to implement an API consistent with this proposal and the costs associated with compliance by January 1, 2020, versus compliance by a future date.

AMIA Response: We anticipate that this timeline will be difficult for stakeholders to meet for a host of reasons. First, the USCDI v1 will likely not be finalized until late in 2019 or early 2020 and there is an open debate over which standards (FHIR Release versions and Implementation Guides) will be engrained in regulation. In response to this question, AMIA has recommended FHIR Release 4 and US Core Implementation Guides.¹⁰ Second, it is not clear that even with an additional six months under-resourced Medicaid and CHIP programs will be able to move at the pace of MAs or QHPs.

As articulated in our transmittal letter, AMIA recommends CMS establish a phased approach to require proposed data be made available via open API. Phase 1 should include the data proposed for Patient Claims and Encounter Data; phase 2 should include Provider Directory Data and Clinical Data including Laboratory Results; and phase 3 should include proposed Drug Benefit Data, including Pharmacy Directory, and Formulary Data. We anticipate that phase 1 data could be feasibly available via API beginning July 2020 for those plans CMS proposes to provide all data

¹⁰ AMIA response to ONC Cures NPRM: <https://www.amia.org/sites/default/files/AMIA-Response-to%20-ONC-Cures-NPRM.pdf>

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types beginning January 2020. We recommend a staggered approach for the other plans and subsequent phases, aligning USCDI requirements with ONC timelines for developers. CMS should encourage ONC to establish a specific timeline for certified health IT to comply with the USCDI standard by January 2021. This would enable phase two to begin in July 2021 and phase 3 near January 2022. We do not anticipate that more aggressive timelines will be feasible nor warranted.

[X. Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals \(CAHs\)](#)

Given responses to the recent RFI on Conditions of Participation, as well as previous rulemaking activities, CMS is seeking to further expand CMS requirements for interoperability within the hospital and CAH CoPs as part of this proposed rulemaking by focusing on electronic patient event notifications. CMS proposes to revise the CoPs for Medicare- and Medicaid-participating hospitals at 42 CFR 482.24 by adding a new standard at paragraph (d), “Electronic Notifications,” that would require hospitals to send electronic patient event notifications of a patient’s admission, discharge, and/or transfer to another health care facility or to another community provider.

AMIA Response: In comments submitted to CMS in June 2018 as part of the IPPS NPRM we recommend that CMS garner experience and insights under the Information Blocking rule, once finalized, before deciding to modify COP/CfC/RfPs. Further, we recommended CMS focus its inquiry on provider-to-patient information flows and calibrate its policies to ensure that all entities receiving Medicare funds provide patients 24x7x365 access to their information in a persistent manner and without special effort. We are heartened to see the latter of these recommendations being pursued by HHS.

In these comments we also recommend that “Should CMS endeavor in this direction, we recommend considering Admission, Discharge, Transfer (ADT) feeds as potential candidates for incorporation into CoPs/CfCs/RfPs updates.”

Given CMS is pursuing these changes, we recommend that CMS proceed with the strategy articulated in this NPRM to require hospitals that possess certified EHRs to demonstrate that its system sends notifications that include the minimum patient health information (1) patient name, (2) treating practitioner name, (3) sending institution name, and, if not prohibited by other applicable law, (4) patient diagnosis. We recommend that hospitals demonstrate this capacity for both scenarios described in this NPRM (at admission and at discharge) for a single patient during FY 2020. Rather than requiring eNotifications for all admissions or discharges, a single patient will ensure basic capability over the near-term and allow CMS to monitor industry compliance with HHS’s Information Blocking provision.

Further, we recommend that CMS not specify a specific standard for these transactions at this time, but compile stakeholder feedback over the next payment year to better understand which standards and technical approaches are preferred by industry.

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[XI. Request for Information on Advancing Interoperability Across the Care Continuum](#)

CMS is soliciting comment on several potential strategies for advancing interoperability across care settings to inform future rulemaking activity in this area. To enable the bidirectional exchange of this health information, **CMS is seeking public comment on whether hospitals and physicians should adopt the capability to collect and electronically exchange a subset of the same PAC standardized patient assessment data elements (for example, functional status, pressure ulcers/injuries) in their EHRs.**

CMS is seeking comment on whether to move toward the adoption of PAC standardized data elements through the expansion of the USCDI process. CMS is interested in whether the standardized patient assessment data elements that are implemented in CMS PAC assessment instruments in satisfaction of the IMPACT Act would be appropriate. If the full set of such standardized patient assessment data elements is not appropriate, CMS is seeking comment on whether a subset of these standardized items would be appropriate, and input on which data elements should be prioritized as part of a subset. CMS is also seeking information on what implementation timeline would be most appropriate for requiring adoption of these data elements in provider and hospital systems under the ONC Health IT Certification Program. CMS is also seeking comment on the administrative, development, and implementation burden that may be associated with adopting these data elements.

AMIA Response: We are strong advocates for CMS to help promote the adoption and advanced use of health IT. We see CMS as the primary driver for the use of such tools through payment and reimbursement incentives. While mandates to adopt or use health IT, such as through ONC's recent proposal, may be expedient, such requirements fail to reward investment in health IT.

CMS policies, such as the Quality Payment Program, reward clinicians who invest in health IT by creating bonus potential in reimbursement, rather than simply penalize for the lack of such capability. So too must CMS work to establish similar dynamics across the care continuum.

While we acknowledge CMS efforts to compel the adoption and use of health IT via reporting of electronic PAC assessment data, such efforts will continue to fail because these policies do not provide upside payment incentives – only downward payment adjustments. Overwhelming evidence suggests that PAC settings have lagged the rest of the care continuum in adoption and advanced use of health IT because a large share of these settings were not eligible for EHR Incentives. To improve interoperability across these settings, AMIA recommends CMS look for mechanisms provide PAC settings with bonus payments for exemplary use of health IT.

As for requiring collection of PAC data elements by hospitals and physicians, we do not support such an approach. Requiring EHR-enabled institutions to collect data for transmission to

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stakeholders who do not possess commensurate technology will not improve adoption of EHRs in this latter group.

XII. Advancing Interoperability in Innovative Models

CMS plans to utilize Center for Medicare and Medicaid Innovation ("Innovation Center") authority under section 1115A of the Act to test ways to promote interoperability across the health care spectrum.

AMIA Response: Generally, AMIA strongly supports efforts by CMMI to improve interoperability and the advanced use of health informatics through its statutory authorities. Given the state of health IT adoption among inpatient and ambulatory settings, we are supportive of CMMI efforts to view its portfolio of models as means to encourage investment in advanced health IT capabilities and to understand how emerging technology / data can best be utilized to improve outcomes and costs for beneficiaries.

* * *

CMS requests public comment on the following general principles around interoperability within Innovation Center models for integration into new models, through provisions in model participation agreements or other governing documents.

1. Provide Patients Access to their Own Electronic Health Information
2. Promote Trusted Health Information Exchange
3. Adopt Leading Health IT Standards and Pilot Emerging Standards

AMIA Response: AMIA strongly supports the use of model participation agreements or other governing documents to improve interoperability, encourage advanced use of health IT, and the application of novel data to beneficiary care. In response to the 2017 Request for Information on "CMS Innovation Center New Directions," AMIA urged CMMI to place a "greater emphasis on the interdependency of payment and delivery reforms, supported by health IT and health informatics."¹¹

While we appreciate that CMMI has limited authority to establish specific pilots / models for purposes of technology pilots, it has wide latitude to develop service delivery models that preference applications that promote interoperability and advance health IT. Specifically, AMIA recommends CMMI should explore ways to leverage enhanced application requirements to optimize the use of informatics in support of patient care for priority diseases, conditions, and/or populations.

AMIA recommends CMMI evaluate application requirements across models to ensure they convey how informatics will be leveraged. Informatics tools and methods will be central to the success of many, if not all, new models established by CMMI, and this will require that applicants describe their informatics infrastructure and capacity, including key personnel. Such a focus on enhanced

¹¹ <https://www.amia.org/sites/default/files/AMIA-Response-to-CMS-Innovation-Center-New-Direction-RFI.pdf>

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application requirements will have both near-term and long-term benefits. For example, near-term benefits include:

- More thoughtful consideration of informatics tools, methodologies, and approaches among potential CMMI awardees;
- More coordination among key stakeholders within CMMI awardee organizations to develop such strategies; and
- More critical assessments of capabilities, needs, and metrics to be successful.

Further, the benefits of enhancing application requirements to explicitly outline awardees' informatics strategy will increase over time. We anticipate that – in aggregate – awardee applications will:

- Encourage the private-sector to coalesce on specific data standards and implementation methodologies, which will increase the likelihood that successful efforts are generalizable;
- Enable successful awardees to develop and disseminate best practices and education models;
- Create opportunities to organize “innovation commons” for shared resources, such as workflow redesigns, software integration strategies, natural language processing, and shared clinical decision support services; and
- Help CMS better understand large-scale approaches to support population health management, social determinants of health in clinical care, chronic care management and other kinds of care coordination.

To be successful, CMMI must ensure that application reviewers possess requisite competencies in informatics to discern quality applications. This will not only be important for the assessment of awardee applications, but for program evaluation as well. Financial savings is an important marker of model success, but it cannot be the only marker. Understanding what worked and didn't work from an informatics perspective may elucidate potential vagaries related to cost and quality. Including informatics professionals as part of the program management and evaluation of all future models is prerequisite for CMMI to attain the near-term and long-term benefits described above.

As it pertains to the general principles outlined by CMMI, we view the first two as tactics that could be better generalized as:

1. **Align health IT adoption and use requirements across Medicare & Medicaid programs and CMMI models.** This principle would dictate, where appropriate, that CMMI model participants would be expected to provide similar or the same digital functionalities as what Medicare/Medicaid require. For example, adoption of the USCDI and requirements to make patient data available through APIs should become the norm for innovation models, if they are required of Medicare participants. The same should be true for participation in “trusted exchange” and eNotifications, should that proposal be finalized.
2. **Identify ways to further HHS goals for trusted exchange and interoperability through CMMI models.** This principle would encourage activities such as those outlined in principle 3 above and it should encourage CMMI model participants to identify activities and

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functionalities that are more advanced than what is generally required of Medicare/Medicaid participants.

3. If CMS proceeds with the principles as outlined, the third principle to “Adopt Leading Health IT Standards and Pilot Emerging Standards,” seems appropriately scoped for various models and we enthusiastically support this focus and leadership role for CMMI.

* * *

Additionally, the Innovation Center is requesting public comment on other ways in which the Innovation Center may further promote interoperability among model participants and other health care providers as part of the design and testing of innovative payment and service delivery models.

AMIA Response: The future of medicine must be characterized by the delivery of superior care with measurable improvements in outcomes and reduced cost. Necessary for this future are an optimized, usable and interoperable health IT and trained clinicians with expertise in the systematic collection, analysis, and application of data. Board certified Clinical Informaticians provide such expertise in leveraging HIT and health data for patient care and quality improvement.^{12,13} Clinical Informatics experts possess the requisite skills and competencies to make systems-level improvements in care delivery using HIT, workflow and data analytics, knowledge acquisition, clinical decision support, data visualization, and related informatics tools. However, the sustainability and growth of this new and promising medical subspecialty – and its effect on care delivery – are threatened by outdated and inconsistent funding models that fail to support the education and professional growth of Clinical Informaticians when compared to other clinical specialties.¹⁴ Currently, only approximately 70 fellowship positions are available annually for Clinical Informatics. Considering the more than 5,500 hospitals in the US, it becomes apparent that without an increased pipeline of trained and educated informaticians, health care systems will continue to struggle to find the talent needed to implement, maintain, update, and optimize their clinical information systems and data. Subsequently, a lack of appropriately trained and educated Clinical Informaticians perpetuates underperformance in the pillars of value-based care – patient safety, care quality, and cost reduction.

AMIA urges Congress and the current Administration to establish structural and specified funding mechanisms for the training of Clinical Informatics fellows. Specifically, we call on policymakers and

¹² Lehmann CU, Gundlapalli AV, Williamson JJ, Fridsma DB, Hersh WR, Krousel-Wood M, Ondrula CJ, Munger B. Five Years of Clinical Informatics Board Certification for Physicians in the United States of America. *Yearb Med Inform.* 2018 Apr 22. doi: 10.1055/s-0038-1641198. [Epub ahead of print] PubMed PMID: 29681038.

¹³ Lehmann CU, Shorte V, Gundlapalli AV. Clinical informatics sub-specialty board certification. *Pediatr Rev.* 2013 Nov;34(11):525-30. doi: 10.1542/pir.34-11-525. Review. PubMed PMID: 24187144

¹⁴ Lehmann CU, Longhurst CA, Hersh W, Mohan V, Levy BP, Embi PJ, Finnell JT, Turner AM, Martin R, Williamson J, Munger B. Clinical Informatics Fellowship Programs: In Search of a Viable Financial Model: An open letter to the Centers for Medicare and Medicaid Services. *Appl Clin Inform.* 2015 Apr 15;6(2):267-70. doi: 10.4338/ACI-2015-03-IE-0030. eCollection 2015. PubMed PMID: 26171074; PubMed Central PMCID: PMC4493329.

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federal funders to create direct support for Clinical Informatics fellowships through competitive, institutional grants funded through CMMI. To operationalize this recommendation, we offer below a series of options leading towards funding of ACGME accredited Clinical Informatics fellowships.

First, CMMI could establish a multi-year innovation model for ACGME-accredited institutions to propose how Clinical Informatics fellows would improve the quality and cost of care. Then, CMMI should engage in targeted evaluations to identify the benefits created by participants, who employ trained physicians in Clinical Informatics. These models could determine average costs savings per program / fellow, a portion of which could be dedicated to expanding institutional limits of ACGME trainees, with the goal of creating a long-term, sustainable funding model.

While AMIA's primary recommendation is for a new innovation model, an additional tactic would be for CMMI to implement enhanced application requirements that further promote and optimize the use of informatics tools and capabilities in select payment models tested by CMMI. Based on the results of these informatics-enhanced payment models, appropriate steps by CMS could find sustainable funding mechanisms or implement incentives for institutions to prioritize training for these specialists.

We have entered an era, where the practice of medicine is no longer limited to medical devices and drugs to improve patient outcomes. Clinical Informatics and data are an integral part of the practice of medicine in the 21st century. Practicing medicine without the help of Clinical Informatics equals practicing outdated or inefficient medicine. Just as clinicians are expected to use medical devices and pharmaceuticals to improve patient outcomes, so too must we expect them to leverage evidence-based informatics tools and methodologies. We recognize that evaluating implementation of informatics as an intervention is difficult, but we strongly believe it is important aspect to this this increasingly important dimension of care delivery.

Dedication to rigorously reviewing the informatics components of CMMI grantees will allow for greater involvement and integration with real-world environments and will improve the generalizability of models beyond the pilot stage of CMMI grants.

[XIII. Request for Information on Policies to Improve Patient Matching](#)

AMIA has collaborated with the Pew Charitable Trusts on the issue of patient matching and we echo comments developed by Pew for this RFI.

CMS' proposed rule includes an RFI on patient matching to obtain input on steps the agency can take to address this challenge. In issuing this RFI, CMS correctly recognizes that to achieve interoperable exchange of medical data, health organizations must also know that they are communicating about the same person. Presently, up to half of the information exchanges made by

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health care organizations may fail to accurately match records for the same patient.¹⁵ Congress, in Cures, also recognized that ineffective patient matching can inhibit interoperability by commencing a Government Accountability Office (GAO) study, which was released in January of this year.¹⁶

Ineffective patient matching can have patient safety and cost ramifications. Patients may receive inappropriate care and face the possibility of medical errors if information used for treatment is missing or inaccurate; one in five hospital chief information officers surveyed said that patient harm occurred within the last year due to a mismatch.¹⁷ In an extreme example, the care for an 11-month-old twin was documented in her sister's record, resulting in the failure of the health system to recoup \$43,000 in costs from the insurer.¹⁸

To accurately match records held at different health care facilities, organizations typically compare patients' names, dates of birth, and other demographic data to determine if records refer to the same individual. Health care facilities use algorithms to conduct these matches, and also employ staff to manually review records. This process often fails to accurately link records because of typos entered into the system; similarities in names, birth dates or addresses among different patients; changing information, such as when individuals move or get married; and many other reasons.¹⁹

While some private sector technologies—such as referential matching, wherein third-party data are used to support matches—show promise, market forces have been unable to solve the patient matching problem for decades. In fact, patient matching requires collaboration between unaffiliated organizations, even competitors, that lack incentive to agree to a set of standards or develop systems that seamlessly exchange information.

Pew conducted two years of research—including interviews with health care providers, focus groups with patients, and contracted studies—to examine different ways to address matching challenges. This research revealed two critical ways that the federal government can improve patient matching. CMS should collaborate with ONC to ensure that these steps are taken.

Standardize certain demographic data already collected

First, CMS should work with ONC to require the use of standards for certain demographic data

¹⁵ Genevieve Morris et al., “Patient Identification and Matching Final Report” (2014),

https://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf.

¹⁶ Government Accountability Office, “Health Information Technology: Approaches and Challenges to Electronically Matching Patients’ Records across Providers” (2019), <https://www.gao.gov/products/GAO-19-197>

¹⁷ College of Healthcare Information Management Executives, “Summary of CHIME Survey on Patient Data-Matching” (2012), https://chimecentral.org/wpcontent/uploads/2014/11/Summary_of_CHIME_Survey_on_Patient_Data.pdf

¹⁸ Beth Haenke Just and Karen Proffitt, “Do You Know Who’s Who in Your EHR?” *Healthcare Financial Management* 63, no. 8 (2009): 68-73,

https://www.justassociates.com/application/files/2514/9124/7591/HFM_August_2009_Do_You_Know_Whos_In_Your_EHR.pdf.

¹⁹ Congressional testimony (<https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2019/03/26/electronic-health-records-see-both-improvement-and-persistent-gaps-since-2016-law>)

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elements—an approach long recommended by many other organizations, including Audacious Inquiry in a report contracted by ONC.²⁰

In Pew-funded research published recently in the *Journal of the American Medical Informatics Association*, experts at Indiana University studied whether the standardization of different data elements improves patient matching rates.²¹ Researchers attempted to match records in four databases, standardized the data in those databases, and then retried matching the records to determine whether that standardization yielded better results. The researchers culled tens of thousands of records from the Indiana Health Information Exchange; a county public health registry; Social Security’s Death Master file; and a newborn screening laboratory. Each of these databases had already been reviewed to ensure that the record matches were accurate, which allowed researchers to understand the number of correct and inaccurate matches both before and after the standardization of select demographic data.

The research revealed that the standardization of address to the standard employed by USPS, which details the preferred abbreviations for street suffixes and states, for example, would improve match rates by approximately 3 percent. One technology developer indicated that this would help their system match an additional tens of thousands of records per day. Separately, standardizing last name to the standard used by the Council for Affordable Quality Healthcare—while showing limited utility on its own—would further improve match rates up to 8 percent if standardized along with address.

As part of ONC’s proposed rule, the agency incorporates phone number and address in the U.S. Code Data for Interoperability (USCDI), a collection of critical health information that should be exchanged and made available by EHRs via APIs. ONC could further improve match rates by requiring use of the USPS standard for address within the USCDI. To further promote use of this standard, ONC and CMS should also coordinate with USPS to ensure that health care organizations can use the postal service’s online, API-based tool—or another easily accessible mechanism—to convert addresses to the USPS standard. There may also be scenarios—such as for military personnel stationed abroad—where the use of the USPS standard is not feasible. ONC could restrict use of the USPS standard to domestic, non-military addresses if challenges arise in the broader use of the standard.

Adopt additional data elements for patient matching

Second, CMS should encourage ONC to require use of other regularly collected demographic data elements for patient matching. ONC currently requires EHRs to make some demographic data—such as name, birth date, and sex—available, and proposes to add address and phone number to the

²⁰ Genevieve Morris et al.

²¹ Shaun J Grannis et al., “Evaluating the effect of data standardization and validation on patient matching accuracy,” *Journal of the American Medical Informatics Association* 26, no. 5 (May 2019): 447–456, <https://doi.org/10.1093/jamia/ocy191>

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USCDI. However, health records contain other demographic data routinely collected that aren't typically used or made available to match records.

For example, research published in 2017 showed that email addresses are already being captured in more than half of patient records.²² The documentation of email is likely higher today given the adoption of patient-facing tools, like portals, that often require emails to register.

CMS should encourage ONC to improve match rates by identifying and including in the USCDI readily available data elements—such as email address, mother's maiden name, or insurance policy identification number—that health information technologies should use for matching.

Specific comments on CMS' patient matching RFI

CMS seeks input on a variety of steps the agency can take to address patient matching.

First, CMS requests information on whether the agency should advance more standardized data elements across all appropriate programs for matching purposes, perhaps leveraging the USCDI proposed by ONC. As mentioned above, CMS should work with ONC and then adopt enhanced standards for demographic data. Specifically, CMS should encourage ONC to use the USPS standard for address and facilitate the addition of other regularly collected demographic data, such as email address, to the USCDI.

Second, CMS solicits input on whether to require use of a patient matching algorithm or solution with a “proven” success validated by the Department of Health and Human Services or a third-party. While not requiring the use of a specific technology, benchmarking different approaches would help shed a spotlight on matching deficiencies and the wide variation in quality across different algorithms. Technology developers could then use that information to improve their algorithms, and health care providers could adopt the most promising approaches. CMS should work with ONC to determine how to benchmark different matching approaches; this likely requires the identification of a large, real-world data set to test different algorithms. The use of real-world data, rather than synthetic data, is essential given that some innovative approaches—such as referential matching—use third-party databases to support their algorithms. CMS or ONC may be able to use grantmaking authorities or other policies to obtain such a data set for benchmarking. This benchmarking could assess duplicate creation rates, the number of records correctly matched, and the frequency with which records are incorrectly merged.

Third, CMS requests input on whether to expand recent efforts to issue new Medicare identification numbers to support patient matching. Implementing an agency-wide identifier may help CMS better serve beneficiaries and improve matching. However, this approach is still insufficient to address matching on a nationwide scale. A unique identifier would still face limitations in matching patients

²² Adam Culbertson et al., “The Building Blocks of Interoperability: A Multisite Analysis of Patient Demographic Attributes Available for Matching,” *Applied Clinical Informatics* 8, no. 2 (2017): 322-336, <https://doi.org/10.4338/ACI-2016-11-RA-0196>.

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to information prior to enrollment in federal health insurance programs, and they may still be susceptible to errors (e.g. typos that exist today with the use of Social Security numbers). Pew conducted [focus groups](#) with patients on patient matching that highlighted frustration with having to remember a number or card that could be lost or stolen, just like Social Security numbers. Health care providers interviewed by Pew in collaboration with the Massachusetts eHealth Collaborative also voiced concerns with adoption, implementation costs, and human errors that affect data quality. Given those limitations, even if CMS pursues broader use of a CMS-wide identifier, the agency should still push forward with optimizing the use of other demographic data, including adoption of the USPS standard for address and the use of additional data elements.

Fourth, CMS seeks information on the number and type of third-party data sources to use for identity proofing and verification, as well as limitations. Referential matching—wherein these third-party data sources are used to support matches—has shown promise for improving patient matching.²³ However, use of third-party data also has limitations. These data sources may contain inaccuracies, and lack information for some populations.²⁴ For example, these data sources do not contain information on children, and therefore have limitations in providing an added benefit for matching pediatric records.

Finally, CMS request into on how patient-generated data can complement patient matching efforts. Pew collaborated with the RAND Corporation to examine patient involvement in record matching.²⁵ The research revealed two key ways for patients to support record matching. For one, patients could validate their demographic information by verifying their mobile phone number and other data. In addition, EHRs could support smartphone applications that use standard APIs to allow patients to update their demographic data. CMS could coordinate with ONC and the technology industry to pilot these patient-led approaches. In addition, Pew research revealed a promising approach to patient matching that has not yet been widely used in health care: biometrics, such as fingerprint or facial recognition scans. In Pew-led focus groups on patient matching, patients overwhelmingly preferred the use of biometric over other options.²⁶ Patients in the focus groups indicated that they already use biometrics in other aspects of their lives—such as to unlock smartphones or board airplanes—and should be able to use the same approach for record matching. Pew intends to conduct further research on how the health care system could use biometrics to match records across different organizations while protecting patient privacy and the security of data.

²³ [The Pew Charitable Trusts, “Enhanced Patient Matching Is Critical to Achieving Full Promise of Digital Health Records: Accurately linking individuals with their records essential to improving care,” Oct. 2, 2018,
\[https://www.pewtrusts.org//media/assets/2018/09/healthit_enhancedpatientmatching_report_final.pdf\]\(https://www.pewtrusts.org//media/assets/2018/09/healthit_enhancedpatientmatching_report_final.pdf\)](#)

²⁴ <https://www.cujournal.com/opinion/want-better-analysis-consider-the-data>; <https://www.cnbc.com/2017/09/27/the-real-problem-with-credit-reports-is-the-astounding-number-of-errors-equifax-commentary.html>

²⁵ [Robert S. Rudin et al., “Defining and Evaluating Patient-Empowered Approaches to Improving Record Matching,” RAND Corp., accessed Aug. 27, 2018, \[https://www.rand.org/pubs/research_reports/RR2275.html\]\(https://www.rand.org/pubs/research_reports/RR2275.html\)](#).

²⁶ Cite pew focus group brief