OeHI
Office of eHealth Innovation

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U.S. Department of Health and Human Services

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To Whom it May Concern,

Recently the U.S. Department of Health and Human Services (HHS) published two proposed regulations (CMS-9115-P and RIN-0955-AA01). The proposed rules were drafted in close concert between staff at the Centers for Medicare and Medicaid Services (CMS) and the HHS Office of the National Coordinator for Health IT (ONC). Additionally, ONC recently published a second version of the Trusted Exchange Framework and Common Agreement (TEFCA). HHS seeks public comments on all three of these items.

Due to the common goals and dependencies, we are respectfully submitting a combined set of comments for all three items on behalf of Colorado's Office of eHealth Innovation (OeHI), an Office of the Governor, and the Colorado eHealth Commission- a governor appointed advisory committee to OeHI and steering committee for Colorado's Health IT Roadmap efforts. To cohesively explain the impact to Colorado, OeHI and the eHealth Commission are submitting comments together.

Comments

Global comments that apply to both proposed rules and TEFCA version 2:

- Overall, OeHI and the eHealth Commission support the comments submitted by the Colorado Department of Health Care Policy and Financing (HCPF) and the Health Information Exchanges (HIEs) of Colorado. We support all comments submitted by these organizations in response to the U.S. Department of Health and Human Services' proposed rules (CMS-9115-P and RIN-0955-AA01) and version 2 of TEFCA and the associated documents.
- The eHealth Commission, as expressed during their April eHealth Commission meeting, is deeply concerned about the costs associated with all aspects of these initiatives. More federal support is needed to create or modify the state infrastructure. HHS has invested heavily in the current health information exchange infrastructure -- both through ONC grants and Medicaid IT funding. The eHealth Commission is in support of moving toward a model that benefits most parties and state investments and we are not in favor of a new model that favors certain organizations and standards through program requirements. Achieving full coverage for all patients will involve reducing the anti-competitive and anti-cooperative practices, not reducing the number of players in the market.
- HHS should consider all of these efforts as part of the infrastructure needed to measure and improve whole person care which includes both health and social aspects of care. This means that HHS should look for opportunities to align policy and integrate data from federal, state, and local initiatives that collect related information and outcomes for matters related to: justice, education, housing, and employment. Additionally, HHS should support states through funding opportunities and collaboration to better align efforts underway and to leverage social information in an actionable way.

- CMS and ONC should conduct a specialized overview for states of the Transformed Medicaid Statistical Information System (T-MSIS), TEFCA, the proposed rules, the Recognized Coordinating Entity (RCE) funding opportunity, and the HIPAA FAQs. With so many touchpoints, the timelines and dependencies between these closely related interoperability programs may not be clear to each audience.
- The Colorado eHealth Commission is largely in support of the concepts within the proposed regulations, especially innovation, improved interoperability, and more options for patients to own and share their ePHI. However, in a recent survey of Colorado healthcare consumers, OeHI learned that the top concerns of most patients would not be addressed by these proposed rules or TEFCA. Rather, the survey respondents were overwhelmingly more concerned with understanding their insurance options and benefits, as well as more information about how to effectively evaluate the costs and value of services. We encourage HHS to consider these priorities as they create the infrastructure to build towards these goals.
- Timelines are too aggressive on all proposed requirements. CMS and ONC should consider the timelines for states related to procurements, CMS approvals, conducting roadmap analysis, and building/testing/running new technology. Furthermore, there are dependencies that are somewhat misaligned. For example, several managed care entities (e.g., Medicaid and CHIP MCOs, Medicare Advantage Organizations, and QHPs on the Federally Facilitated Exchange) would be required to participate in a Trusted Exchange Framework, which we assume is TEFCA, by January 1, 2020. The TEFCA RCE is not even expected to be awarded until late 2019 and the Common Agreement is expected in 2020.
- As a result of this timeline misalignment, Colorado's eHealth Commission earnestly requests that CMS and ONC consider the dependencies for each step in implementing these requirements. HHS may wish to convene a planning group to discuss the implementation of the ultimate requirements from the proposed rules and TEFCA. This group could discuss the competing priorities and the trade-offs of an aggressive timeline, as well as the timeline for requesting IT funds from CMS, procuring vendors, and establishing new policies and procedures.
- The HIPAA FAQs that HHS released on April 19, 2019 clarified the responsibility of providers and patients when there are questions about the technicalities of the law. However, Colorado's eHealth Commission has concerns about the spirit of HIPAA and how patients will truly understand if they are exposing their sensitive healthcare data, to whom, and for what purposes. The state will not have control over the patient's identity and consent and patients may have difficulty managing or understanding this. We are concerned about applying a free-market *laissez-faire* approach to something so volatile and complex. Software application ownership chains (i.e., who ultimately owns the application, including how that changes over time) may expose patients' data to foreign companies' ownership and rules. These risks may not always be clear to patients and the applications' stated terms and conditions are often ignored. This issue around consent management and full understanding presents a great concern for our state.
- As touched upon above, HHS has dramatically underestimated the costs associated to stakeholders in this arrangement.
  - Any requirements for managed care plans will be added to the administrative costs of their capitation rates, a cost borne by the state downstream.
  - In Colorado, we have spent over a decade of time and resources into cultivating a state-specific health information exchange effort. We have invested heavily into our HIEs, as has HHS. We talk more below about the costs that HIEs and other health data exchange participants will bear in order to make TEFCA effective.
  - As discussed below, CMS needs to be more clear about Medicaid IT spending commitments. We understand that this would be outside of the rule, but it is challenging for states to make commitments without this information.
- There are more opportunities for efficiency in the right places. CMS and ONC have a number of efforts underway related to interoperability, but the roadmap is not clear. Previous roadmaps have offered temporary clarity, but they are often focused on one agency or the other. Colorado recommends that CMS and ONC invest some time in stakeholder management by truly

educating and persuading stakeholders of the path forward. CMS and ONC should consider the full range of activities underway to support interoperability, the various stakeholders on each effort, the timelines, the costs, and competing priorities. For example, T-MSIS could be leveraged better in this effort, and there are a lot of unanswered questions around patient identity management across multiple systems.

- HHS is enthusiastically supporting FHIR standards. The Colorado eHealth Commission requests that CMS and ONC consider potential challenges and vulnerabilities. Furthermore, there should be technical assistance and a clear glide path from FHIR 2.0 to FHIR 4.
- Regarding the Request for Information (RFI) to support a national patient matching strategy, we are in support of a solution that requires social service and healthcare organizations to collect key and consistent data points in order to match individuals and families across multiple systems. At a minimum, this should include requiring widespread use of the U.S. Postal Service's standard address protocol. Furthermore, we encourage HHS to think about any solution in concert with Social Determinants of Health (SDoH). This may mean that HHS creates an inter-department stakeholder group including, but not limited to, the Department of Justice, Department of Housing and Urban Development, the Veterans Administration, and the Department of Education.

Comments that apply to TEFCA only:

In February 2018, Colorado submitted public comments on the first version of TEFCA. This set of comments is focused on how TEFCA enables or hinders the Colorado Health IT Roadmap.

- TEFCA version 2 largely supports the objectives and initiatives in Colorado's Health IT Roadmap, with the exception of issues related to Governance and Policy, Data Governance, Consent Management.
- Colorado has committed at least a decade of time and funding to the current HIE landscape. The proposed TEFCA model may upset states with stable HIE models. CMS and ONC should clarify how they expect the current marketplace to change to comply with TEFCA. As discussed above in the global comments, HHS and Colorado should protect the investments made and look for ways to cultivate important roles for all players that achieves the goals of TEFCA.
- Regardless of disruption to current HIE business models, any entity attempting to become a Qualified Health Information Network (QHIN) will need new infrastructure to connect to other QHINs and exchange data. Furthermore, HINs will need on-ramp infrastructure to serve up stored data. As mentioned above, the Colorado eHealth Commission has concerns about how those costs will or will not be offset by value-added services and consolidation or efficiency in the current market.
- There is an insufficiency of business cases for healthcare providers, HINs, and QHINs to absorb the costs associated with building this infrastructure. For example, if there are too few federal or other payer obligations (e.g., Medicare reimbursement consequences) and the costs to participants are too high, participants will opt not to participate. Furthermore, Medicaid has the opportunity to create some market equity, particularly for rural providers, who might otherwise find fees too high and data exchange opportunities too few, to commit to new fees.
- CMS and ONC should establish clear commitments for how each agency expects the needed infrastructure to be funded. In order to make plans, states need firm commitments for federal funding such as Medicaid Management Information System (MMIS) Federal Medical Assistance Percentage (FMAP) at the 90% or 75% level.
- Notwithstanding Medicaid's cost allocation rules for health information exchange, it is unclear how Medicare will contribute.
- As Colorado commented in 2018, we still have a great deal of concern about the governance of the RCE and opportunities to learn from stakeholders and address concerns. HHS may wish to

augment an existing Federal Advisory Committee Act (FACA) committee by creating a subcommittee that would advise ONC and the RCE, as well as providing some public transparency around the policymaking and decisions.

Thank you for your careful consideration in reviewing and applying the comments herein from the Colorado OeHI. If you have any questions, please contact our office.

Thank you,

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