

June 20, 2023

Submitted electronically via: https://www.regulations.gov/

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20201

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (RIN 0955–AA03)

Dear Dr. Tripathi,

Vizient, Inc. appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology's proposed rule regarding the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (RIN 0955-AA03) (hereinafter, "Proposed Rule"). Many of the topics in the Proposed Rule have a significant impact on our members and the patients they serve given the critical role of health information technology (HIT) in the healthcare system.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than \$130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to various issues and proposals provided in the Proposed Rule, including those related to the United States Core Data for Interoperability (USCDI) and predictive support interventions. In addition, we offer our support for ONC's efforts to implement provisions of the 21st Century Cures Act and update the ONC Health IT Certification Program with new standards, specifications and certification criteria, as this will help advance interoperability and information exchange.

Transition to USCDI v3

ONC proposes to adopt USCDI v3 as the new baseline for certification and provides that only v3 could be used after December 31, 2024. Also, as noted by ONC, if finalized, the adoption of USCDI v3 would update the standard to include data elements such as sexual orientation and social determinants of health (SDoH). Vizient has often highlighted the need to standardize data elements, including those related to SDoH. Vizient appreciates the proposed transition from USCDI v1 to v3, as this will be an important step towards more standardized data.

In the Proposed Rule, ONC does not address when stakeholders could anticipate future iterations of USCDI to be updated in regulation. As ONC is aware, USCDI v4 is in the process of being finalized and stakeholders, including Vizient, have offered <u>recommendations</u> to ONC regarding an updated version. In addition, the Office of Management and Budget is in the process of updating race and ethnicity statistical <u>standards</u> which could result in USCDI v3 being outdated. Vizient suggests ONC clarify when stakeholders may anticipate future updates to the certification criteria.

Lastly, Vizient encourages ONC to provide resources and support to healthcare providers to ensure any change of standards is not disruptive and not implemented in a burdensome manner.

Requirements for Decision Support Interventions and Predictive Models (Algorithmic Transparency)

In the Proposed Rule, ONC proposes to update existing decision support criteria to clearly include predictive decision support (PDS). As noted in the Proposed Rule, PDS intervention means, "Technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis." Also, to shed light on the impetus for the new requirements that aim to increase transparency regarding PDS, ONC describes the "outputs" from PDS interventions as recommendations (e.g., "for new sets of information that are necessary to guide decision-making based on recommendations (outputs) from predictive DSIs"). However, the proposed definition of PDS intervention includes examples for outputs that are significantly broader than recommendations since it includes "prediction, classification, evaluation or analysis". Vizient is concerned that the proposed definition of PDS intervention is overly broad, as it could be interpreted to include any type of information or analysis, even if no recommendation or specific prediction is provided. Vizient suggests ONC narrow the definition of PDS intervention to focus on outputs that are recommendations. Should the Proposed Rule be finalized, we also encourage ONC to work with providers to provide additional education regarding PDS interventions and to ensure that development of PDS interventions, including those developed by providers, are not unreasonably limited by the Proposed Rule's requirements.

Conclusion

Vizient appreciates ONC's efforts to gain additional feedback regarding the Proposed Rule. Vizient membership includes a variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. In closing, on behalf of Vizient, I would like to thank ONC for providing the opportunity to respond to this Proposed Rule. Please feel free to contact me, or Jenna Stern at ienna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

Shodhomakula

Shoshana Krilow

Senior Vice President of Public Policy and Government Relations

Vizient, Inc.