June 20, 2023

Dr. Micky Tripathi
National Coordinator
The Office of the National Coordinator for Health Information Technology
330 C St. SW
Washington, DC 20024

RE: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing [88 FR 23746]

Dear Dr. Tripathi:

The College of Healthcare Information Management Executives (CHIME) respectfully submits our comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule, as published on April 18, 2023 in the *Federal Register* (Vol. 88, No. 74).

Background

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With over 5,000 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate for the effective use of information management to improve the health and healthcare in the communities they serve.

Key Recommendations

CHIME appreciates the opportunity to comment on ONC's "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule – henceforth referred to as "HTI-1" or the "HTI-1 proposed rule."

With the insight CHIME and its members have from being at the forefront of health IT issues, we urge ONC when finalizing the HTI-1 proposed rule – to at a minimum, delay the proposed timelines, prioritize reducing provider burden and burden across the whole healthcare continuum when implementing provisions of the 21st Century Cures Act and updating the ONC Health IT Certification Program (Certification Program).

In our comments, we respond to various issues raised in the proposed rule and offer recommendations to constructively improve the final rule. We thank you for the opportunity to share our views on ONC's proposals. CHIME believes the following areas are important for ONC to consider when finalizing the HTI-1 proposed rule.

- **Timelines**: We strongly recommend that no timelines be imposed any sooner than 24 months following publication of the final rule.
- **Interagency Coordination:** CHIME encourages ONC and other agencies, especially the Food and Drug Administration (FDA), to continue to coordinate – including engaging with the healthcare industry – to ensure that this proposal and the FDA's ongoing efforts around artificial intelligence (AI) and clinical decision support (CDS) do not add redundancy and burden to the healthcare industry via regulations and guidance.
- **Impact on Innovation & Burden on Healthcare Industry**: Our concerns regarding the unintended hindrance on innovation and the substantial burden on the healthcare industry – especially hospitals and healthcare systems – are detailed throughout our comments below.
- **New Definition of "Predictive DSI"**: ONC is proposing a definition of "predictive DSI" to mean "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." CHIME broadly supports the proposed definition of "predictive DSI." Additionally, we broadly agree that it is important for purchasers – of "predictive DSI" to have "source attribute" information.
    - CHIME strongly believes that when our members build alternative solutions to be used "in-house" (i.e., within their own HDO), they should: 1) not be subject to the entirety of "predictive DSI" requirements; and 2) not be penalized – either by ONC or their EHR vendor who could pass on any "costs" to the HDO to use their own health IT tools.
    - An HDO that self-develops predictive DSIs and who choose to share source attribute information with an EHR vendor should be protected by a "hold harmless" agreement/clause (i.e., release of liability).
    - We generally support requiring IT developers to share the build, test, and train data – however, CHIME opposes ONC directing and/or mandating where healthcare delivery organizations (HDOs) must display any source attribute data.
    - Additional recommendations are included throughout our comment letter.
- **New Advisory Committee/HITAC Subcommittee**: Given the magnitude, impact, and burden of this proposed rule – especially on hospitals and healthcare systems, as well as providers, clinicians, and the patients they serve – CHIME is recommending that ONC create a new, semi-permanent subcommittee under the HITAC to focus on the final HTI-1 rule and its implementation.
- **Information Blocking Enhancements**: CHIME supports ONC's proposal to modify the definition of a "health IT developer of certified health IT" to make clear that healthcare providers who self-develop certified health IT for their own use would continue to be excluded from this definition. However, we continue to recommend that providers who offer instances of their EHR to other HDOs should not be considered a health IT developer.

Detailed Recommendations

As ONC states, "implementation of the proposed rule's provisions will advance interoperability, improve transparency, and support the access, exchange, and use of electronic health

information."[1] While we have significant concerns with ONC's proposal regarding predictive DSIs – as discussed further below – we appreciate ONC's ongoing efforts to advance health data exchange and interoperability while promoting health equity for all.

HTI-1 General Comments

ONC notes that "this proposed rule is consistent with Executive Order (E.O.) 13985 of January 20, 2021, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government[2] and E.O. 14091 of February 16, 2023, Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.[3] Section 1 of E.O. 13985 states that "the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality." Section 1 of E.O. 13985 also states that because "advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies must recognize and work to redress inequities in any policies and programs that serve as barriers to equal opportunity."

The healthcare sector has evolved significantly to help shape, adapt, and adopt technology to support key healthcare goals around the exchange of information, privacy, security, and equity. ONC has taken a laudable approach in their commitment to advancing health equity. However, while we have achieved tremendous progress, many gaps and challenges persist alongside new and emerging ones for the healthcare industry, providers, and patients.

CHIME remains supportive of efforts to promote accessibility to healthcare services including technology and devices, as well as expanding data collection, reporting, and analysis to identify disparities and track any improvements. However, we encourage ONC to ensure coordination with the Department of Health and Human Services (HHS) and other agencies, including the Centers for Medicare & Medicaid Services (CMS), which has ongoing efforts focusing on enhanced payment policies to improve access to those who experience social risk factors that impact their health outside of the four walls of their provider's office and those who may experience other barriers to accessing the care they need. **Our members are dedicated to making care safer and encouraging the highest-quality care. Patient safety, not just for all or some patients, but for each individual patient, is of the utmost importance for hospitals and health systems.**

ONC notes that this proposed rule would "provide transparency; ***advance […] innovation,*** [emphasis added] and interoperability; and support the access, exchange, and use of electronic health information (EHI)." **CHIME members have expressed significant concerns that this**

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[1] *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule | HealthIT.gov*. (n.d.). Retrieved May 16, 2023, from https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program

[2] United States, Executive Office of the President [Joseph Biden]. Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Jan 20, 2021. 86 FR 7009-7013, https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.

[3] United States, Executive Office of the President [Joseph Biden]. Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Feb 16, 2023. 88 FR 10825-10833, https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal.

proposal may unintentionally stifle innovation in the healthcare industry. While we acknowledge the importance of government oversight, it is essential to strike a balance that fosters a culture of innovation and advancement in healthcare. Excessive regulation can inadvertently impede progress and hinder the development of innovation and interoperability, which we agree with ONC can greatly benefit patients, providers, and the healthcare system as a whole.

Innovation plays a crucial role in addressing the evolving challenges and complexities of the healthcare landscape. By encouraging new ideas, technologies, and approaches, we can unlock transformative advancements that enhance efficiency, advance innovation and interoperability, and improve patient care. However, as proposed, we are concerned that ONC is creating an overly burdensome regulatory environment that stifles entrepreneurial spirit and discourages – and potentially disables – healthcare providers' ability to invest in new, innovative solutions. CHIME details further concerns regarding innovation throughout our comments below. Finally, new policies should strive to improve quality in healthcare, when applicable.

Before this regulation becomes effective, and throughout its implementation, ONC, alongside other agencies such as the Agency for Healthcare Research and Quality (AHRQ), should fund and carry out peer-reviewed, comprehensive studies to assess both the actual and real impact of these proposals, specifically regarding the implementation burden imposed on healthcare stakeholders and quality of care improvements.

A recent Congressionally-required study from AHRQ and others, which according to the authors, is the first study evaluating information from stakeholders on racial and ethnic bias related to healthcare algorithms found that:[4]

> *Low health literacy, poor clinician awareness, and the technical complexity of many algorithms likely affect patients' low level of familiarity.* ***Increased research and communication to enhance patient health literacy regarding the use of algorithms and their potential for bias is needed. The complexity and sensitivity of the topic also calls for prudence when communicating with patients and the public*** [emphasis added]***.***

This shows further – directly from HHS counterparts – that a careful approach must be taken when regulating predictive DSI and AI in healthcare. The same study noted that: "Algorithms require maintaining and updating after initial development and implementation. Algorithms developed and updated via automated machine learning processes could eventually become inadvertently biased."

It also noted that specific solutions to address bias in healthcare algorithms "include standardizing approaches for variable definitions and data collection; standardizing risk-adjustment models used in health care algorithms; endorsing systematic and rigorous methods for algorithm development, testing, and implementation; and independent monitoring of algorithm implementation and outcomes." Further, it suggests: "Government could establish national standards for algorithm development, testing, and reporting to create standard frameworks for risk adjustments and to audit algorithms in use."

[4] Jain A, Brooks JR, Alford CC, et al. Awareness of Racial and Ethnic Bias and Potential Solutions to Address Bias With Use of Health Care Algorithms. *JAMA Health Forum*. 2023;4(6):e231197. doi:10.1001/jamahealthforum.2023.1197

As far as our knowledge extends, no rigorous studies have been conducted to determine whether the proposed policies in this rule will advance interoperability, support the access, exchange, and use of electronic health information (EHI), or provide improvement in care. Implementing changes as seismic as the ones proposed in this rule related to predictive DSIs should be studied before exacting wholesale changes on healthcare providers and other stakeholders.

Impact on CHIME Members

CHIME has significant concerns regarding the cost-estimate[5] ONC has prepared in the regulatory impact analysis (RIA), as directed by Section 3(f)(1)) of E.O. 12866 – that to "the best of [their] ability presents the costs and benefits of this proposed rule."[6] ONC estimates "that the total annual cost for this proposed rule for the first year after it is finalized" to "health IT developers to be $742 million and estimate the government (ONC) costs to be between $62,000 to $124,000."

ONC's cost calculations quantify health IT developers' time and effort to implement these proposals through new development and administrative activities. Further, ONC:

> *recognize[s] that the costs developer incur as a result of these proposals may be passed on to certified technology end-users. These end-users include but are not limited to the nearly 5,000 non-federal hospitals who provide acute, inpatient care and over 1 million clinicians who provide outpatient care to all Americans. Official statistics show that nearly all U.S. non-federal acute care hospitals[7] and the vast majority of outpatient physicians use certified health IT.[8] These proposals affect the technology all these health care providers use.*

What is of extreme concern to CHIME and our members is that ONC states:

> *To this end, we acknowledge that these estimated costs may not be borne solely by the health IT developers and could be passed on to end-users through health IT developers' licensing, maintenance, and other operating fees and costs.* ***We assume health IT developers may pass on up to the estimated costs of these proposals, but not amounts above those estimated totals. […] To the extent the costs associated with the updates we have proposed have not been taken into account, these costs may be passed on to end-users in different ways by health IT developers and across different health care provider organization types.*** *[emphasis added]*

In other words, ONC assumes and acknowledges that health IT developers will pass up to $742 million – in the first year alone – in costs onto HDOs. Not only will the costs be insurmountable for some – especially safety-net, critical access hospitals (CAHs), and rural hospitals and health systems – but our members will need to address EHR usability challenges and concerns as a result of this proposal. Further, they will need to create and implement significant clinician and staff education efforts. Additionally, these proposals will necessitate arduous workflow and

[5] https://www.federalregister.gov/d/2023-07229/p-223
[6] https://www.federalregister.gov/d/2023-07229/p-222
[7] *National Trends in Hospital and Physician Adoption of Electronic Health Records | HealthIT.gov*. (n.d.). https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-record
[8] *Office-based Physician Electronic Health Record Adoption | HealthIT.gov*. (n.d.). https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption

configuration of EHRs, which requires individual EHR system usability and safety testing – a resource intensive and costly undertaking. CHIME strongly believes that this proposal will – or as ONC "assumes" – impose a substantial financial burden in terms of implementation without providing clear or defined advantages or benefits.

CHIME has and continues to be a staunch champion when it comes to the need for the use of technology standards aimed at facilitating better patient care. However, a "one size fits all" approach – as this rule proposes – will be especially detrimental to long-term and post-acute care providers that have invested in EHRs, including certified EHRs (CEHRT). It furthermore could constitute a significant burden on small, rural, and under-resourced providers. Many HDOs and healthcare providers are experiencing significant challenges related to pandemic burnout and workforce shortages. Therefore, CHIME is concerned that this proposal could inadvertently hinder the success of advancing interoperability across the healthcare continuum which ONC has acknowledged is an ongoing challenge.

Additionally, CHIME strongly believes that advancing interoperability will improve healthcare, but reducing financial burden and complexity must take a front seat. As proposed, we are concerned that these policies, while well-intended, will not achieve this goal. Furthermore, it could threaten to upend access to care which is already seeing erosion among some providers due to the aforementioned post-pandemic burnout and workforce challenges.

Imposing mandates of this magnitude disproportionately impact some providers in our sector more unevenly – especially safety-net providers and long-term and post-acute care providers who never received EHR incentives. While the Health Information Technology for Economic and Clinical Health (HITECH) Act[9] made significant investments in certain areas of our sector, more robust funding is needed to improve interoperability across the entire care continuum.

Moreover, the overall privacy and cybersecurity landscape has become infinitely more complex for all providers. Cybersecurity attacks are on the rise for providers of all sizes which pose a direct threat to patient safety. In fact, this issue has garnered so much attention that HHS issued a landmark report in April on this very issue, the Hospital Cyber Resiliency Initiative Landscape Analysis.[10] Hospitals and other providers are under siege from cyberattacks and already challenged to locate the resources needed to mitigate these hostilities. These issues are particularly exacerbated for small, rural, and safety-net providers, and LTPAC providers that never received EHR incentives. Any new ONC mandates must be carefully balanced with the needs of providers to fend off these attacks on them and their patients - which is a threat to patient safety and our national security.

Relationship to Other Federal Agencies' Relevant Activities, Interests, and Regulatory Authority

As ONC acknowledges, "there is broad interest across the Department in the development, implementation, and use of algorithms and AI in healthcare." ONC notes "that the questions of whether DSIs enabled by or interfaced with certified health IT are subject to FDA regulations, under the Federal Food, Drug, & Cosmetic Act, or are used by entities subject to the HIPAA

[9] Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009), codified at 42 U.S.C. §§300jj et seq.; §§17901 et seq.
10 405d-hospital-resiliency-analysis.pdf (hhs.gov)

Rules, federal nondiscrimination laws,[11] federal consumer protection laws[12] or other federal regulations,[13] are separate and distinct from the question of whether a developer or such technology is subject to regulatory oversight by ONC's Health IT Certification Program, to which [their] proposals pertain." In this proposal, ONC is taking an approach that is both reflective of their authorities and aligned with others in the Department and federal government. ONC states that they are not establishing requirements for technology not certified under the Program.[14]

Given the intersecting nature and interest across the Department to address the use of AI for purposes of health, ONC states that they "consulted extensively with [their] HHS partners." Specifically, ONC states they worked with "counterparts at AHRQ, FDA, and OCR in developing proposals to advance [their] shared goals of promoting predictive DSIs in healthcare that are valid, fair, appropriate, effective, and safe to deliver patient care." ONC "plan[s] to continue to coordinate with these and other federal agencies so that to the extent practicable, federal requirements that may apply to certified health IT and developers of certified health IT are aligned and not duplicative."

While CHIME is appreciative and supportive of a "harmonized and complementing approach" – we wish to emphasize that even ONC acknowledges the National Coordinator has "existing intersecting regulatory oversight" with the FDA around predictive technology; therefore, it is essential that ongoing coordination is prioritized. **CHIME encourages ONC and other agencies, especially FDA, to continue to coordinate (including engaging with the healthcare industry) to ensure that this proposal and FDA's ongoing efforts do not add redundancy and burden to healthcare regulations and guidance.** FDA releases guidance documents on a rolling basis, including recently released draft guidance on "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Function."

ONC notes that the National Coordinator's authority "to regulate developers of certified health IT under the Program is separate and distinct from other federal agencies' regulatory authorities focused on the same or similar entities and technology." ONC provides the following example – "the safety and effectiveness of a software function, including clinical decision support or other kinds of decision support interventions, is within the purview of Food and Drug Administration (FDA) regulatory oversight, if such software functionality meets the definition of a "device." ONC states: "In the area of predictive technology, **ONC and FDA support a harmonized and complementing approach, independent of the platform that the technology exists on, in accordance with our existing intersecting regulatory oversight** [emphasis added]**."**

It will be incumbent upon both agencies to work together as this guidance document is finalized to ensure that there are no redundant requirements for healthcare stakeholders. CHIME members have expressed concern regarding the existing authority that the FDA already has over device CDS, which may result in a duplication of efforts with differing

[11] For more information about covered entities that must comply with federal nondiscrimination laws enforced by OCR, please visit: https://www.hhs.gov/civil-rights/for-providers/index.html.
[12] See FTC, Report to Congress on Privacy and Security, September 2021, https://www.ftc.gov/system/files/documents/reports/ftc-report-congress-privacy-security/report_to_congress_on_privacy_and_data_security_2021.pdf.
[13] See, e.g., SACHRP, *Considerations for IRB Review of Research Involving AI* (discussing the Common Rule), (July 2022) https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-e-july-25-2022-letter/index.html.
[14] See the ONC Health IT Certification Program, https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program.

requirements, meaning providers and EHR vendors would need to satisfy two sets of regulations.

ONC states this proposal is "not establishing new requirements for FDA regulation of software as a device or expectations for software functions that meet the definition of a device,[15] including "Device CDS" software functions that are regulated by FDA as devices." **However, CHIME members believe that it is crucial that ONC take every possible precaution – continuing ongoing coordination with the FDA – to ensure that they do not attempt to regulate the provider and HDO CDS tools that would fall under the proposed definition of "predictive DSI" <u>when they are only used within the HDO that developed the tool.</u> If this means that the FDA needs to release new guidance and/or update existing guidance, this should be done before ONC finalizes their policies.**

<u>Proposed Timelines</u>

ONC has proposed to establish a deadline of December 31, 2024, for developers of certified health IT with Health IT Modules to which the proposed requirements[16] apply to engage in intervention risk management practices and develop both detailed documentation and summary information. This proposed deadline corresponds with other proposals,[17] and supports the proposal to update the Base EHR definition. These timelines, as proposed, are overly ambitious at best, aggressive and detrimental at worst.

Many of our members are extremely concerned about the proposed timelines; their EHR vendors must comply with the magnitude of policies in this proposed rule. They are skeptical and unsure if their EHR vendor will realistically be able to meet these deadlines – and, in turn, their organizations will be unable to support and financially bear the burden of the continuous, ongoing series of upgrades. The timelines need to be extended, and the operational expenses passed onto HDOs should be limited.

We recommend that ONC implement a reasonable timeline that takes into account not only the timelines required for both EHR vendor development and provider training and implementation, but also one that factors in workforce shortages and other competing mandates including existing ones (i.e., providers are still wrestling with implementing Information Blocking rules, which had a deadline of October 6, 2022 – less than a year ago) and forthcoming ones (i.e., CMS's recently proposed Medicare Promoting Interoperability (PI) Program mandated reporting of the Safety Assurance Factors for EHR Resilience (SAFER) guides in the annual proposed inpatient prospective payment system (IPPS) proposed rule for fiscal year (FY 2024). **Therefore, we strongly recommend that any timeline in this proposed rule not be effective any sooner than 24 months following the publication of the final rule.**

The HTI-1 proposals will require that our members develop guidelines, policies, procedures and gather the data required to meet the requirements along with their vendor partners. Once that work is complete, the decisions need to be implemented and communicated across their organizations. This work will take a minimum of 18 to 24 months. Furthermore, ONC must ensure that hospitals and healthcare systems have the time needed to understand the significance of the policies included in the final rule, are

[15] Section 201(h) of the FD&C Act.
[16] § 170.315(b)(11)(vii)
[17] § 170.315(a)(9)(vi)

prepared to meet its requirements, and have the technology and funding to support implementation. Thus, at the earliest, the compliance deadlines should be December 31, 2026.

The United States Core Data for Interoperability Standard (USCDI) v3

If finalized, the adoption of USCDI v3 would update the USCDI standard to include data elements such as sexual orientation and social determinants of health. ONC further notes that expanding the data elements included in USCDI would increase the amount and type of data available to be used and exchanged through CEHRT. CHIME agrees the proposed updates to help capture more accurate and complete patient characteristics would promote the establishment and use of interoperable data sets of EHI for interoperable health data exchange, leading to safer care for patients. However, members have shared concerns that there is a significant cost burden that will stem from implementation of USCDIv3. For example, members have noted that with each new data element added to the USCDI, EHR vendors often charge healthcare providers for a new application programming interface (API). **Given the already substantial cost and burden of the HTI-1 proposal for healthcare providers, we urge ONC to recognize that there is sometimes "hidden" financial burden throughout these policies.**

New and Revised Standards and Certification Criteria: Decision Support Interventions and Predictive Models

This proposed rule would "revise the existing clinical decision support (CDS) certification criterion by proposing a "Decision Support Interventions" (DSIs) certification criterion to keep pace with advances in software that developers of certified health IT enable or interface with to aid decision-making in healthcare." ONC further notes that this "criterion would also advance health equity by design by making it known to users of certified Health IT Modules certified to the criterion whether demographic, social determinants of health (SDOH) assessment data are used in DSIs."

The DSI criterion is a revised certification criterion as it serves as both an iterative and replacement criterion for the CDS criterion. It would reflect an array of contemporary functionalities, data elements, and software applications, including the use of predictive models or algorithms, that certified Health IT Module(s) enable or interface with to aid decision-making in healthcare.

As part of the DSI criterion, ONC is proposing to add "predictive decision support interventions" (predictive DSIs) – and the corresponding proposed definition would include predictive DSIs and the list of current intervention types, including evidence-based decision support in and linked referential DSI. ONC believes together, these intervention types are reflective of the variety of DSIs increasingly enabled by or interfaced with certified Health IT Modules.

ONC is proposing a definition of "predictive DSI" to mean "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."

CHIME broadly supports the proposed definition of "predictive DSI." Additionally, we broadly agree that it is important for purchasers – of "predictive DSI" to have "source attribute" information.

We agree that transparency to the processes that were used to develop the algorithms, and using a standard for ensuring that bias is removed or noted in the development process is important. Thus, while **CHIME generally supports the proposed definition of "predictive DSI," we nonetheless continue to harbor concerns about the overall deterring effect on innovation resulting from this proposed regulation.**

The validation processes involved with clinical trials can be significantly burdensome for some providers. We urge ONC to coordinate with the FDA to ensure there is no duplicative requirements with the FDA's guidance[18] on the "Use of Electronic Health Record Data in Clinical Investigations Guidance for Industry." The FDA guidance states under the validation section: "Sponsors should ensure that the interoperability of EHR and EDC systems (e.g., involving the automated electronic transmission of relevant EHR data to the EDC system) functions in the manner intended in a consistent and repeatable fashion and that the data are transmitted accurately, consistently, and completely."

Additionally, in a "post-meaningful use era", providers have made dramatic advancements in healthcare analytics and are beginning to realize what their data can do to suggest patient-tailored, precision medicine in how treatment plans and care pathways are ultimately activated and determined by a clinician. **By adding additional regulation to how healthcare providers are currently administering safe practices in statistics and data science – the underpinning practices behind predictive analytics – down to the algorithmic level will add additional regulatory burden. In turn, hospitals and healthcare systems' ability to leverage significant IT investments, which support safer and higher quality care, will be ultimately slowed down. We respectfully request that ONC be cognizant of these, and other unintended consequences, as they finalize this rulemaking.**

ONC further states that they "believe that the continued evolution of decision support software, especially as it relates to AI and ML-driven predictive DSIs, necessitates new requirements for the Program's CDS criterion. These include proposed requirements for new sets of information that are necessary to guide decision-making based on recommendations (outputs) from predictive DSIs, such as an expanded set of "source attributes" and information related to how intervention risk is managed by developers of certified HIT with HIT Modules that enable or interface with predictive DSIs." ONC further notes that these "source attributes" must "enable a user to review a plain language description of source attribute information as indicated and at a minimum via direct display, drill down, or link out from a Health IT Module."

CHIME has had a long-standing commitment to fostering an interoperable healthcare ecosystem. As the key standard setting body whose mission is focused on the standards for exchange, integration, sharing and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services, Health Level Seven (HL7) International has had a key role in fostering greater interoperability across our sector. Therefore, we would like to reinforce and reiterate HL7's messaging included in their public comments to this rulemaking – specifically regarding the proposed guidance to include various

[18] U.S. Food And Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-industry

detailed metadata on predictive and evidence-based DSIs. CHIME members strongly agree with our colleagues at HL7 that, as proposed, these regulations create significant implementation burden with unclear benefits. Further, they may also paradoxically increase disparities by reducing innovation and the implementation of DSIs due to increased regulatory burden.

To HL7's knowledge – and further, CHIME's – there have been no rigorous studies evaluating whether the proposed approach leads to any actual improvement in care. Even just for providing a simple literature reference for a DSI, the only directly relevant randomized controlled trial our organizations are aware of is the study conducted by Dr. Clem McDonald over 40 years ago.[19] This study directly evaluated the impact of computer-generated DSI reminders with and without the provision of bibliographic citations and did not find a statistically significant difference in clinician response to the reminders.

Therefore, CHIME reiterates our concerns about the impact burden of this proposal – and previous recommendation that before this regulation becomes effective, and throughout its implementation, ONC, alongside other agencies such as AHRQ, should fund and carry out peer-reviewed, comprehensive studies to assess both the actual and the real impact burden.

ONC further proposes that while they do not prescribe "how a certified Health IT Module must indicate that an attribute is missing, [they] clarify that the certified Health IT Module ***must communicate an attribute is missing unambiguously and in a conspicuous manner to a user*** [emphasis added]" – regardless if the "other parties" have a contractual relationship with the developer of certified health IT.

As proposed, ONC would allow compliance by noting not the specified source attribute or attributes, but that the source attribute or attributes are "missing" or not available. CHIME strongly agrees with HL7 that this addition could cause unintended harm; many clinicians and healthcare providers have alert fatigue and adding yet more irrelevant information, especially a new alert that, more often than not has links to information that, when clicked, simply notes that the proposed required source attributes are not available, is of considerable concern to our members.

We agree with HL7 that this is likely to contribute to further provider burnout, dissatisfaction, and alert fatigue. CHIME wishes to strongly reiterate HL7's concern that it is even possible, and potentially probable, that such an approach would lead to patient harm by increasing the likelihood that providers ignore relevant alerts, including alerts critical for ensuring patient safety, due to an increase in alert fatigue. Finally, CHIME wishes to strongly echo HL7's recommendations that if the source attribute information is not available, that ONC allow Health IT Modules to provide no information or additional links, rather than a link noting that information is not available.

ONC believes that source attributes, as proposed, are foundational for users' understanding of the DSI regardless of whether the intervention developer is a developer of CEHRT, a customer of the developer of CEHRT, an academic health system, integrated delivery network, a third-party software developer, or other party. ONC clarifies that "other parties" includes any party that develops a DSI, a model, or an algorithm that is used by a DSI and is not a developer of CEHRT. These can include, but are not limited to: a customer of the developer of CEHRT, such

[19] McDonald, C. J., Wilson, G. J., & McCabe, G. P. (1980). Physician Response to Computer Reminders. *JAMA*, *244*(14), 1579. https://doi.org/10.1001/jama.1980.03310140037026

as an individual healthcare provider, provider group, hospital, health system, academic medical center, or integrated delivery network; a third-party software developer, such as those that publish or sell medical content or literature used by a DSI; or researchers and data scientists, such as those who develop a model or algorithm that is used by a DSI.

Computerized clinical decision support systems (CDSS), used to augment clinicians in their complex decision-making processes have been used since the 1980s – and have rapidly evolved. "They are now commonly administered through electronic medical records and other computerized clinical workflows, which has been facilitated by increasing global adoption of electronic medical records with advanced capabilities."[20] **Under this proposal, our members are concerned that every invocation of CDS would be regulated – including tools that have been used in healthcare for years to assist clinicians and providers. There are thousands, if not tens of thousands, of existing tools and algorithms that are used in health IT today that do not and should not need oversight. ONC's HTI-1 proposal has the capacity to overwhelm providers if finalized as proposed.**

For example, the Patient Health Questionnaire-9 (PHQ-9) is a nine-item questionnaire designed to screen for depression in primary care and other medical settings.[21] International guidelines recommend screening for depression – and the PHQ-9 has been identified as the most reliable screening tool.[21] Furthermore, PHQ-9 has been widely validated and is recommended in a two-stage screening process.[22] This has all been established by the medical and academic communities with peer-reviewed research, absent the stringent new oversight that ONC is proposing. However, the PHQ-9 would fall under the HTI-1's newly proposed definition of "predictive DSI." To further illustrate using the example of the PHQ-9, our members are already facing undue financial burden to complete and report them correctly. Under this proposal, our members would be doubly regulated and thus, doubly burdened. Therefore, many standard instruments and other forms of CDS should be carefully considered for potential exclusion from the HTI-1 definition of "predictive DSI" requiring oversight.

This is just one of the numerous examples of already thoroughly peer-reviewed clinical decision support tools that should be carefully examined before including them in the newly proposed definition of "predictive DSI."

Additional Comments Regarding Predictive DSIs Developed by Healthcare Providers

CHIME has significant concerns that, as "other parties", our members that have invested significant time as well as financial and workforce resources developing what – as proposed – would be considered "predictive DSIs." Some members only build alternative solutions when they are not commercially available from vendors; they do this to improve and enhance the purchased products (i.e., the EHR system) with the goal of improving patient care. For HDOs that self-develop "predictive DSIs", cataloging and providing EHR access – if they choose to do

[20] Sutton, R. T., Pincock, D., Baumgart, D. C., Sadowski, D. C., Fedorak, R. N., & Kroeker, K. I. (2020). An overview of clinical decision support systems: benefits, risks, and strategies for success. *NPJ digital medicine*, *3*, 17. https://doi.org/10.1038/s41746-020-0221-y

[21] Levis, B., Benedetti, A., & Thombs, B. D. (2019). Accuracy of Patient Health Questionnaire-9 (PHQ-9) for screening to detect major depression: individual participant data meta-analysis. *BMJ*, l1476. https://doi.org/10.1136/bmj.l1476

[22] Costantini, L., Pasquarella, C., Odone, A., Colucci, M. E., Costanza, A., Serafini, G., Aguglia, A., Belvederi Murri, M., Brakoulias, V., Amore, M., Ghaemi, S. N., & Amerio, A. (2021). Screening for depression in primary care with Patient Health Questionnaire-9 (PHQ-9): A systematic review. *Journal of affective disorders*, *279*, 473–483. https://doi.org/10.1016/j.jad.2020.09.131

so – would be incredibly arduous. Further, they would be cataloging and providing thousands of source attributes in the resource constricted environment that exists today.

CHIME strongly believes that when our members build alternative solutions to be used "in-house" (i.e., within their own HDO), they should either: 1) not be subject to the entirety of "predictive DSI" requirements; and 2) not be penalized – either by ONC or their EHR vendor who could pass on any "costs" to the HDO to use their own health IT tools.

If a HDO that self-develops predictive DSIs – if they choose to share source attribute information with an EHR vendor, they should be protected by a "hold harmless" agreement/clause. In other words, EHR vendors and HDOs should be required to sign and agree to a release of liability or "hold harmless Agreement" – whereas the EHR vendor is the releasor and the HDO is the releasee. In this situation, HDOs are not legally an EHR vendor,[23] are offering a "right to use" their predictive DSI and have no control over what is or could be done with it – including how it is implemented, used, or altered. Providers need legal assurance and protection in these situations, thus, should be protected by a release of liability when they choose to share (i.e., legally offer a right to use) source attribute information.

Additionally, ONC should take into consideration that there is no protection from legal liability for healthcare providers, especially individual clinicians if – for example, they do not check each source attribute, and an allegation of malpractice due to the lack of checking source attribution is made. Currently, there is no case law offering guidance to assist providers in avoiding potential legal action, and this proposal creates a new, substantial vulnerability for clinicians and providers. Judicial decisions constitute one of the most important sources of legal authority, along with legislative and regulatory enactments, in our common law system. Even statutes must be read in conjunction with case law which construe the correct application of the legislation.[24]

Source Attribute Information Format

ONC is seeking comment on the "desirability and feasibility of requiring a standardized format to display and communicate source attributes information as a requirement of the Program." ONC is also requesting comment on "how to ensure that users are aware that this information is available for them to review and how users can readily and easily access information about these source attributes as part of their overall workflow."

Although this might be burdensome for EHR vendors and health IT developers to implement a standardized format we believe this will be beneficial to reduce bias in decision making and will encourage smaller, third-party applications to be more transparent and responsible in their development. CHIME believes there are potential benefits to requiring documentation of what a clinical decision support algorithm does, and providing certainty that a level of testing and trials has been done to ensure the relevance and accuracy of the model.

However, and crucially, we do not believe that the standardized format to display and communicate source attributes information should be imposed on HDOs; our members

[23] 45 CFR 171.102

[24] *The Judiciary: Courts and Case Law*. (2021, October 27). U.S. Department of The Interior. https://www.doi.gov/library/collections/law/caselaw

should be able to choose how to display this information for the efficiency of their organization and well-being of their clinicians. CHIME recommends creating a standard data set and method of reporting on and presenting this data to users in health IT tools. It is crucial for ONC to realize when finalizing this proposal that that a "one-size fits all" approach may not be appropriate for all providers – nor all predictive DSI.

CHIME has broad concerns about these proposed policies and their adverse impact on workflow and efficiency. ONC's proposal to require the addition of this information into clinical workflow or health IT modules could add clutter and complexity in systems that our members are already working hard to simplify and streamline to combat provider and staff EHR burden and burnout. For example, too many attributes will be difficult to cleanly manage without having a negative impact on workflow and will clutter clinician's screens.

A recent study found that "the variability in time to complete tasks, number of clicks, and error rates with the most frequently used EHR products highlights the need for improved implementation processes."[25] If a provider is unable to review the reference database (source attributes) behind the predictive DSIs quickly and easily, it will simply be another contributor to alert fatigue. **Thus, while we generally support requiring IT developers to share the build, test, and train data – CHIME opposes ONC directing and/or mandating where HDOs must display any source attribute data.**

While CHIME believes that guardrails and transparency will help to ensure the responsible development and evaluation of predictive DSI, and having source attribution information of a trained model will be beneficial to purchasers of health IT – we want to ensure that this information can be displayed and communicated by decision-makers within a hospital or healthcare system that understand them. Our members – CIOs, CISOs, CMIOs, CNIOs – and their respective governance committees and board members should be provided flexibility within their organization to choose how to implement the display and communication of source attribution information in a way that is safest for their clinicians.

Furthermore, research has found that:

> *Use of electronic health records (EHRs) is directly associated with physician burnout. Many physicians have voiced dissatisfaction with the click-heavy, data-busy interfaces of existing EHRs. Other factors associated with EHR frustration include scrolling through pages of notes and navigating through multiscreen workflows in the search for information. Excess EHR screen time leads to emotional distress in physicians and limits face-to-face contact with patients, resulting in higher rates of medical errors. Thus, common attitudes among physicians toward the EHR include "inefficient," "time-consuming," and "exhausting."*[26]

As with many other peer-reviewed research findings, this study noted in its findings that "future research is needed to better understand the complex association between EHR-related fatigue

[25] Ratwani, R. M., Savage, E., Will, A., Arnold, R., Khairat, S., Miller, K., Fairbanks, R. J., Hodgkins, M., & Hettinger, A. Z. (2018). A usability and safety analysis of electronic health records: a multi-center study. *Journal of the American Medical Informatics Association : JAMIA*, *25*(9), 1197–1201. https://doi.org/10.1093/jamia/ocy088

[26] Khairat S, Coleman C, Ottmar P, Jayachander DI, Bice T, Carson SS. Association of Electronic Health Record Use With Physician Fatigue and Efficiency. *JAMA Netw Open.* 2020;3(6):e207385. doi:10.1001/jamanetworkopen.2020.7385

and care outcomes." Until ONC has a full understanding of the relationship between "alert fatigue", solutions that can ultimately improve patient care and outcomes will elude the healthcare industry.

Additional Comments for Consideration – Advisory Committee Needed

Given the magnitude, impact, and burden of this proposed rule – especially on hospitals and healthcare systems, as well as healthcare providers and clinicians – and the patients they serve, CHIME is recommending that ONC seek authority to create an Advisory Committee. The notice-and-comment period for these extensive and far-reaching proposals was 60-days – and ONC declined (received on June 6, 2023) CHIME's request (made on May 17, 2023) for a 30-day extension of the comment period. **Thus, it would be particularly beneficial to the entire healthcare industry and American patients for ONC to ensure a thorough and thoughtful approach is taken, with comprehensive, ongoing feedback taken into consideration, and if necessary, incorporated.**

Additionally, upon release of the final rule, we strongly urge ONC to host a series of informational meetings. These can be similar to the informational meetings held during the notice-and-comment period[27] to educate healthcare stakeholders. These informational meetings should begin no later than five business days after the final rule is released, and well in advance of the effective date. Additionally, there should be several informational sessions specifically structured to educate hospitals and healthcare systems, providers, and clinicians. They should also include a 'Question and Answer' portion of the session so that providers can gain much needed clarity regarding the final rule's policies. ONC should also consider setting up a way to communicate questions directly to the National Coordinator, such as a dedicated inbox related to HTI-1.

Advisory Committee Recommendations

The Comptroller General of the United States is mandated in law to make appointments to certain health care-related commissions, advisory boards, and governing boards.[28] **An Advisory Committee would be especially critical to advance the "responsible use of AI" – they could examine the clinical, operational, ethical, legal, privacy and security dimensions, as we continue to harness the true potential of advancements in AI.**

Furthermore, this would be in line with the Biden-Harris administration's ongoing efforts regarding AI, including but not limited to, the landmark Blueprint for an AI Bill of Rights[29] and related executive actions, the AI Risk Management Framework,[30] a roadmap for standing up a National AI Research Resource,[31] active work to address the national

[27] *HTI-1 Proposed Rule Information Sessions | HealthIT.gov*. (n.d.). https://www.healthit.gov/news/events/hti-1-proposed-rule-information-sessions
[28] *Health Care Advisory Committees*. (n.d.). U.S. GAO. https://www.gao.gov/about/what-gao-does/hcac
[29] The White House. (2023, March 16). *Blueprint for an AI Bill of Rights | OSTP | The White House*. https://www.whitehouse.gov/ostp/ai-bill-of-rights/
[30] AI Risk Management Framework | NIST. (2023). *NIST*. https://www.nist.gov/itl/ai-risk-management-framework
[31] https://www.ai.gov/wp-content/uploads/2023/01/NAIRR-TF-Final-Report-2023.pdf

security concerns raised by AI, the Office of Science and Technology Policy (OSTP)'s National AI R&D Strategic Plan[32], as well as recent investments and actions.

The Health Information Technology Advisory Committee (HITAC)[33], currently recommends to the National Coordinator for Health Information Technology policies, standards, implementation specifications, and certification criteria. As defined in the Cures Act – HITAC has focused on five target areas: 1) Design and Use of Technologies that Advance Health Equity; 2) Use of Technologies that Support Public Health; 3) Interoperability; 4) Privacy; and 5) Security, and Patient Access to Information.[34]

The Cures Act provides[35] "Authority for Temporary Additional Priority Target Areas" – whereas the HITAC may identify "an area to be considered for purposes of recommendations […] if — "(i) the area is so identified for purposes of responding to new circumstances that have arisen in the health information technology community that affect the interoperability, privacy, or security of health information, or affect patient safety; and "(ii) at least 30 days prior to treating such area as if it were a target area […] the National Coordinator provides adequate notice to Congress of the intent to treat such area as so described.

We believe that the authority granted under "General Duties" and "Priority Areas" outlined in the Cures Act clearly provide the ability for the HITAC to "update such recommendations and make new recommendations as appropriate." – including:

> *Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.*

Further, under "Additional Target Areas," HITAC "may make recommendations […] in addition to […] with respect to any of the following areas, including, but not limited to:

> *"(i) The use of health information technology to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, reducing medical errors, improving population health, reducing chronic disease, and advancing research and education.*
> *"(ii) The use of technologies that address the needs of children and other vulnerable populations.*
> *"(iii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including at a minimum, race, ethnicity, primary language, and gender information.*
> *"(v) The use of technologies that meet the needs of diverse populations.*
> *"(vi) The use of technologies that support—*

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[32] Executive Office of the President of the United States, Select Committee on Artificial Intelligence, & National Science and Technology Council. (2023, May). *National Artificial Intelligence Research and Development Strategic Plan 2023 Update*. www.whitehouse.gov. https://www.whitehouse.gov/wp-content/uploads/2023/05/National-Artificial-Intelligence-Research-and-Development-Strategic-Plan-2023-Update.pdf

[33] Established by the 21st Century Cures Act (P.L. 114-255) and is governed by the provisions of the Federal Advisory Committee Act (FACA), P.L. 92-463, as amended, 5 U.S.C. App. 2

[34] *Health Information Technology Advisory Committee (HITAC) History & Highlights | HealthIT.gov*. (n.d.). https://www.healthit.gov/topic/federal-advisory-committees/health-information-technology-advisory-committee-hitac-history

[35] P.L. 114-244. 21st Century Cures Act, § 3002, § 3003. Dec. 13, 2016. https://www.govinfo.gov/content/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf

"(I) data for use in quality and public reporting programs;
"(II) public health;
"(viii) The use of a certified health information technology for each individual in the United States.

We strongly believe that many – if not all – of the proposals included in HTI-1 would fall under HITAC's five target areas as required by the Cures Act, and further, under several of the "Additional Target Areas."

Task forces and workgroups are formed as subcommittees to the HITAC – and meet periodically to discuss topics, present findings at HITAC meetings, and make recommendations to the HITAC. These subcommittee meetings are held in public and notices for each meeting appear on the ONC website. **We are aware that the HITAC formed "The HTI-1 Proposed Rule Task Force 2023" to evaluate and provide draft recommendations to the HITAC on the HTI-1 proposed rule[36], and CHIME applauds their efforts. However, we believe that the National Coordinator should form a long-term HITAC subcommittee focused on the HTI-1 final rule and throughout its implementation.**

Furthermore, the HITAC is ideally situated to form a semi-permanent subcommittee given that the Cures Act requires that members at least reflect providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity. [37]

This subcommittee can provide ongoing recommendations and refinements to the National Coordinator after the finalization of this rule and throughout its implementation. Further, with this HITAC subcommittee, ONC could seek to revise the rule if requested by recommendations provided by the Committee – as permitted under the Administrative Procedure Act (APA).[38]

Additionally, a semi-permanent subcommittee of HITAC dedicated to HTI-1 could provide the National Coordinator with recommendations and refinements, specifically regarding the policies included in the final rule. **As ONC acknowledges, given the intersecting nature and interest across the Department to address the use of AI for purposes of health, the HITAC is uniquely positioned as it already includes representatives from many of the federal agencies across the Department that have an intersect or interest.**

CHIME broadly agrees that standards around predictive DSI will be necessary. Of note, specific recommendations related to individual or specific predictive DSI tools may be needed, and in turn, the expertise of a HITAC subcommittee could collectively indicate which of these tools should fall under ONC's regulatory authority and ensure there are no new or ongoing duplicative regulatory requirements. Additionally, they could be utilized to discuss recommendations related to specific "predictive DSI" tools, and in turn, they could collectively indicate which predictive DSI tools should be regulated by ONC.

[36] *HTI-1 Proposed Rule Task Force 2023* | *HealthIT.gov*. (n.d.). https://www.healthit.gov/hitac/committees/hti-1-proposed-rule-task-force-2023
[37] *Health Care Advisory Committees*. (n.d.). U.S. GAO. https://www.gao.gov/about/what-gao-does/hcac
[38] APA sec. 551(5) (5 U.S.C. 551(5)).

Information Blocking Enhancements

Offer Health Information Technology or Offer Health IT

ONC previously explained that "an individual or entity that offers certified health IT" would include "any individual or entity that under any arrangement makes certified health IT available for purchase or license."[39] Both individuals or entities that otherwise fall into at least one category of actor as defined in current statute[40], such as healthcare providers, and individuals or entities who otherwise would not fit the definition of any category of actor could offer certified health IT that they did not themselves develop or present for certification. As offerors of certified health IT, these individuals or entities could engage in conduct that constitutes information blocking[41], such as through contractual terms or practices undertaken in operating and maintaining health IT used by another individual or entity.

To give clarity about the definitional implications under information blocking regulations of making available funding subsidies and certain features or uses of certified health IT, ONC is now proposing to codify a definition of what it means to *offer* certified health IT. The proposed definition of what it means to "offer" certified health IT generally includes providing, supplying, or otherwise making available certified health IT under any arrangement or terms, but explicitly excludes certain activities for one of two purposes:

> *(1) to encourage beneficial arrangements under which providers in need can receive subsidies for the cost of obtaining, maintaining, or upgrading certified health IT; or*
>
> *(2) to give health care providers (and others) who use certified health IT concrete certainty that implementing certain health IT features and functionalities, as well as engaging in certain practices that are common and beneficial in an EHR-enabled healthcare environment, will **not** be considered an offering of certified health IT (regardless of who developed that health IT).*

ONC is proposing that "if an individual or entity engages in conduct that meets the *offer health IT* definition, it would be considered a *health IT developer of certified health IT* under the definition, even if it engages in other conduct that meets an exclusion."

ONC is further proposing to modify the definition of a "health IT developer of certified health IT" so that it remains clear that healthcare providers who self-develop certified health IT for their own use would continue to be excluded from this definition if they do not offer any certified health IT to others. While CHIME strongly supports ONC's proposed modification, we continue to have concerns that providers who offer instances of their EHRs to other providers in need, should also be carved out. Without a clear carveout, these providers will continue to be hesitant and disinclined to continue to offer to extend their products to other lesser-resourced providers.

We appreciate that ONC has acknowledged awareness "of concerns regarding the potential inclination of some health care providers and other donors to stop making available funding subsidies toward the cost of certified health IT for providers who may not otherwise be able to afford it." Additional clarity and assurances should be included in the final rule to ensure that policies not only "encourage the provision of grants of funding subsidies, consistent with other

[39] 85 FR 25798
[40] 45 CFR 171.102
[41] As defined in § 171.103

applicable laws, to healthcare providers who may otherwise struggle to afford modern, interoperable health IT" – but that they are explicitly permitted. CHIME agrees with ONC that "arrangements that help small or safety net providers afford certified health IT items and services are generally beneficial to the recipient providers and their patients."

Conclusion

As ONC states, "implementation of the proposed rule's provisions will advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information."[42] CHIME appreciates ONC's ongoing efforts to advance health data exchange and interoperability while promoting health equity for all.

CHIME members remain steadfast in their commitment to using technology to deliver high-quality care and facilitating interoperability and appropriate and secure access to records across the care continuum. Furthermore, CHIME has consistently been supportive of ONC's efforts towards improving technologies used by clinicians.

While we were not offered additional time to comment, which would have allowed for more meaningful feedback, we nonetheless appreciate the opportunity to comment and share our constructive feedback. Some of our comments were informed by a member survey. As we analyze the survey results from CIOs who are directly responsible for overseeing the proposed policies, if requested, we would be pleased to share detailed insights with you.

In conclusion, we urge ONC as they consider stakeholder feedback and work to finalize this regulation, that they adopt policies that do not inadvertently create overly duplicative requirements, penalize healthcare providers unfairly, and add burden to an already highly regulated industry. If you have any questions or if we can be of assistance, please contact Chelsea Arnone, Director, Federal Affairs at carnone@chimecentral.org.

Sincerely,

Russell P. Branzell, CHCIO, LCHIME
President and CEO
CHIME

[42] *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule | HealthIT.gov*. (n.d.). Retrieved May 16, 2023, from https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program