OeHI
Office of eHealth Innovation

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Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology,
The Office of the National Coordinator for Health Information Technology,
Office of the Secretary, United States Department of Health and Human Services

Re: Comments for the 2024-2030 Health Information Technology Plan

Dear Dr. Tripathi,

Colorado appreciates the opportunity to submit comments regarding the Office of the National Coordinator for Health Information Technology (ONC) draft 2024-2030 Health Information Technology Plan (Draft Plan). Our comments are grouped by category with a reference to the Draft Plan's goals and objectives following the specific comment. We recognize that other stakeholders and entities affected by the Draft Plan will be submitting their own comments expressing their views. Colorado submits these comments on behalf of the following state departments and entities: Office of eHealth Innovation, eHealth Commission, Office of Information Technology, and Department of Health Care Policy and Financing (Colorado's single state agency for the administration of the Medicaid and Children's Health Insurance (CHIP) programs).

I. General Comments on the Draft Plan

Colorado recognizes that the ONC and participating agencies aimed to identify all major health IT components in developing the Draft Plan. The result is that the Draft Plan's goals are very ambitious, yet silent on how (and who) would fund the activities to accomplish the lofty goals. It indicates that it is designed to "prioritize resources, align efforts, benchmark, and signal priorities to industry," yet makes no mention of quantifying the costs or benefits of the objectives and strategies. The Draft Plan would greatly benefit from prioritizing the goals, incorporating actionable objectives with measurable strategies and timeframes, and including a framework for determining a Return on Investment along with potential funding sources. The additions would enable the ONC and stakeholders to trace the progress being made and to help ensure that activities remain on track. Additionally, having more definition for the objectives and strategies would better enable states to develop and implement their own HIT strategic plans that complement the ONC Draft Plan where appropriate.

Colorado was pleased that 25 federal organizations collaborated with the ONC to develop the draft Plan. Although the Draft Plan contemplates coordination among the federal agencies to collaborate and accomplish similar goals, it does not include a strategy for how that coordination would happen. It has been increasingly apparent over the past several years, particularly in response to the COVID-19 pandemic, that while federal (and state) agencies have their own individual responsibilities, those responsibilities cannot be met in isolation. It requires sustainable and ongoing collaborative processes among the agencies to successfully meet their mandates and accomplish their goals. The draft Plan recognizes that improving health outcomes and populations requires interoperability among the various technologies and systems. It should also recognize that those same synergies are needed

among the various agencies and organizations, and that technology needs and opportunities extend well beyond any one individual agency.

Colorado concurs with the Draft Plan's focus on advancing interoperability and Health Information Exchange (HIE); enabling seamless exchange of data, including Social Determinants of Health (SDoH) and merging clinical and claims data; using technology that is private and secure; expanding use of patient portals and mobile health applications; improving informed patient consent; ensuring that AI applications and uses promote digital equity; and encouraging adoption of emerging technologies such as telehealth, remote monitoring, and precision medicine.

We believe that full interoperability can only be achieved through national standards. Colorado supports the Draft Plan's objective of building national standards for SDoH. We have witnessed the challenges associated with major Electronic Health Record systems adopting their own specific workflows and SDoH elements. Consistency in SDoH metrics is needed to obtain and analyze data to develop strategies for improving whole-health outcomes.

Colorado agrees that expanding the use of patient portals and mobile health applications will provide patients with more timely and useful information to make informed decisions. Consent becomes more critical as additional data such as SDoH and mobile applications are added to the mix. The Draft Plan should include a strategy for interoperable consent protocols to ensure that all HIT systems have the capability of sharing consent preferences regardless of the system or application. Further, patients should be able to make consent decisions at the granular level, such as SDoH may be shared with a specific provider type, or consent for research projects.

Colorado supports the strategic plans' emphasis on expanding patient engagement through the use of patient portals and mobile health applications. Since these tools will incorporate sensitive data types such as SDoH and will integrate broadly with various HIT systems, the need for strong interoperable consent protocols is critical.

We recommend that the plan explicitly address the development and implementation of interoperable consent protocols. These protocols will ensure that all HIT systems can recognize and respect patient consent preferences regardless of the application or platform involved. In addition, it is crucial that these consent frameworks allow for granular consent decisions to enable patients to specify that certain types of data be shared only with designated types of providers or used exclusively for certain research projects.

In summary, the strategic plan should include a comprehensive approach to consent management that not only supports the technical capabilities for nuanced consent interactions but also promotes transparency, autonomy, and trust, which will empower patients to make truly informed decisions about their health data.

One of the Draft Plan's objectives is that "underserved communities and populations have access to infrastructure [broadband] that supports HIT use." It supports identifying broadband needs and gaps, followed by expanding equitable and affordable broadband access to all households and businesses. For HIT, this means that all health care providers and patients,

including Tribal, rural, and underserved communities, must have access to broadband and it must be affordable. Colorado recommends adding language for a proposed framework for interagency coordination to accomplish this objective. We further recommend that the draft Plan support making broadband subsidies (e.g., Affordable Connectivity Program) permanent.

II. Modernize "Health" terms to reflect digital equity and whole-person wellness

The CMS Promoting Interoperability (PI) Program resulted in significant improvements in the delivery and exchange of health care and related data. Yet, in the 15 years since the PI Program began, significant HIT technological advancements have occurred; SDoH is recognized as being as important to whole-person wellness as physical health; broadband and telehealth have become vital service delivery tools; and digital disparities are being reduced, particularly in rural and economically disadvantaged communities. Yet, the traditional term "health care" as described and defined in federal and state rules and regulations, continues to reflect the outdated view that "health care" is "physical" health.

Social service agencies and home-health organizations provide valuable whole-person health related services to help elders and those with disabilities to age-in-place and remain in their homes. Yet, these services are generally not deemed to be "health care" nor are the professionals providing that care deemed to be "health care providers." The historical use of these terms in HIT and Health Information Exchange (the noun and the verb) result in the continuation of health and digital inequality. For example, historically, HIEs (the noun) restricted participation in the HIE to "health care providers" which exclude most social and home care services; payers such as Medicaid and private payers; and certain research and public health reporting.

The Draft Plan supports sharing Electronic Health Information (EHI) among health care providers and "community organizations," and interoperability among "health systems and applications," and merging claims and clinical data to promote transparency, foster competition, and provide valuable data for analytic purposes. Yet there are no strategies to modernize and expand health related terms and HIE practices to permit payer access to clinical data in the HIE and claims data which are generally found in a state's All Payer Claims Database or important data for SDoH services.

The Draft Plan should include a strategy of further clarifying (expanding) the definition of health and health care to include SDoH, home health services, social services programs, payers, and other appropriate users. There should be guidance in the Draft Plan on where and how the merge would happen. If not, HIEs will continue to lack complete whole-person records; health and care-givers will not have access to clinical data or the ability to exchange records; and unnecessary and duplicative federal Medicare and Medicaid (and other payer) costs will continue. Additionally, Colorado recommends ONC add language providing guidance and expectations for merging claims and clinical data, including designating a federal agency to lead that effort.

III. Continue to Build on Federal Standards for Technology

Colorado agrees with building upon existing rules and regulations from the 21st Century Cures Act, common standards for US Core Data for Interoperability (USCDI); HL7 FHIR

standards and exchange of data; and the Trusted Exchange Framework & Common Agreement (TEFCA) standards for universal governance and as the technology floor for interoperability. We also support using Health Data, Technology, & Interoperability: Certification Program Updates, Algorithm Transparency & Information Sharing, or HTI1, for health IT certification and information blocking. Colorado further encourages the ONC to make all reasonable attempts to have developers of HIT meet the phased two to four year compliance timeframes.

The Draft Plan notes that in late 2023, DHHS issued a concept paper with voluntary Cybersecurity Performance Goals (CPGs) with enforcement and accountability to be led by a "one-stop cyber security shop" within the DHHS's Administration of Strategic Preparedness and Response (ASPR). As conceived, the performance goals apply only to hospitals which generally have the highest risk of cybersecurity issues based on volume of patients and services. We recommend that the ONC Draft Plan strongly encourage DHHS to move forward with formal adoption of CPGs, with measurable objectives and strategies that are tied to reimbursement in Medicare incentive programs.

The Draft Plan relies heavily on APIs to accurately match patients with their records. While APIs are a useful tool, they are not inherently and automatically secure. Merging claims and clinical data, and adding SDoH to the mix adds another layer of complexity to the API technology needed to accomplish accurate matching while meeting security and privacy requirements. We recommend that ONC further address this issue in the Draft Plan through objectives and strategies designed to address the technical and security issues surrounding APIs as it develops national standards. Additionally, we recommend that ONC and federal partners specify additional security standards to support secure interoperability and data transfer. The lack of clarity and standards particularly during data transfer opens a notable security gap in our health information ecosystem.

IV. Expand Goals and Objectives that Promote Digital Equity, Especially the Use of Telehealth

The Draft Plan indicates it promotes digital equity, yet contains no specifics on how digital equity could be achieved. Further, using historical data and practices to determine baselines may skew the results. For example, until recently, telehealth services were greatly restricted by health care payers. Yet, any conclusions or baselines drawn about telehealth from pre-pandemic data, do not accurately reflect the evolution of telehealth. Barriers such as outdated payer rules on telehealth, old internet technology, and lack of access to broadband in rural areas are rapidly changing how we obtain quality health care and are also incorporating non-clinical and SDoH services into whole-person health. The use of outdated data (especially for rural areas) do not fully reflect the importance of telehealth and broadband access to digital equity.

The Draft Plan supports expanded use of telehealth which have proven to be a valuable tool for providing health and social services, especially for behavioral health with its shortage of providers and in rural areas. CMS wisely expanded telehealth during the COVID-19 pandemic by removing mileage and other barriers, eventually making tele-behavioral health services a permanently covered Medicare service. Many other temporary "expansions" and "waivers" continue in place until at least December 31, 2024. The Draft Plan should

recognize that the expansion of telehealth brings real and tangible health benefits and we encourage CMS to carefully consider making additional telehealth services permanent.

The real benefits of telehealth can only be realized when broadband is accessible and affordable. The Federal Communications Commission (FCC) and the National Telecommunications and Information Administration (NTIA) are funding billions of dollars in Broadband Equity, Access, & Deployment (BEAD broadband infrastructure) and Digital Equity grants to states for distribution. Yet access is only part of the equation- broadband must be affordable. In fact, state broadband offices have built their FCC required BEAD and Digital Equity plans based on the assumption that federal subsidies for broadband (i.e., ACP) would continue permanently. The Draft Plan should emphasize federal public subsidies be made permanent to achieve ONC and NTIA goals and objectives. Additionally, broadband and telehealth, along with workforce development and digital equity, provide important opportunities for Medicaid and other health care payers/providers and broadband offices to collaborate on leveraging BEAD and Digital Equity Grant Program funding with Medicaid HIT strategic plan funding. The potential synergy is too important of an opportunity to pass up.

The Digital Equity program focuses on education of the benefits of broadband and workforce development. The Draft Plan should encourage education to include the benefits of telehealth and HIT for consumers and SDoH entities, and be expanded to include informing consumers about patient consent at the granular level.

V. Set Parameters for Transparency and Security for AI Applications

It is well recognized that AI has the power to be a useful tool, particularly in the HIT context. Currently, AI may be appropriate for research projects using encrypted or de-identified data, and/or “administrative tasks” that do not involve AI making eligibility determinations or final decisions on services a patient could receive. (For example, using an AI prompt to help patients get to the right “person” to make that determination would be an appropriate administrative use.) However, before allowing AI for clinical uses, enforceable transparency and accountability standards must be developed and implemented at the state and/or the federal level. Although some AI transparency and security standards may be best established by the federal government, this would require a significant amount of time, and run the risk that national standards could only be met by large organizations, thus defeating the Draft Plan’s goals of transparency, and promoting competition. The Draft Plan should recognize that states are already engaged in developing AI standards for specific applications via their BEAD and Digital Equity plans, IT services, and legislative task forces. The data and analyses from these states could help inform national policy for AI applications.

The Draft Plan should encourage collaboration among states through legislative organizations or other entities that have developed systematic approaches to addressing issues important to individual states, regions, and at multi-state levels. These efforts could provide useful data and reports for the ONC to gather data and information on broadly accepted AI use principles to draft guidance on an AI application “floor” accompanied by a tool that states use to weigh AI HIT applications. Clinical AI applications would require more scrutiny and must demonstrate that the AI application would not contribute to digital inequity. This framework may avoid situations where an AI application would be developed, and even used, only to have that AI use invalidated when federal digital equity standards are finalized. It would also allow states to roll-out their BEAD and Digital Equity grants programs and

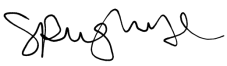
provide useful data to the ONC and other federal agencies, giving the federal government time to gather, analyze, and develop federal standards where appropriate.

Technical standards for cybersecurity have been, and continue to be, developed and implemented at the federal level. Regardless of the ultimate use case for a set of data, best practices and appropriate technology for the secure transfer and exchange of those data would apply. The Draft Plan should make the distinction that the standards are in place, and that it is appropriate to enforce HIT cyber security standards through the HHS Administration for Strategic Preparedness and Response (ASPR) division.

VI. Conclusion

Again, Colorado appreciates the opportunity to submit comments on this critical and timely update of the ONC draft Strategic Plan. We look forward to working with ONC and CMS, federal and state broadband agencies, social and community service partners, and other stakeholders and the public to bring the plan to fruition.

If you have any questions or seek further information, please contact (Stephanie Pugliese, Director, Office of eHealth Innovation.



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