collectivemedical ®

p   801.205.0770
e   Info@collectivemedical.com
w   www.collectivemedical.com

March 17, 2020

Attention: Donald W. Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator (ONC)
Department of Health and Human Services

Re: Draft 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker:

On behalf of Collective Medical (Collective), it is our pleasure to submit comments on the Draft 2020-2025 Federal Health IT Strategic Plan, released for public comment on January 15, 2020. Collective commends ONC's development of a comprehensive strategic plan to serve as a roadmap and to establish overarching priorities for the development and use of health IT.

Through a nationwide network, Collective empowers physicians, nurses, and other care providers with actionable real-time notifications powered by advanced analytics based upon patient histories, ADT information, Continuity of Care Documents (CCDs), collaborative care plans, and other various data sources to identify vulnerable patients and help care teams address their needs at the point of care. Collective helps providers optimize value-based care programs, meet the needs of patients with substance use disorder, collaborate with behavioral health care providers, prevent workplace violence, and optimize emergency department (ED) workflows, just to name a few of our capabilities. We serve all points of care, supporting care teams across emergent, inpatient, post-acute, mental and behavioral health, and ambulatory care settings, as well as stakeholders in Accountable Care Organizations and health plans. Use of the Collective network has been proven to reduce avoidable hospital admissions and readmissions, reduce avoidable ED visits by patients with identified patterns of high utilization, reduce unnecessary opioid prescriptions, increase savings, and improve provider satisfaction.

Re: Challenges in Healthcare

Collective agrees with ONC's assessment and summary of the primary challenges in health care that must be considered in the Federal Health IT Strategic Plan. Collective would encourage ONC to also consider adding the challenge of creating continuity of care by making health information meaningful and actionable across the continuum. The proliferation of health care data and information creates exciting opportunities, but it also creates challenges when providers and patients do not have the right information or become overloaded with information that is not actionable or relevant. We would recommend that this be included as a challenge and a priority in the Health IT Strategic Plan.

Re: Goal 1, Promote Health and Wellness
Objective 1b: Advance healthy and safe practices through health IT

- *Strategy: Leverage all levels of data (e.g., individual- and community-level) to predict epidemics, inform and monitor public health action outcomes, improve quality of life, and address disease occurrence and preventable deaths.*

Collective supports ONC's objective of advancing healthy and safe practices through health IT, and particularly its strategy to leverage all levels of data to predict epidemics, inform and monitor public health action outcomes, improve quality of life, and address disease occurrence and preventable deaths. With improved access, the public and private sectors will be better able to ensure that data is delivered to the right entity at the right time to enhance efforts to improve individual and population health. We believe that the combination of industry-wide standards (e.g., HL7) and the proliferation of new value-based payment models (e.g., shared savings, bundled reimbursement) are critical. In addition, we believe that better coordination and alignment of objectives between agencies tasked with healthcare delivery (e.g., CMS) and public health (e.g., CDC) is essential to meeting this important objective.

In protecting privacy rights, administrative requirements and limitations around patient consent are sometimes a barrier to transmitting data that would be beneficial to the care team and would enhance treatment. For example, with regards to 42 CFR Part 2 (Confidentiality of Patient Substance Use Disorder Records), it would be beneficial to expand the applicability of the general designation provision such that it is not limited only to disclosures to individuals and entities which have a treating provider relationship with the patient whose information is being disclosed, but to any individual or entity which has a treating provider, healthcare operations, or payment relationship with the patient whose information is being disclosed, all consistent with traditional HIPAA-provided release provisions. Collective believes that such an expansion would empower the patient to consent to the release and use of their health information in a manner which is more aligned with permissible uses and disclosures of information under HIPAA while remaining consistent with other statutory and regulatory protections designed to ensure the integrity of the consent process. Collective also believes this would significantly enhance efforts to achieve interoperability and getting information where and when it is needed at the point of care. Collective believes that this and other regulatory changes around patient consent, aimed at empowering and reducing burden for the patient, are worth exploring as part of this strategy.

Objective 1c: Integrate health and human services information

- *Strategy: Foster greater understanding of how to use health IT to assess and address unmet health and social needs for individuals and communities and available health IT solutions that can be utilized for improvement.*

- *Strategy: Capture and integrate social determinants of health data into EHRs to assist in care processes, such as clinical decision support and referrals, integration of medical and social care, and address health disparities in a manner that is ethical and consistent with routine patient care.*

Collective supports ONC's objective to integrate health and human services information, particularly the strategies listed above. However, we believe that the integration of this data should be patient-centered and sensitive to stigma and bias that still exist around many social determinants. With increased recognition of the importance of social determinants (such as housing and food security) and their impacts on health, capturing and integrating social needs alongside health data is increasingly critical. Social needs information can help healthcare providers obtain a more complete picture of individuals' needs and assists with assessment, risk stratification, patient-centered care planning, and referrals. However, connecting and coordinating between health care and social service agencies or community-based organizations with limited IT capacity presents challenges. These organizations would benefit not only from a greater understanding of how to use health IT and available solutions, but also from additional resources and technical assistance to deploy and train their staff on such technologies. In order to fully actualize the potential of this objective, efforts such as the Gravity Project will require ongoing support. Furthermore, the development of HL7 standards will enable widespread adoption.

Re: Goal 2, Enhance the Delivery and Experience of Care
Objective 2a: Ensure safe and high-quality care through the use of health IT

- *Strategy: Optimize care delivery by applying advanced capabilities like machine learning, evidence-based clinical decision support, and smart dashboards and alerts.*

Based on our decade-long experience, we have the evidence to support the impact that alerts can have on ensuring high-quality patient care. We fully support broadening the use of this technology to achieve better outcomes. We find it noteworthy that CMS is modifying Conditions of Participation (CoPs) to require hospitals, including psychiatric hospitals and Critical Access Hospitals (CAHs), to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another healthcare facility or to another community provider or practitioner. We believe this will greatly support the optimization of care delivery and aligns well with ONC's Federal Health IT Strategic Plan. We also believe that these requirements can go even further, ultimately specifying better-integrated, workflow-specific requirements which ensure that this high-value information is not only transmitted from hospitals, but is appropriately received by downstream providers who are best positioned to continue to care for the patient long after discharge.

In the relatively new domain of machine learning, the Food and Drug Administration (FDA) is considering a total lifecycle-based regulatory framework. It is very important that proposed regulations not undermine the iterative process of innovation, learning, and development while still promoting the needs of patients. We believe it would be beneficial for ONC to coordinate and align with the FDA in the development of future regulations regarding machine learning. This will be essential, as the magnitude of the regulatory task at hand is consequential and challenging. Innovation, speed, and agility must be balanced with quality, reliability, and safety. We believe the healthcare provider and payer market, as consumers of these technologies, may be best positioned to approve or reject these systems and encourage ONC and FDA to take a light-touch approach to regulating the same, instead focusing on establishing a principles-based approach that the market can then follow and enforce.

- *Strategy: Continue efforts to establish identity solutions that improve patient matching across data systems.*

Accurate patient matching is essential for identifying patients, obtaining accurate contact information for outreach purposes, and establishing a single longitudinal record of patients' health and care that can support care coordination and collaboration. Patient matching errors can lead to a host of problems including duplicate patient records, missing medical information, difficulty contacting patients, and medical errors that can even lead to death. Therefore, Collective supports this ONC strategy to improve patient matching across data systems. This will necessitate cross-sector collaboration and engagement between health IT companies, the federal government, healthcare providers, and other stakeholders to develop solutions to enhance data quality, completeness, and standardization. HIEs and health IT developers play an important role in this and, although strides have been made, we continue to improve upon existing matching capabilities and data integrity processes. Emerging best practices also include steps that can be taken by healthcare organizations such as prioritizing identity management, standardizing data collection, ensuring that the right type of data is collected, educating registration personnel, and engaging patients. Ideas have also surfaced such as establishing either national or HIE-specific patient identifiers that travel with the patient[1], which Collective would generally support depending on how it is structured and implemented, and whether appropriate patient privacy protections are in place. Collective has extensive experience in this domain, having rapidly, securely, and accurately matched billions of healthcare records across hundreds of millions of patient encounters for tens of millions of patients, and would be interested in discussing this approach as well as other best practices for patient matching with ONC or other interested agencies and stakeholders.

- *Strategy: Support expanded use of health IT for promoting safer clinical practices by automating patient safety and rapid reporting features into the health IT infrastructure to prevent and address adverse events, including overprescribing of controlled substances.*

In addition to automating patient safety, Collective also recommends that ONC consider including provider workplace safety. There is significant evidence to suggest that providers who feel safe in the workplace are better focused and deliver better patient care. And yet, in a recent American College of Emergency Physicians (ACEP) survey of ED physicians, 8 of 10 reported that violence in the ED interrupted patient care[2].

Furthermore, Collective would encourage state and federal efforts to strengthen and improve the regulations related to the access and retention of an individual's opioid prescription medication history, by streamlining them and making them consistent across states. This would improve providers' ability to use this information to reduce overprescribing. This effort would require better alignment of regulations between and among states, as well as the federal government – an effort in which ONC could provide leadership.

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[1] Eramo, Lisa A. "Close Doesn't Count: Patient Matching Challenges in HIEs" Journal of AHIMA 90, no.9 (September 2019): 14-17. https://bok.ahima.org/doc?oid=302840#.XmKpsKhKg2w
[2] Survey conducted online between 8.21.2018 and 8.27.2018 with 3,539 emergency physicians; newsroom.acep.org

Finally, health IT has the immense potential to better support medication reconciliation and promote safer clinical practices in this area. As one example, Collective can deploy a "Triple Threat" flag using our platform, which indicates when a member is on a combination of three drugs (opioids, benzodiazepines and muscle relaxants), which places them at a very high risk of death from overdose. Collective would encourage ONC to include medication reconciliation as a component of this patient safety strategy and to consider a unified effort and methodology around medication reconciliation.

- *Strategy: Implement mechanisms of data governance and provenance to promote safety, security, and accountability through all stages of care and uses of health IT.*

With the anticipated broad expansion in the use of data and health IT, Collective agrees that data governance and provenance is going to become increasingly critical. Many HIEs and states across the country have made data governance a priority. We applaud these efforts and welcome the opportunity for private sector companies such as Collective to be a meaningful part of conversations regarding data governance. We believe a public-private partnership on data governance is especially important in light of recent rulemaking regarding interoperability and ONC's recently released Cures Act Final Rule.

- *Strategy: Promote interoperability and data sharing through widely-accepted standards to ensure health information is freely available across care settings for patient care, public health, research, and emergency and disaster preparedness, response, and recovery.*

Collective fully supports this strategy and uses HL7, FHIR, and CDA document exchange, to name a few, to enhance interoperability. Collective supports the recently released ONC and CMS interoperability rules and the identification of HL7 FHIR Release 4.0.1 as the foundational standard to support data exchange via secure APIs. We believe strongly in the need for an interoperable health information ecosystem where data is shared.

Objective 2c: Reduce regulatory and administrative burden on providers

- *Strategy: Monitor the impact of health IT on provider workflows to better understand and optimize the use of technology in ways that minimize unnecessary steps or negative outcomes for patients.*

We are very supportive of strategies to optimize the use of technology in ways that minimize unnecessary steps and minimize negative outcomes for patients. Health IT should enhance, not complicate or detract from, provider workflows by providing the information they need, in real time, and at the right point in the workflow. Alert fatigue is a very real problem for many providers, therefore alerts and flags should be designed to fit seamlessly into provider workflows and include relevant, actionable information that providers can use to care for the patient sitting in front of them. Administrative burden also continues to present challenges for providers, resulting in increased dissatisfaction and burnout, therefore aiming to provide synthesized and curated content is crucial to helping remove some of that burden. ONC has already been a leader of combatting the challenges of alert fatigue and administrative burden, and Collective looks forward to being part of the solution related to this strategy.

Re: Goal 4, Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure
Objective 4a: Advance the development and use of health IT capabilities

- *Strategy: Promote a digital economy that leverages research and development, and that can lead to the development of new business models in healthcare in a manner that protects privacy rights.*

Heathcare IT in the United States must continue to lead the world in innovative technology and business models. ONC should provide pathways for startups and innovation that allow them to launch and grow.

Data should never be disclosed in a manner that would violate patient privacy rights. Collective has a unique consent model in place to ensure that patient authorization requirements (e.g., under 42 CFR Part 2 and other laws) are followed and verified. These consent models apply both to the web portal and to reports and notifications. New business models should seek to protect and strengthen privacy rights to ensure that confidence and trust is retained as new capabilities are developed. Collective would also recommend revisiting and updating the HIPAA Privacy Rule to address present-day privacy concerns and priorities, including enabling the secure aggregation of deidentified and identified patient data to aid in deeper levels of research and development in support of improved patient care. ONC could also play a leading or significant role in this effort.

- *Strategy: Reduce financial and regulatory barriers that are perceived to prevent new health IT developers from entering and competing in the health IT marketplace.*

Collective supports reducing financial and regulatory barriers in health IT, which will inevitably promote innovation, and we applaud the deregulation actions and other pro-competitive policies in ONC's Cures Act Final Rule that will encourage a thriving health IT marketplace. However, we would encourage adding language to this strategy to reflect that these barriers should be reduced in ways that continue to maintain high standards of privacy, security, safety, and patient-centeredness. Patients, providers, and other stakeholders entrust health IT developers with their information, and while we support the streamlining or elimination of unnecessary or obsolete requirements, the industry should continue to have guardrails that help preserve trust and promote interoperability and coordination between health IT developers and their users. We would also encourage greater standardization across different electronic medical records (EMRs) as the system of record, which could reduce overall economic barriers to entry, improve data sharing, improve the ease of switching between EMRs, and reduce unnecessary costs. Further, we encourage ONC to take a hard look at various EMRs' app store fees which, in many instances, appear to stifle innovation by placing onerous financial burdens on otherwise innovative health IT developers simply seeking authorized and secure access to patient data. We look forward to future discussion and comment opportunities related to changes to financial and regulatory requirements.

- *Strategy: Promote trustworthiness of health IT through rigorous enforcement of information blocking and privacy and security laws when applicable, and by encouraging consumer reviews and reports on health IT products.*

Enforcement of information-blocking and privacy and security laws will greatly improve trust and transparency and will be paramount as we work together to ensure that patients have access to their data. The recent release of ONC's Cures Act Final Rule has provided clarity on what constitutes information blocking and paves the way for

implementation and enforcement. Collective fully supports enabling patients to access a complete copy of their medical records in a timely manner. Application programming interface (API) access for third-party applications to a machine-readable version of the patient medical record will also be important. We support API access broadly so that patient-oriented applications may access them and so that other EMRs, HIEs and other health IT applications (e.g., care management tools) may use these APIs as an alternate to point-to-point HL7-based integrations. We also recommend ensuring that existing EMR platforms not be permitted to place onerous economic tolls or other barriers to access of these APIs, but rather, the patient data should be able to freely flow for purposes of treatment, payment, and healthcare operations so as to encourage continued innovation by both EMR providers themselves as well as other public- and private-market solution providers. Consumer reviews and reports on health IT products will be useful, and we would welcome this as an excellent quality improvement tool and incentive for all health IT companies to improve their products and address deficiencies. In some cases, consumer reviews may be challenging to obtain for health IT products that are not directly consumer-facing (i.e., products that operate behind the scenes to transmit, package, or store data), and there are many products that integrate multiple solutions from different companies. Therefore, Collective would recommend that consumer reviews and reports be validated, and that all types of users (patients and providers) be able to offer reviews.

- *Strategy: Adopt and advance nationally endorsed standards, implementation specifications, and certification criteria through continued collaboration across public and private sectors.*

Collective supports rigorous standards, implementation specifications, and certification criteria developed and deployed collaboratively across public and private sectors. Collective is HITRUST CSF certified, which represents thousands of hours invested in both third-party onsite assessments, penetration testing, internal risk mitigation, and control development. HITRUST also issued Collective Medical the HITRUST Certification of the NIST Cybersecurity Framework. A mapping of the Trust Services Criteria to HITRUST has been made available publicly. These types of certifications are useful to help ensure quality and consistency in products on the market, can assure purchasers and end users of the reliability of the product, and can reduce overall economic barriers to entry. Additionally, data transport standards such as FHIR are extremely valuable in advancing interoperability so that developers can focus less on data access and more on value creation; ONC is, again, uniquely positioned to promote these, though Collective urges continued restraint, as ONC has already demonstrated, to promote but not regulate standards so as not to unintentionally stifle innovation through an inability of the regulation itself to keep pace with the rate of change.

Objective 4b: Establish transparent expectations for data sharing

- *Strategy: Address information blocking and other actions taken by healthcare providers, health IT developers, and other regulated entities that limit the access, exchange, and use of electronic health information.*

As stated above, Collective supports and looks forward to being an active participant in efforts to address information blocking. This strategy supports the principle of patient-centeredness and will help ensure that individuals have access to their health data. The coming years will represent a monumental shift as providers and

health IT developers adapt to and operationalize the provisions of the Final Rule addressing information blocking. Collective applauds the inclusion of this strategy in the Federal Health IT Strategic Plan and we are prepared to play a key role in executing it.

- *Strategy: Develop resources and communications plans including guidance for healthcare providers and other staff at healthcare organizations on how to comply with regulations.*

Collective agrees with this strategy, and we have great appreciation for any resources and guidance developed to support busy healthcare providers in complying with voluminous and frequently changing regulations. Just as important as the regulations themselves are how the regulations are interpreted and applied; therefore, user-friendly resources, including federal guidance and communications are incredibly valuable.

- *Strategy: Support a common agreement for nationwide exchange of health information that drives interoperability, supports federal agencies' strategies, and promotes effective governance.*

A common agreement for nationwide exchange of health information would be very valuable in achieving the goal of interoperability. As this strategy is pursued, Collective recommends ensuring that all of the appropriate stakeholders (e.g., consumers, the full spectrum of healthcare providers, payers, health IT developers, health information exchanges) are included in the process and have the opportunity to help shape the common agreement. Collective has submitted its application to become a member of the Common Agreement Work Group led by the Sequoia Project, as another indicator of our commitment to the common agreement. As part of this process, Collective suggests establishing deadlines along with incentives and/or penalties to force industry progress on a common agreement and the terms of the agreement.

- *Strategy: Promote data liquidity by working with developers, healthcare providers, payers, and state and federal entities to eliminate unnecessarily restrictive data sharing practices and to use endorsed standards, implementation specifications, and certification criteria.*

Collective supports the promotion of data liquidity and a collaborative approach to eliminating unnecessarily restrictive data sharing practices. We already adhere to standards and specifications that support this aim—HL7, CCD, FHIR, and HITRUST certification to ensure data is protected—and we look forward to participating in these efforts alongside other stakeholders.

Objective 4d: Promote secure health information that protects patient privacy

Collective fully supports the objective of promoting secure health information that protects patient privacy and protecting individuals' health data from misuse and threats like cybersecurity attacks, fraud, and other harms. Health IT companies including Collective have a duty to protect the data its clients share with them. Industry best practices such as HITRUST CSF certification support this aim. We look forward to additional guidance and technical assistance pursuant to this strategic plan on policies and regulations at the federal, state, and tribal level that pertain to the secure exchange of health information and enforce such rules.

Collective would welcome the opportunity to be actively engaged with ONC as the 2020-2025 Federal Health IT Strategic Plan is finalized and implemented in the coming years. We wish you every success and look forward to partnering with you in the future.

Warmest,

Chris Klomp
Chief Executive Officer
Collective Medical
chris.klomp@collectivemedical.com

Vatsala Kapur Pathy
Vice President of Regulatory & Government Affairs
Collective Medical
vatsala.pathy@collectivemedical.com