April 3, 2020

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Re: CoverMyMeds Comments to the ONC Proposed 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker,

On behalf of CoverMyMeds, I appreciate the opportunity to provide feedback on the draft "2020-2025 Federal Health IT Strategic Plan."

About CoverMyMeds

CoverMyMeds, part of McKesson Prescription Technology Solutions, is one of the fastest growing health care technology companies in the U.S. and consistently recognized as one of the best places to work in the country. CoverMyMeds' solutions help patients get the medications they need to be healthy by seamlessly connecting the health care network to improve medication access; thereby increasing speed to therapy and reducing prescription abandonment. CoverMyMeds' network includes more than 500 electronic health record systems (EHRs), 60,000 pharmacies, 700,000 providers and most health plans and PBMs. By facilitating appropriate access to medications, the company can help its customers avoid billions of dollars each year in administrative waste and avoidable medical spending caused by prescription abandonment.

General Comments | Interoperability and Patient Empowerment

We believe that healthcare interoperability should enforce the assurance to patients that their healthcare data and related information is assessible nationwide in a real-time, confidential and secure manner, with the inherent ability for the patient to directly access and control their healthcare data. This means that all relevant data, written or electronic, is readily available to patients and the applications or intermediaries they choose to enable access, for the consumption and/or exchange of their healthcare data.

Dr. Rucker, in his opening letter within the ONC Proposed 2020-2025 Federal Health IT Strategic Plan (" Plan"), stated accurately that the system's transformation is "hindered by the entrenched interests looking to prohibit access to that information". We, therefore, look forward to seeing more specificity from ONC on the methods they will use to address information blocking as this is one of the prime contributing factors impacting data fluidity, provider burden and access to patient specific information to inform clinical decisions.

In addition to the lack of willingness between trading partners to exchange information, the lack of consistent requirements for sharing patient information between stakeholders is also a significant barrier to interoperability.

Specifically, in requesting and timely responding to a request for said patient record(s), organizations are using privacy and security as a pretext to engage in anti-competitive practices by applying unique requirements to access patient information, even with patient consent.

Additionally, an area that should be further addressed by the Plan is related to the quality and usefulness of the data to be exchanged. As ONC and others have expressed many times, many providers are burdened by the various administrative functions they undertake in the course of patient treatment. We encourage ONC to ensure specificity in the final Plan that not only provides for patients to have access to and direct their health care information but also ensures that the information the provider and/or their intermediary is receiving is consumed, passed downstream into the provider's workflow in a valuable and useful way with actionable construct.   ONC's guidance in this area should ensure entities are not just exchanging data for the purpose of sharing data to meet the letter of the law, but that the data is valuable to the requestor and appropriately aides in the overall patient healthcare journey.

Further, relative to industry interoperability and data exchange, CoverMyMeds acknowledges that ONC promotes the interoperability data exchange through the FHIR standard for APIs however, we also encourage ONC to evaluate and outline all applicable ANSI-accredited standards capabilities of data exchange. Effective and comprehensive industry interoperability through ANSI accredited standards will only add to the healthcare industries efficiencies and further assist the goal of empowering the patient in their healthcare management and journey.

CoverMyMeds is supports the efforts of this Administration to empower the patient. Overall, we support the four main goals of the Plan, focusing on value and putting individuals first in an effort to improve the lives of individuals and communities in our nation's healthcare system; however, we feel that the ONC should have provided greater details on the tactics it plans to deploy to deliver on the strategies outlined in the Plan. We, therefore, strongly encourage the ONC to publish further details on how it will meet these initiatives as listed within the Plan.

Specific Comments | Goals, Objectives and Strategies

Promote Health and Wellness
Objective 1a: Improve individual access to health information
Evidence supports person-centered care needs to allow for individual direct access to health information through technology. We are supportive of the strategy and promotion of greater portability through open APIs and other interoperable health IT, improving access to smartphone APPs and other technologies that puts the patient in the driver's seat to access, receive, consume and send their information to promote their individual health and wellness

CoverMyMeds understands and advocates that for patients to directly interact with their health information, they must be able to trust, understand, and identify how they use and share their data in a real-time manner. As ONC and the other federal partners continues to evaluate and build on its strategies to improve individual access to health information, we encourage the continued consideration of the modernization of the health data framework to enhance not only direct patient access, but also the use and protection of data to improve health-outcomes and enable efficiency within the patient's healthcare journey. In order to do this, a modern health data framework should by patient-centric, have strong privacy protections, promote interoperability where data is shared electronically and freely with entities that enable the patient journey. Further, the framework should be risk-based, where all actors accessing data are aware of their rights, responsibilities, restrictions and repercussions with the accessible and needed data being uniform and consistent nationwide.

Objective 1b: Advance healthy and safe practices through health IT
Per the Plan, Health IT should be used to empower patients through the strategy of enabling individual patient access to view and interact with their health information.

CoverMyMeds agrees that to promote health and wellness of patients, empowerment is a key to success; patients, however, must also have appropriately curated information. Providing patients with the ability to view and interact directly with their health information that has been organized and presented appropriately will allow for quicker therapeutic decision-making, enable person-centered care, shared decision-making with health care providers and overall patient outcomes.

Objective 1c: Integrate health and human services information
One of the strategies to integrate health and human services information is to capture and integrate social determinants of health (SDOH) into the EHR. CoverMyMeds supports this strategy. SDOH creates patients' daily environments and lays the foundation for what resources are available to them. In the context of medication access, this can mean transportation to a preferred pharmacy, access to coupons and vouchers and even public safety measures and additional factors that affect whether or not a medication is affordable. Infusion of this information in EHRs and passed through to the care support team into their decision support tools, like a real-time benefit solution (RTBT) will provide opportunities for the care team to make decisions taking into considerations SDOH.

Many entities are actively working to better inform processes impacted by SDOH, such as standards development organizations like the National Council for Prescription Drug Programs (NCPDP). We encourage ONC and other federal stakeholders to actively participate in the standards development work ongoing at NCPDP in work group 10 where standards work is ongoing related to the electronic referral process and also the identification of social determinants of health. ONC and other federal stakeholder participation would help the task groups in their development, as well as, help inform the agencies on the current status of standards development in these areas.

Enhance the Delivery and Care Experience
Objective 2a: Ensure safe and high-quality care through the use of health IT
The Plan correctly identifies that "care choices made in our current healthcare system are largely driven by payer preferences rather than active consumer choice". Rising financial pressures, restricted choice, administrative bottlenecks and limited support are keeping patients from the medications and services they need to live healthy lives. Healthcare IT solutions offer strategies to overcome many of the challenges facing patients.[1]

Integration and adoption are key factors in meeting the objectives outlined in goal 2. Patient specific information, provided in real-time and freely available across care settings and also put into the hands of patients via secure, widely acceptable standards will assist in ensuring safe and high-quality care.

While CoverMyMeds does not think patient-matching is the most significant barrier to interoperability, we do support efforts to identifying scalable patient matching options. CoverMyMeds recommends ONC recognize the previous and current work done within the industry to address patient matching inconsistencies and provide specific guidance relative to the standards and implementation of a National UPI. We specifically recommend the use of NCPDP's Universal Patient Identifier (UPI) which leverages Experian's consumer demographic information and referential matching methodologies to identify patient files.

Objective 2b: Foster competition, transparency, and affordability in healthcare

CoverMyMeds agrees that affordability of healthcare services and treatment remains a key barrier to accessing quality care for many individuals. Information on price and quality should be readily available for the patient and their healthcare providers. The lack of transparency has been a factor that has led to the poor healthcare outcomes and disparities that remain in our healthcare system today.

Real-time patient price transparency tools offer great promise to effectuate positive health and cost outcomes for patients. However, the tools and the policy must be equitable to all patients. In the Plan, ONC correctly identified the need for equitable and accessible solutions when stating "Health insurance coverage is a significant determinant to access to healthcare". As health insurance continues to increase, so does the rate of uninsured individuals in the US. Being uninsured increases the likelihood that people will avoid care and face financial hardships when care is received." Current RTBT policies are not equitable as they only take into consideration plan driven information. CoverMyMeds has advocated and continues to advocate for RTBT policies to be equitable and inclusive of all information needed by the patient – insured and uninsured - and their provider to make informed, affordable decisions about the patient's needed therapy, such as cash and discount options. Our price transparency solution empowers all patients, regardless of coverage. RxBenefit Clarity™ provides benefit insights at the point of prescribing, and cash discount programs show medication price outside of insurance — offering another affordability option for the 109 million under-insured and uninsured. (cbo.gov/ cdc.gov).

To foster competition, transparency and affordability in healthcare a RTBT must be capable of integrating with a prescribing and dispensing health care professional's electronic prescribing or electronic health record (EHR) system for the transmission of real-time, patient-specific drug benefit and prescription price transparency information. Additionally, this technology should be deliverable via health apps accessible by the patient.

In order to ensure all patients benefit from this technology, a RTBT must provide healthcare professionals and patients information to make treatment/therapy choices on and off a patient's drug formulary or their benefit, such as clinically-appropriate alternatives (when appropriate), cash price, patient assistance and support programs with cost available at the patient's pharmacy of choice.

A recent study associated with medication access and the impact of costs related to said access, revealed that as out-of-pocket costs increase, prescription abandonment appears to rise exponentially at a rate **of ~0.6 percent** for every dollar, before leveling off around 69 percent as costs **exceed $250**. [1]

In this same study, most surveyed patients prioritized paying the lowest price as the most important decision-making factor. As a result, empowering patients to be informed consumers of health may be the most effective strategy for improving medication access, and without all options being included in a RTBT, the patient is not be fully empowered to make the best decisions for their care.

We offer that the availability of the technology or certification of said technology is not the regulatory issue. It is the lack of equitable policies. We look forward to the continued efforts of ONC in this area and being a resource to effectuate change.

Objective 2c: Reduce regulatory and administrative burden on providers.

While there will always be administrative tasks required of clinicians, we concur that they spend a significant amount of time performing administrative job duties, including time committed to completing prior

authorization(s). Through advances in healthcare IT, CoverMyMeds has simplified and expedited the ePA process for the entire healthcare network and has been successful in reducing the amount of time required to perform these administrative tasks. However, there is still opportunity available for healthcare IT to provide further insight on prescription medication requirements to providers. While prescribing a medication, providers are often unaware if a prior authorization (PA) will be required due to the lack of having real-time, consistent and transparent, patient specific coverage information available at the point of prescribing versus stagnant formulary and benefit information.

Efforts from CoverMyMeds, industry stakeholders and legislators have driven widespread adoption of ePA technologies – producing value, improving workflows and accelerating patient time to therapy. For ePA to continue having a positive impact on healthcare, provider adoption of the technology remains a key initiative.

The use of American National Standards Institute approved standards is a means to facilitate adoption. Standards including but not limited to the National Council for Prescription Drug Programs (NCPDP) SCRIPT ePA transactions, Health Level 9 (HL7) Application Program Interfaces (APIs) and Fast Healthcare Interoperability Resources (FHIR) facilitate the expeditious, real-time exchange of appropriate clinical decision details, reducing the friction found in the system today.

We are encouraged that ONC, in the March 9th release of the final *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Rule* called out the optional use of ePA via the NCPDP SCRIPT Standard ePA transactions for medications.

Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation
Objective 3a: Advance individual- and population-level transfer of health data
We are supportive of ONC's strategies to harmonize data elements and standards-based APIs to further build on the integration of the healthcare ecosystem. Apps for patient access to their health record, as well as, costs associated with care and prescriptions are available in the healthcare market today. However, as ONC has pointed out in various comments and rulemaking, access to the data to consistently surface patient specific cost and coverage information is hindered in the marketplace today. We encourage ONC to continue to focus on ensuring open access to patient specific information via secure, standards-based APIs.

Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure
Objective 4a: Advance the development and use of health IT capabilities
The major law governing health data (HIPAA) is outdated and did not take into consideration today's innovation. Since its passage, an abundance of new digital tools and platforms have emerged to improve health care. In the next five years, there will be 42 billion connected devices sharing 74 zettabytes of data every year. This massive, swiftly evolving system means more health problems can be identified and addressed.[2]

In turn, this means that there will be that much more health data for patients, providers and healthcare organizations to consume and use effectively when enabling the patient's healthcare journey. The ability for patients, providers, and health care entities to access and use this necessary data is critical for effective diagnosis, treatment, research and processing payments. However, to be effective, data must be unlocked while remaining secure as it moves throughout the healthcare universe.

The variability in federal and state data laws, including privacy and security, has created an abundance of confusion on when and how data should be shared, as well as, created opportunities for data hoarding, blocking and gamesmanship.

We encourage ONC, in partnership with other federal agencies to work collaboratively to establish a patient-centric, national and uniform data framework, enforced at the federal level, in which data is electronically and freely shared with the people who need to have it to treat, pay, coordinate, and improve patient care, including patients. Key considerations should be made to ensure timely payment, increased value and outcomes, and advance scientific understanding, better treatments, and cures for diseases.

CoverMyMeds recommends that ONC establish very specific enforcement actions to further discourage inappropriate behavior by organizations to block data needed to facilitate the interoperability desired by the industry and ONC.

Objective 4b: Establish transparent expectations for data sharing

It is clear that ONC is promoting interoperability through standards. To provide for greater clarity, guardrails and continuity on the use of standards to securely exchange information but ensure the continued advancement of data exchange and recognizing that the industry is continually evolving in this area, we recommend ONC adopt language by calling for the use of the most recently adopted version of an ANSI-accredited standard. ONC should also provide specific guidance on implementation to ensure that all participants within the healthcare space have a clear understanding of ONC's expectations. The utilization of APIs, as referenced by ONC many times, is pertinent to effective and expeditious data exchange, but if ONC does not fully address the monopolistic behavior of data-blocking within the industry and without fully addressing this issue with specificity, interoperability will not be accomplished.

Further and in conjunction with transparency and interoperability between healthcare entities from an industry perspective, the same level of transparency of healthcare records/data should be afforded directly to the patient. Industry interoperability in the manner described above will enable individuals to have seamless, secure and free access to their health record.

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

CoverMyMeds considers information security, privacy, compliance, and risk management as a major priority in the lens of creating and sustaining products and services that truly enable the patient to have ownership over their healthcare information, management, and journey.

The need for data fluidity and interoperability within the healthcare industry is evident and overdue. This transformation has been hindered by entrenched interests looking to prohibit access to or monopolize patient health data and ownership of data. We are therefore encouraged by the ONC's attention to this very important aspect of interoperability.

We offer that privacy and interoperability rules should apply to data based on intended use regardless of what entity handles the data. This promotes clarity and ensures that any entity who uses protected data is covered by the same rules. Additionally, entities who do not meet strong security protocols, or who expose patient health data to risk of financial or reputational harm, face strict penalties, including civil and criminal penalties for inappropriate use and disclosure that become more severe the greater the level of risk and actual harm to an individual.

CONCLUSION

Without significant change patients, providers, plans and other stakeholders will still struggle to have comprehensive data sharing and interoperability that improves the patient's healthcare journey.

Given that the technology and capability to expand interoperability within the industry are currently available and innovative solutions are continually being created, ONC should provide specific guidance about how technology can and should be used within the industry relative to each goal, objective and strategy. We submit that ONC's strategy and tactics to support that strategy should be transparent, be patient-centric and have strong data protections.

Thank you again for the opportunity to provide comments, recommendations and questions of the Plan. If you have questions, please contact Kim Diehl-Boyd, Vice President, Industry Relations and Government Affairs, at kdiehlboyd@covermymeds.com or (615) 663-5579.

Sincerely,

Kim Boyd

Kim Diehl-Boyd
Vice President, Industry Relations & Government Affairs

[1] CoverMyMeds Medication Access Report, 2020
[2] IDC - The Growth of Connected IoT Devices, 6/18/2019