

March 18, 2020

Donald W. Rucker, MD National Coordinator for Health Information Technology Office of the National Coordinator for Health Information Technology 330 C Street SW, Room 7009A Washington DC 20024

Submitted electronically to: www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan RE: Comments on the 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker:

POCP is a leading management consulting firm assisting healthcare organizations in the evaluation, development and implementation of winning health information management strategies in a rapidly evolving electronic world. One of our areas of specialty is electronic medication management and, through work with a diverse set of clients -- including bio-pharmaceutical companies, payers, pharmacy benefit managers and technology vendors -- we have come to know the unique challenges that threaten to impede continued progress towards the health care system of tomorrow. We thank you for your leadership in this area, and are excited to review and provide comment on the 2020-2025 Federal Health It Strategic Plan, and look forward to the progress we will make as a nation.

Goal 1: Promote Health and Wellness

POCP agrees that the use of health IT must go beyond the sharing of electronic health information between healthcare providers and the enabling of administrative tasks. We are supportive of the listed objectives and provide the following comments.

Regarding Objective 1b: Advance healthy and safe practices through health IT, we request that ONC consult with the FDA and industry experts on appropriate definitions and use of the term "digital therapeutics". The use of "evidence-based digital therapeutics" will be transformative for certain diseases and populations, however there are members of the health care community such as payers and managed care stakeholders that distinguish digital therapeutics as FDA approved digital therapies or FDA cleared devices from general wellness apps and electronic devices. These distinctions are important given the implications for how such therapies may be regulated and paid for.

Goal 2: Enhance the Delivery and Experience of Care

POCP agrees that health IT is a vital tool for assessing and improving the quality of healthcare while also improving patient choice and customization of care. We are supportive of the listed objectives and provide the following comments.

Regarding Objective 2b: Foster competition, transparency, and affordability in healthcare, we encourage ONC and CMS to continue efforts to further industry adoption of real-time prescription benefit check functionality that allows providers access to patient prescription copay information and therapeutic alternatives at the point of prescribing. Additionally, we encourage ONC to support industry efforts to develop standards and transactions enabling consumer-facing real-time prescription checks. Two industry efforts are underway. POCP leads and consultants are involved in both efforts and are happy to provide ONC leadership and staff with additional information on the progress of each. The first through HL7 led by the CARIN alliance and a second newer task group at NCPDP, which one of our POCP consultants is co-chairing.

Phone: 877.312.7627 Fax: 954.212.0200 www.pocp.com Regarding Objective 2c: Reduce regulatory and administrative burden on providers, first, POCP would like to call your attention to the need for automation for specialty pharmacy. Many of the cures and lifesaving treatments fall into the category of specialty medications. These are high-cost complex medications that require special handling, delivery and/or administration to patients. Today, 80% of drug approvals are considered specialty prescriptions, and it is estimated they will account for at least 50% percent of all prescriptions in 2020.¹ Due to their complex nature, the prescribing process for specialty medications includes a detailed patient enrollment process, that requires coordination between the provider, health plan, specialty pharmacy, and/or facility where the medication will be administered. Unlike typical prescriptions that can be written and transmitted electronically, there is no standardized way to electronically manage and prescribe specialty medications. Paper and fax are routinely used which add unnecessary burden to the prescribing process and create delays for patients who need to start these treatments as soon as possible. One of the major challenges to automation, is that, unlike other prescriptions that are covered under the pharmacy benefit, 50% of specialty medications are covered under the medical benefit which is only sparsely automated.

Second, POCP encourages ONC to continue efforts to reduce provider burden by promoting the adoption and use of electronic prior authorization (ePA). We encourage ONC to work with CMS to establish simplified prior authorization rules and criteria that can be modelled across the industry. Additionally, we encourage ONC to pursue ePA standards and solutions for healthcare products and services beyond medications. POCP leads and subject matter experts have written about the evolution of ePA and the need to advance this real-time capability for future use cases. You may learn more here: ePA 2.0: Taking Electronic Prior Authorization to the Next Level.²

Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation POCP agrees that analytic advancements like machine learning and forecasting have the potential to transform patient care and improve health. We are supportive of the listed objectives and provide the following comments.

Regarding Objective 3a: Advance individual- and population-level transfer of health data, and Objective 3b: Support research and analysis using health IT and data at the individual and population levels, POCP cautions ONC and federal partners as to growing concerns of bias in AI which have the potential to exacerbate existing health disparities or potentially create new ones. ^{3,4} We encourage ONC to invest in research on the impact of bias in AI on health care decision making, and how to prevent it. Various potential solutions exist, including creation and use of synthetic data sets. POCP has written extensively on AI and its application within health care. Specifically, you may learn more about the need for synthetic data from one of our Practice leads here: Three Cutting Edge Areas to Consider as AI Turns to More Practical Matters.5

Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

POCP agrees when patients, caregivers, and healthcare providers are equipped with complete and accurate health records, they can establish comprehensive and tailored care plans, make informed decisions about care and engage in preventive care. We are supportive of the listed objectives and provide the following comments.

¹ Pahlavan P. "Specialty Pharmacy By the Numbers". Available online: https://www.pharmacytimes.com/news/specialty-pharmacy-by-the-numbers Accessed March 17, 2020.

² Keegan J and Kleinberg K. "ePA 2.0: Taking Electronic prior Authorization to the Next Level" Available online: https://www.pocp.com/ePA 2.0 Accessed March 17, 2020

³ Brookings Institute. https://www.brookings.edu/series/ai-and-bias/ Accessed March 17, 2020.

⁴ Taulli T. "How Bias Distorts AI (Artificial Intelligence)" https://www.forbes.com/sites/tomtaulli/2019/08/04/bias-the-silent-killer-of-ai-artificial-intelligence/#70a399f97d87 Accessed March 17, 2020

Kleinberg K. "Three Cutting Edge Areas to Consider as Al Turns to More Practical Matters" Available online: https://www.pocp.com/three-cutting-edge-Al-areas Accessed March 17, 2020

Regarding Objective 4a: Advance the development and use of health IT capabilities, and Objective 4b: Establish transparent expectations for data sharing, POCP encourages ONC and federal partners to work to incentivize the adoption and use of health IT by all health care providers in all settings of care. Strategies to "reduce financial and regulatory barriers" must acknowledge and address the financial and regulatory barriers that exist for health care providers such as pharmacists. Similarly, strategies to "address information blocking" and "a common agreement for nationwide exchange of health information" must include all settings of care and providers including pharmacies and pharmacists. As a leading management consulting firm specializing in strategies for electronic medication management, we work hand in hand with clients whose ability to deliver value-based care is hindered by their lack of inclusion in federal interoperability programs and information blocking. We are at a critical point in furthering national interoperability, however, not all sectors of health care are positioned to move forward-of no fault of their own.

Regarding Objective 4c: Enhance technology and communications infrastructure, in light of the current COVID-19 pandemic, POCP would like to emphasize the great need for telehealth services and supporting infrastructure to ensure the continuity of health services in safe and effective manners during times of a public health crisis. POCP leads and subject matter experts have written on the topic of telehealth services and are currently working on releasing several articles on critical success factors for addressing COVID-19 using health IT and telehealth services. You may learn more about our telehealth insights here: Why Telehealth is At an Inflection Point.6

Again, POCP thanks you for the opportunity to provide comment on this Strategic Plan, and applauds your continued work to advance our health system and improve the health of the nation. Should you or your staff have any questions or require additional information on our comments, please contact Tricia Lee Rolle at tricialee.rolle@pocp.com. We are happy to further discuss these recommendations with you.

Singerely,

Anthony J Schueth

CEO and Managing Partner Point-of-Care Partners, LLC

⁶ Rolle TL. "Why Telehealth is At an Inflection Point". Available online: https://www.pocp.com/telehealth-drivers/. Accessed March 17, 2020.