

# ALSTON & BIRD

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May 28, 2024

VIA ELECTRONIC SUBMISSION

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

RE: Draft 2024-2030 Federal Health IT Strategic Plan

To Whom It May Concern:

Thank you for the opportunity to comment on the Office of the National Coordinator for Health IT (ONC) draft 2024-2030 Federal Health IT Strategic Plan (the Strategic Plan).

On behalf of our many health care clients, we appreciate the chance to share feedback on the goals, objectives, and strategies the federal government will pursue to improve health experiences and outcomes for individuals, populations, and communities while also striving to promote opportunities for improving health equity, advancing scientific discovery and innovation, and modernizing the nation's public health infrastructure. We support these aims. Our comments reflect the collective concerns of many of our clients in the industry, and focus on anti-competitive practices including contractual agreements, enforcement of information blocking requirements, and advisory opinion authority.

Thank you for the opportunity to share our feedback with you. Should you need any additional information or if you have any questions, please feel free to contact me at [sean.sullivan@alston.com](mailto:sean.sullivan@alston.com) or 404-881-4254.

Sincerely,



Sean T. Sullivan  
Partner  
Alston & Bird LLP

## I. Anti-Competitive Practices

As ONC asserts in the Strategic Plan, health care is improved through greater competition and transparency. The federal government plans to encourage pro-competitive business practices for the appropriate sharing of electronic health information (EHI) so that individuals and healthcare organizations can easily select software and vendors of their choice and can use health applications and other health IT tools without special effort. In addition, the federal government plans to support efforts to merge clinical and administrative data streams, including payment data, so that health care providers and patients have access to real-time financial data at the point of care and can leverage patient trust models to ensure patients are enabled to make informed decisions regarding their care.<sup>1</sup> Further, ONC explicitly encourages innovation and competition. Specifically, the Strategic Plan strives to support and protect innovation and competition in health IT that result in new solutions and business models for better care and improved outcomes.<sup>2</sup>

We agree with these aims. In order to support competition, **we encourage ONC to prohibit anti-competitive restrictions in contracts, including non-compete agreements and restrictive contractual provisions between health care actors.**

ONC has previously raised concern regarding contract terms that interfere with the access, exchange, and use of EHI. In addition to contract terms that specify unreasonable fees and commercially unreasonable licensing terms, ONC has noted that, for example, “a contract may implicate the information blocking provision if it included unconscionable terms for the access, exchange, or use of EHI or licensing of an interoperability element.”<sup>3</sup> There may be disparities in bargaining power between different actors that could lead to these types of problematic contract terms.

Further, many health IT companies vary contractual terms for different vendors based on whether they view a given vendor as a competitor. Necessary data is often restricted for some vendors but not others without explanation. These types of restrictive and anti-competitive contractual terms inhibit vendors—who are already business associates of covered entity health care providers under the *Health Insurance Portability and Accountability Act* (HIPAA) and have a permissible purpose and legal authority to access their customers’ PHI—from effectively and efficiently doing their jobs on behalf of a healthcare organization and their patients. For instance, some companies will arbitrarily restrict the use of certain basic software application tools, such as search capabilities, in an effort to subvert certain vendors’ work. We encourage ONC to evaluate company practices that vary access to data based on whether the vendor being granted access is seen as a competitor.

In addition to contracts that interfere with information sharing, many contracts in the health care industry have also become very restrictive for employees. For instance, a major electronic health record (EHR) system with over one third of the U.S. hospital market share,<sup>4</sup> has drawn attention by requiring employees to sign non-compete agreements that purportedly included about 4,500 companies by 2021, including nine health systems.<sup>5</sup> This type of restrictive behavior stifles innovation and competition.

There are serious implications for anti-competitive behavior in health care. Recent Congressional hearings have explored anticompetitive behavior in health care and the negative impacts of significant market share in the industry. For example, when a single company holds a substantial market share, it can be destabilizing when there is a market-disrupting event, such as a cybersecurity breach. Similarly, if powerful actors prohibit information sharing, for instance through contractual terms as described above, there are also widespread negative impacts to patients, providers, and other stakeholders. This creates significant risk for the industry.

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<sup>1</sup> ONC Strategic Plan, Slide 15.

<sup>2</sup> ONC Strategic Plan, Slide 6.

<sup>3</sup> 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25642, 25848, (May 1, 2020). 25812.

<sup>4</sup> Definitive Healthcare, Most Common Hospital EHR Systems by Market Share, [available here](#).

<sup>5</sup> Becker’s Hospital Review, Why Epic Trimmed its Noncompete List, [available here](#).

The trend of consolidation is only increasing, with fewer vendors in critical spaces. Now, when a disruption occurs with a single vendor, the impact can be extensive and affect patient care.

ONC should ensure that there is competition within the health care industry, so that a restrictive policy or an incident with a single vendor does not cause paralyzing disruption. ONC should support banning non-compete agreements and should also expressly prohibit actors from using anti-competitive restrictions in contracts, which can limit access to necessary data for other vendors.

## II. Information Blocking

ONC states that the federal government plans to promote information sharing practices to ensure that health IT users have clear and shared expectations for data sharing and health information is appropriately exchanged across care settings. ONC highlights the goal of reducing or eliminating information blocking conduct.<sup>6</sup> Information blocking is inherently anti-competitive. As noted above, some companies are explicitly limiting data access for vendors they see as competitors under the guise of protecting intellectual property.

Information blocking practices can interfere with both providers' and patients' abilities to access health care data in a timely manner and can ultimately impede a providers' ability to care for patients. This causes delayed care, increased costs, and worse health outcomes for patients. Health IT vendors should not make decisions for patients, or the healthcare organizations serving those patients, regarding access to the patient's data. Patients and their chosen providers have the right to share certain information, and health IT vendors should not be allowed to inhibit this data sharing based on the vendor's perception of corporate competition. Further, this type of information blocking can exacerbate the problem of siloed health care data in various, disconnected databases, which can threaten patient safety and undermine efforts to make the health system more efficient and effective. **We urge you to take immediate steps to reduce and ultimately eliminate information blocking practices. First, we recommend stricter enforcement of information blocking rules, in accordance with ONC's responsibilities. Second, we encourage you to actively identify and refer cases to the Office of Inspector General for the U.S. Department of Health and Human Services (HHS OIG) for enforcement.**

Congress enacted the *21<sup>st</sup> Century Cures Act* in 2016, thereby prohibiting information blocking by certain actors. ONC is responsible for implementing the *21<sup>st</sup> Century Cures Act* information blocking prohibition in regulations and identifying reasonable and necessary exceptions. ONC defines information blocking as practices that are "likely to interfere with the access, exchange, or use of [EHI]".<sup>7</sup> ONC's final rule entitled, *21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*,<sup>8</sup> promulgated information blocking regulations in May of 2020, with an applicability date of April 5, 2021. In addition, the final rule entitled, *Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules*, provided an enforcement mechanism against information blocking.<sup>9</sup> However, there has not been meaningful enforcement thus far.

This latter rule provides HHS OIG with civil money penalty (CMP) authority for information blocking by authorizing HHS OIG to investigate claims of information blocking and providing the HHS Secretary authority to impose CMPs for information blocking by developers of certified health IT and health information networks and exchanges. We encourage ONC to actively identify and refer cases to HHS OIG for enforcement through CMPs. This would effectively penalize information blocking behavior and discourage future information blocking conduct.

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<sup>6</sup> ONC Strategic Plan, Slide 24.

<sup>7</sup> 45 C.F.R. § 171.103.

<sup>8</sup> 85 Fed. Reg. 25642.

<sup>9</sup> 88 Fed. Reg. 42820.

### III. Advisory Opinion Authority

As part of the Strategic Plan, ONC affirms the federal government's plan to promote interoperable and secure health information sharing through nationally adopted standards. This would help ensure that providers deliver safe, equitable, high-quality, and improved care so that individuals' health information is available across care settings. In addition, ONC encourages the use of interoperable standards that improve public health, emergency medical services, research, and emergency and disaster preparedness, response, and recovery efforts.<sup>10</sup>

We are encouraged by these objectives and agree with these critical aims. However, we contend that **ONC could more effectively reach these goals if the division had the authority to issue advisory opinions.** We support ONC's continued efforts to obtain this authority. There are critical issues identified in the Strategic Plan, and the ability to issue advisory opinions would be an effective mechanism to implement ONC's vision.

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<sup>10</sup> ONC Strategic Plan, Slide 13.