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Submitted via regulations.gov

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U.S. Department of Health and Human Services
330 C Street, SW, 7th Floor
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Re: National Survey of Digital Health Companies - Agency Information Collection Request. 30-Day Public Comment Request [0990-New-30D]

Datavant appreciates the opportunity to respond to the National Survey of Digital Health Companies Agency Information Collection Request. Our comments are informed by our participation in the ASTP/ONC *'Un-Blocking Health Information Bootcamp*' on September 4, 2025, which convened senior regulators and industry leaders for an in-depth discussion of interoperability challenges.

We commend the U.S. Department of Health and Human Services (HHS) for evaluating ASTP/ONC's implementation of the information blocking regulations[1] and Application Programming Interfaces (APIs) "without special effort" policies[2] under the 21st Century Cures Act. We share the administration's goal of modernizing regulatory programs to foster competition and support innovation in healthcare.

Datavant is the data collaboration platform trusted for healthcare, working with more than 80,000 hospitals and clinics, every health insurance company in the U.S., all 20 of the top 20 pharmaceutical companies, government agencies, and more than 300 real-world data partners. We are a company of health information interoperability, privacy, and security experts, on a mission to make the world's health data secure, accessible, and actionable.

As a data collaboration platform working with a wide variety of healthcare industry stakeholders, Datavant has direct experience with the persistent barriers that interfere with access, exchange, and use of electronic health information. We have organized our comments across the following topic areas:

[1] 42 U.S.C. 300jj-52
[2] 42 U.S.C. 300jj-11

1. Experiences with Healthcare APIs and the "Without Special Effort" Policy
2. Implementation of Information Blocking Regulations
3. Nurturing an Ecosystem of Innovation and Transparency

Detailed responses are below:

Experiences with Healthcare APIs and the "Without Special Effort" Policy

Opaque and Anti-Competitive API Pricing

Application Programming Interfaces (APIs) are essential infrastructure for health data exchange. Yet EHR developers' pricing and licensing terms for API access—particularly for proprietary, non-HL7 FHIR, "private" APIs and interfaces used to retrieve non-USCDI data or enable workflow interventions/write-back—remain opaque, non-standardized, and often unrelated to verifiable costs. These pricing and licensing terms have the practical impact of creating significant structural barriers to health information access and use. These fee tollgates sit atop infrastructure that healthcare providers already pay for, creating financial friction and chilling adoption of innovative solutions. This creates a dynamic where healthcare organizations and their innovation partners are forced to pay again and again for access to data maintained within electronic health record systems that cost millions to license and use.

Vendors sometimes argue that the initial setup, credentialing, security, identity, audit, and maintenance of API integrations justify a high fixed charge. That is fair *if* those costs are documented, allocable, and auditable. But current EHR vendor practices—where those costs aren't broken out, change arbitrarily, or include large nonrecurring opportunistic markups—go beyond reasonable cost recovery and shift into competitive toll collection.

As an example, high fixed "access" and per-connection fees (e.g., multi-thousand-dollar setup fees per environment and recurring per-requester API call fees) are essentially ubiquitous across certified health IT developers. These charges are implemented in various frameworks and seem difficult to justify as "without special effort." The fees are also changing regularly, making integration work unpredictable and hard to square with cost-based, non-discriminatory pricing principles in the information blocking regulations.

This dynamic is also consistent with the 2022 survey published in the Journal of the American Medical Informatics Association (JAMIA) referenced in the request for comments. The JAMIA survey clarified that many digital health companies cited high fees and lack of

reasonable testing environments as primary obstacles to adoption, even when standards-based APIs were technically available.

Licensing Restrictions That Undermine Innovation

Beyond fees, licensing terms imposed by EHR vendors on proprietary APIs and interfaces (e.g., narrow enumerated table sets, unilateral revocation, required vendor approval, restrictions on developer activities, and non-reciprocal IP right and data use clauses) erect non-price barriers that limit flexibility, impose switching costs, and blunt downstream innovation—even where a third party legitimately has healthcare provider-authorized access to EHI.

These practices sharply conflict with the statutory and regulatory directives for "access without special effort." When vendors layer on deep fees or restrictive licensing for non-certified APIs (which often unlock critical non-USCDI data or write-back capabilities), those practices can effectively thwart the spirit, and potentially the letter, of the "without special effort" obligation.

Why these practices are inconsistent with the Cures Act's "Without Special Effort" policies

Congress required health IT developers to publish APIs that allow EHI to be "accessed, exchanged, and used without special effort," including access to all data elements of the patient EHR to the extent permitted by applicable law. The Cures Act's bipartisan interoperability goals have been hampered by inconsistent implementation. This is compounded by a tendency of some developers to implement only the minimum needed for certification, undermining the spirit of interoperability.

When vendors layer in heavy setup or per-connection fees (especially outside the scope of the certified APIs), those costs can render "without special effort" aspirational rather than real. When innovators must resort to proprietary APIs (because certified APIs don't fully surface needed data or functionality), EHR vendors effectively create parallel gatekeeping channels beyond regulatory oversight. As another example, the "Manner Exception Exhausted" sub-exception under the information blocking regulations (enabling regulate factors to claim infeasibility after offering limited interoperability options) becomes a potent tool for vendor steering: they can force a requester down constrained or vendor-preferred paths, then reject or delay alternate requests.

Fully realizing "access without special effort" requires stronger enforcement against anti-competitive behaviors and cost-based pricing requirements.

Considerations for Further Survey Work

ASTP/ONC's current request for information—building on ONC's prior survey work—recognizes that standardized APIs have been adopted but experience using these APIs varies significantly due to commercial practices around non-standard APIs and marketplace pathways. Sustained assessment and targeted enforcement are necessary to "nurture an ecosystem of innovation and transparency."

To address these barriers, we recommend a market survey of pricing and licensing practices associated with EHR enablement of health data APIs. These results will likely support **federal policy requiring cost-based pricing for health data APIs, directly aligned with eliminating anti-competitive tollgates** discussed at the ASTP/ONC bootcamp. Pricing should be tied to documented, verifiable technical costs, with no allowance for opportunity-cost or data-monetization-based pricing. This should include mandating transparent, standardized API fee schedules and prohibiting discriminatory pricing structures that target competitors or companies with overlapping software/services.

Implementation of Information Blocking Regulations

Misuse of Information Blocking Exceptions

The survey's assessment comes at a critical moment, as broad and ambiguous information blocking exceptions are increasingly used to undermine the Cures Act's bipartisan intent. Originally reasonable and necessary carveouts have become justifications for preserving control over data and blocking competition. Recent rulemaking has expanded the scope of these exceptions, particularly under the "Infeasibility" and "Manner" exceptions, beyond the original congressional intent.

Exploitation of Information Blocking Exceptions

These expanded exceptions have been exploited by entrenched incumbents to refuse legitimate integration requests under exaggerated technical or financial claims. The "Manner Exception Exhausted" sub-exception, for instance, enables actors to reject requests after steering them to limited exchange options, preventing adoption of modern technologies. Similarly, the Fees Exception creates significant financial barriers deterring third-party integration. **We support HHS leadership's identification of the misuse of exceptions as a primary enforcement priority.**

Restoring the Cures Act's Intent

To restore the original intent of the Cures Act, we recommend that HHS:

- Narrow exceptions to close loopholes and prevent opportunistic interpretations
- Standardize expectations so permissible constraints are consistent and not subject to vendor discretion

We also recommend prioritizing enforcement of the information blocking regulations by the HHS Office of Inspector General (OIG), including timely investigation of complaints and meaningful penalties against misuse of exceptions. Lack of federal enforcement has failed to deter information blocking and spurred state-level litigation to adjudicate industry challenges. Datavant is encouraged by the recent HHS announcement[3] and enforcement alert[4] and believe they are crucial first steps in sending a clear deterrent signal.

Nurturing an Ecosystem of Innovation and Transparency

Expanding the Definition of Interoperability to Support Non-Treatment Use Cases

While much of the focus of interoperability remains centered on clinical data, a critical gap remains in financial, facility-level, and operational data; data that is essential for coding, digitization, and the transition to value-based care, and yet lags far behind clinical interoperability. This data, often commingled with clinical electronic health information, is essential for provider coding, digitization, and the transition to value-based care. To truly nurture an innovative ecosystem, **HHS policy must expand interoperability requirements to include non-clinical datasets.** We urge ASTP/ONC to consider how the information blocking regulations and the Health IT Certification Program should expand to facilitate access to the full spectrum of health data required to modernize the U.S. healthcare system. We are encouraged by the newly adopted HHS Office for Civil Rights FAQ[5] clarifying disclosures for value-based care as an important first step.

Modernizing Regulatory Programs

Federal health IT policy should be modernized to nurture innovation and transparency. Regulatory frameworks like the Promoting Interoperability (PI) Program and the Health IT Certification Program should shift focus from prescriptive technical requirements to

[3] HHS Announces Crackdown on Health Data Blocking

[4] https://oig.hhs.gov/documents/special-advisory-bulletins/10930/information-blocking-enforcement-alert-2025.pdf

[5] Does the HIPAA Privacy Rule permit a covered health care provider to disclose protected health information to value-based care arrangements, such as accountable care organizations, for treatment purposes without the individual's authorization? | HHS.gov

directing real-world outcomes. **Metrics should emphasize exchange volumes, care transitions, as well as patient access.**

Supporting a Competitive Ecosystem

Policymakers should preserve purpose-built exchange pathways, including direct API connections, specialized data networks, and other use-case informed health information technology infrastructure. Information blocking exceptions should not create de facto safe harbors that block more efficient exchange methods.

Embedding Pro-Competitive Principles

Anticompetitive harm in health IT often results from fragmented federal policymaking. To address this, **Datavant recommends establishing a standing interagency task force to embed competition principles in health IT policy proactively**, rather than relying solely on retroactive enforcement.

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Please do not hesitate to contact us at alya@datavant.com if we can be a resource in advancing the 21st Century Cures Act's intent.

Thank you,

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