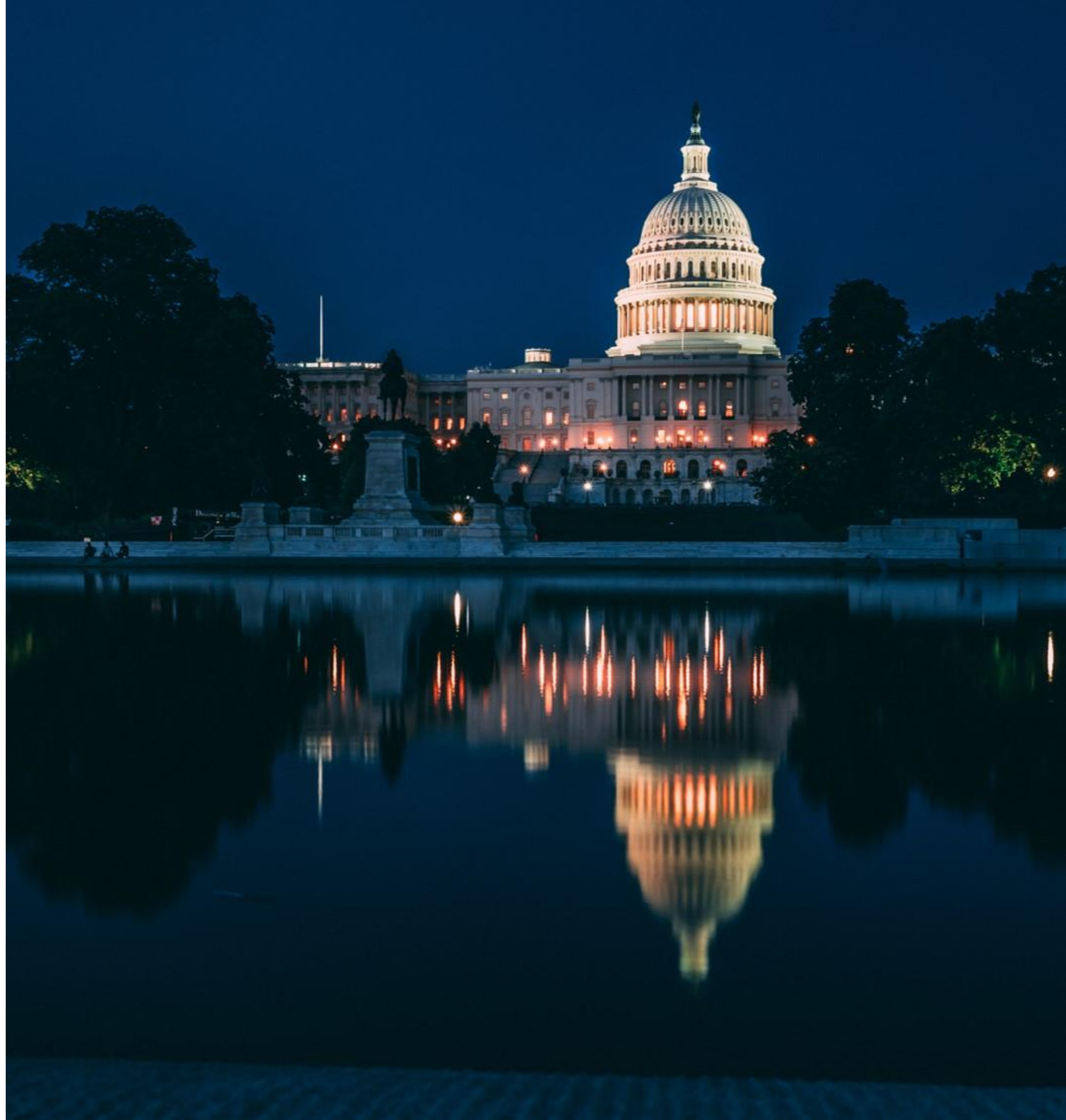


# The **BLOCK** STOPS HERE: Policy Proposals for Cracking Down on Information Blocking

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**December 2025**

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# TODAY'S PRESENTERS

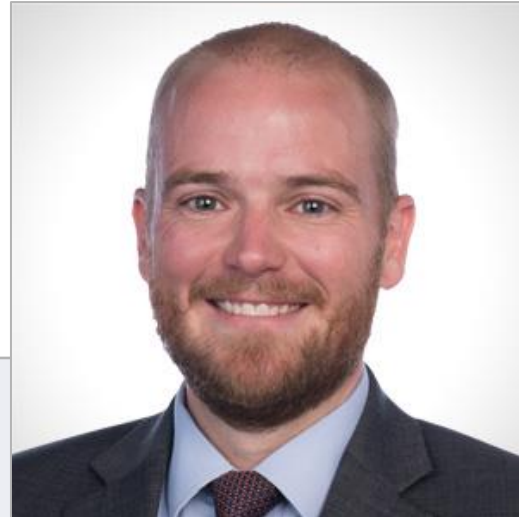


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# Kill the Clipboard!

A Federal Policy and Industry Roadmap to Accelerate Innovation and Cut Administrative Waste

- In March 2025, Leavitt Partners published a paper that included a multi-sector set of ideas for the public and private sectors to consider for how to improve data exchange and interoperability.

**1** Eliminate Antiquated Interoperability Policy and Better Align Across the Federal Government

**2** Improve Patient Access to Health Care Data

**3** Improve Health Care Data Exchange to Ensure Faster Implementation of FHIR APIs for B2B Data Exchange

**4** Improve the Trusted Exchange Framework and Common Agreement (TEFCA) and enforce information blocking

**5** Automate Quality Measurement Reporting

**6** Adopt Digital Identity Services (IAL2/AAL2) for Individuals, Payers, and Providers

[Leavittpartners.com/kill-the-clipboard](https://leavittpartners.com/kill-the-clipboard)



# From Kill the Clipboard to The Block Stops Here: Enforce Information Blocking

Ditch the Clipboard: Policy Ideas for DOGE and the Trump Administration



## Improve Health Care Data Exchange and immediate implementation of FHIR APIs for B2B data exchange

4. **The original wording of the 21st Century Cures Act** requires the administration to "take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks." It also states that **"the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts"** by providing providers and health plans the ability to use existing national networks (e.g., eHealth Exchange) to meet the requirements within TEFCA.
5. **Publish the TEFCA FHIR API endpoint directory publicly immediately**, which includes the recommended data elements suggested on the HL7 website, which lists the technical contact information (phone) and developer portal information to resolve any connectivity issues, thus streamlining registration and onboarding. This could be required under an accreditation program (such as Health Plan Accreditation).
6. **The Office of the Inspector General (OIG) should investigate the more than 1,100 possible information blocking** identified by the public and the ONC, publish the findings, and report to CMS to ensure data exchange is occurring.

Ditch the Clipboard: Policy Ideas for DOGE and the Trump Administration



## Improve Health Care Data Exchange and immediate implementation of FHIR APIs for B2B data exchange

7. ONC can provide a way for organizations to aggregate information blocking complaints and allow an independent third-party association or organization to act on behalf of a group of companies who believe information blocking is occurring. This would encourage additional payers and providers to submit more information blocking complaints since it wouldn't be tied back to their individual organizations. The CARIN Alliance called this a **"complaint clearinghouse" model**.
8. **Provide HHS statutory authority to offer Advisory Opinions for Information Blocking claims**, which allows the agencies to execute their full responsibilities under the 21st Century Cures Act.
9. **Publish all regulated FHIR API endpoints in a publicly available location**, regardless of whether those endpoints exchange data with a proprietary solution or not. Options must be made available to providers and health plans to make the APIs available in ways that are customized to that organization's unique business needs.

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## Information Blocking: What is it?

- Defined by the 21st Century Cures Act, information blocking is a practice by an actor that is likely to interfere with the access, exchange, or use of electronic health information (EHI).
  - A patient requests access to personal health information but encounters delays or denials of access from the primary care provider, compromising their ability to seek a second opinion from another doctor.
  - A specialist receives a patient referral and requests the patient's medical records from the primary care provider, but encounters delays or denials in accessing those records—compromising the ability of the specialist to properly care for the patient.
  - A stage 4 colon cancer patient who wants to share personal health data with an organization that is starting a new clinical trial that could save the patient's life but finds that the hospital's internal data-sharing policies or electronic health record (EHR) technology makes it difficult or impossible to share that data.





## Information Blocking Actors

- The Cures Act defines “Actor” as health care providers, health IT developers, and health information exchanges/health information networks.
  - Penalties for “providers” are different from those of other actors—providers are subject to “appropriate disincentives” while other actors are subject to defined penalties.
  - Under current regulation, HHS has only defined penalties for a subset of provider actors.



# Exceptions







- There are several exceptions that permit actors to engage in practice that could otherwise be considered information blocking, including:
  - Not fulfilling requests to access, exchange, or use EHI: preventing harm, safeguarding privacy or security, the infeasibility of the request, or the limits of health IT performance.
  - Procedures for fulfilling requests to access, exchange, or use EHI, including around licensing, fees, or the manner in which the actor fulfills the request.
  - Practices related to actors' participation in TEFCA.



# Knowledge Standards

- Depending on the actor, there are different standards in place for determining information blocking.
  - For health IT developers and HIEs/HINs, the standard is whether they know, **or should know**, that a practice is likely to interfere with the access, exchange, or use of EHI.
  - For providers, the standard is simply whether **they know** that the practice is likely to interfere with the access, exchange, or use of EHI.

## Info Blocking: Current Process

	Has information blocking occurred?
	ASTP receives an information blocking complaint.
	ONC refers the complaint to OIG.
	OIG determines if the complaint concerns an "Actor" as defined by the 21st Century Cures Act.
	If the "Actor" is a health provider, for which disincentives have been created, OIG must determine if the provider had actual knowledge that their behavior blocked the flow of information.
	If the "Actor" is a health IT developer or HIE/HIN, OIG must determine if they knew, or should have known that their behavior was likely to interfere with the flow of information.



# Penalties and Barriers to Enforcement

- HHS-OIG has the authority to impose civil monetary fines (CMFs) of up to \$1 million on health IT developers and HIEs/HINs found to have committed information blocking.
- Separately, CMS has the authority to establish “appropriate disincentives” for health care providers found to have committed information blocking—depending on the type of provider, impacts to MIPS, the Medicare Promoting Interoperability program, or MSSP.
- **However, enforcement of information blocking has been limited, due to several reasons, including:**
  - **Reporting:** A limited number of submitted information blocking complaints.
  - **Regulation:** Insufficient penalties/disincentives for information blocking.
  - **Resources:** Limited resources for OIG and CMS to conduct enforcement.
  - **Revisit:** Need to revisit the 21st Century Cures Act for specific topics.



## What penalty could apply?



If OIG determines that a regulated health provider has engaged in information blocking, HHS may be subject to “appropriate disincentives.”

**Note:** Only a subset of providers have identified disincentives.

**Note:** All penalties are retained by CMS or HHS.



If OIG determines that a Network, Exchange, or other Certified Health IT has engaged in information blocking, it may impose civil monetary penalties.

**Note:** All CMP's are returned to the Treasury.



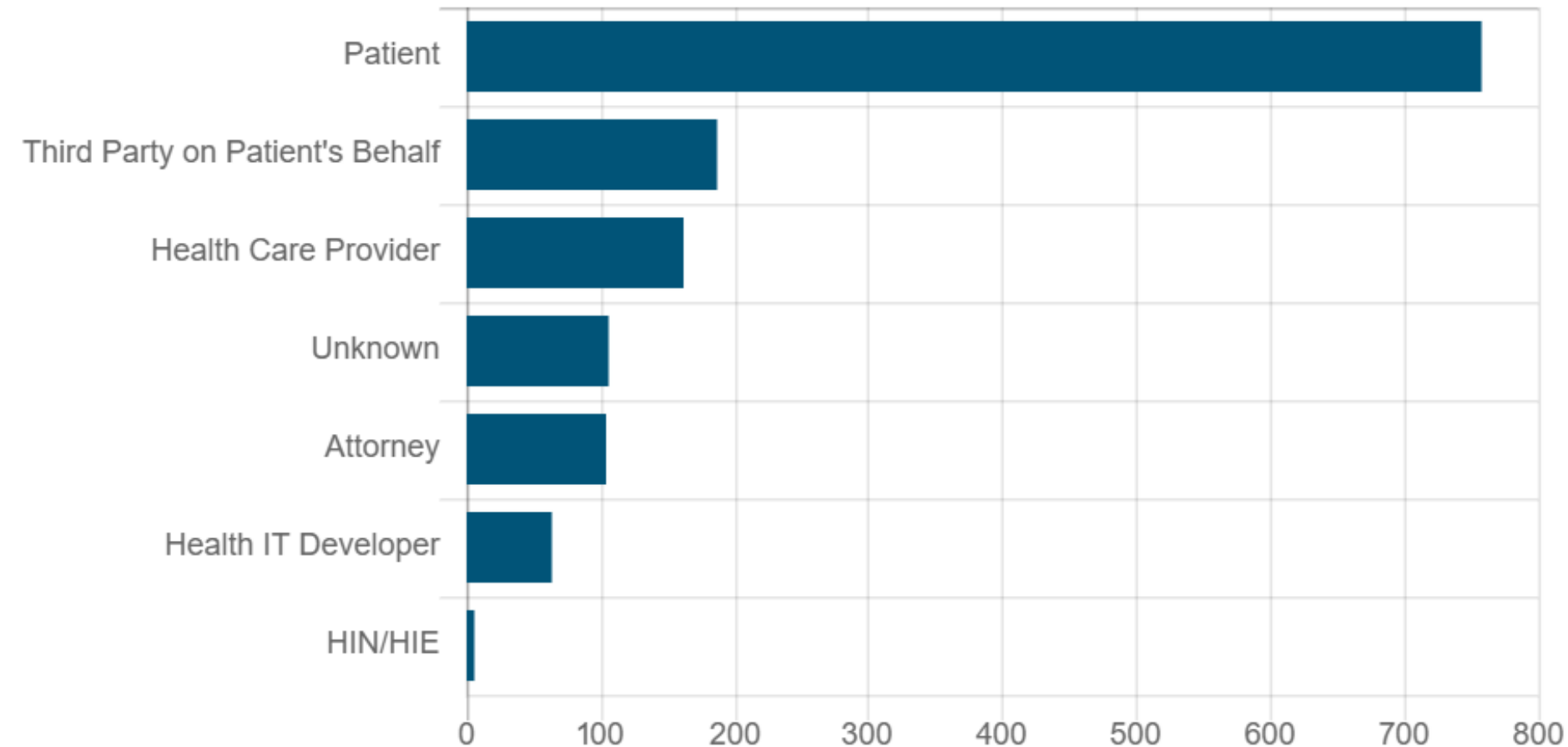
For Certified Health IT, ONC may also take action under the CEHRT program.



**Note:** HHS has not yet identified “appropriate disincentives” for many provider “actors” such as labs, pharmacies, ambulance providers, and others.

# Reporting: HHS NEEDS MORE AWARENESS OF POTENTIAL INFORMATION BLOCKING ACTIVITY

Claims Counts by Types of Claimant



- HHS needs more complaints reported, either individually or in aggregate.
- Need to go after the “big whales” who are engaged in IB behavior to make it worthwhile.
- “Complaint clearinghouse” or anonymous group complaints needed; FAQ clarified this is ok.
- Complaints to ONC related to CEHRT is the faster path.





## **Regulation: HHS Needs Different Statutory and Regulatory Authorities for Enforcement**

### **“Did they knowingly commit”**

- Complaint about a Provider — ONC — OIG — Referred to CMS — Communicate disincentive — Appeal to CMS — If appeal fails, CMS implements disincentive

### **“Should they have known”**

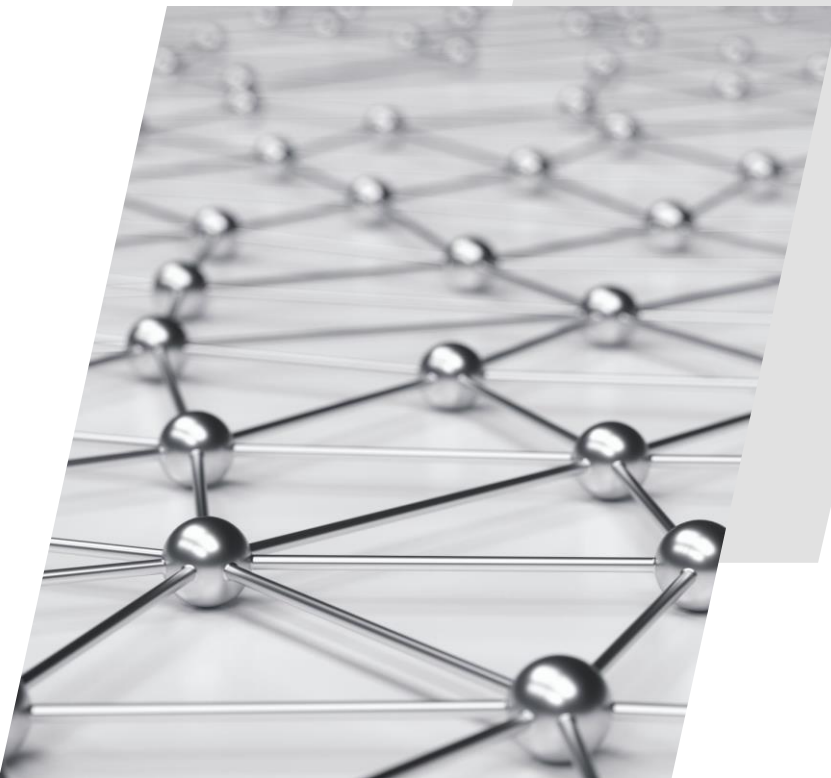
- Complaint about a Developer / Network — ONC — OIG — OIG Appeal (Administrative Law Judge) — If appeal fails, CMS implements a Civil Monetary Penalty (CMP)

### **Potentially a new path**

- Labs (Provider) — OIG — CCSQ (CMS) — Penalty is ambiguous / unknown
- HHS needs pressure from stakeholders to conduct additional rulemaking to add strong disincentives to information blockers.
- ONC needs ‘advisory opinion authority’ from Congress before these processes even start
- Could deduct grant funding for hospitals



# RESOURCES: HHS NEEDS FUNDING TO SUPPORT ENFORCEMENT



- HHS-OIG needs dedicated annual appropriations to plan for and conduct investigations.
- An additional option for funding is the money collected from information blocking penalties—with statutory changes to the 21st Century Cures Act, OIG could reuse these funds to use for its operations or enforcement activities (currently, these funds are deposited in the Treasury).
- Investigation, especially larger ones, take approximately 2-3 years with the current staffing levels which is why funds need to be retained by OIG for successful information blocking actions.



# Revisit: Statutory Provisions Need to be Updated

- ONC needs advisory opinion authority to more quickly address factual information blocking scenarios.
  - This will more quickly resolve issues as a matter of interpretation before needing to wait months or years for OIG to conduct an investigation.
- An additional option for funding is the money collected from information blocking penalties—with statutory changes to the 21st Century Cures Act, OIG could reuse these funds to use for its operations or enforcement activities (currently, these funds are deposited in the treasury).

## Info Blocking: Ideal Process

?	There should be only one knowledge standard and one penalty paradigm:
➡	ONC/ASTP receives a complaint and refers it to OIG.
⚖️	OIG and ONC/ASTP determine if a regulated Actor knew or should have known their actions would lead to information blocking.
\$	If OIG finds information blocking, the Actor should be subject to civil monetary penalties.

# Revisit: Statutory Provisions need to be updated

## SIMPLIFY THE STANDARD OF IB AND THE PENALTIES

### What else is needed?

 <p>ONC/ASTP should be granted "Advisory Opinion" authority to help Actors understand potential violations.</p>	 <p>OIG should receive annual appropriations to support blocking complaints or be allowed to keep a portion of any CMP paid.</p>	 <p>HHS must finalize regulations for all provider "Actors."</p>
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- HHS needs to establish a unified enforcement and penalty structure.
  - For this to happen, the statute should be changed to have a single definition for IB ("blocking is blocking").
  - If unified enforcement isn't feasible then at a minimum change the provider penalty to CMPs (and not disincentives).
- The current disincentives structure leads to complicated questions of authority and therefore, which agency is responsible for issuing penalties for the type of provider that's getting penalized.
- Need to eliminate the "should have known" category.



# The Administration is Already Acting

FOR IMMEDIATE RELEASE

September 3, 2025

Contact: HHS Press Office

202-690-6343

[Submit a Request for Comment](#)

## HHS Announces Crackdown on Health Data Blocking

WASHINGTON--Today, the U.S. Department of Health and Human Services (HHS) announced that Secretary Robert F. Kennedy, Jr. has directed HHS to increase resources dedicated to curbing the harmful practice of information blocking. HHS will take an active enforcement stance against health care entities that restrict patients' engagement in their care by blocking the access, exchange, and use of electronic health information.

The 21st Century Cures Act of 2016 authorized the Office of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT (ASTP/ONC) and HHS Office of Inspector General (OIG) to take enforcement actions to hold those who block patient information accountable and to prevent future violations. As a result, ASTP/ONC, the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology, and the OIG, the primary investigative division of HHS, will play leading roles in this initiative.

### THIS JOB IS OPEN TO:

Hiring Paths: All US citizens

### DUTIES

The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) combats fraud, waste and abuse in HHS programs, including Medicare, Medicaid, , NIH, FDA, CDC, and more. HHS-OIG is the largest civilian inspector general's office in the Federal Government, employing a nationwide network of auditors, investigators, attorneys, and evaluators who provide program recommendations to decision-makers, distribute educational resources to the industry and public, and investigate cases to root out fraud. Our vision is to drive positive change in HHS programs and in the lives of the people served by these programs.

The Office of Counsel to the Inspector General (OCIG) is OIG's legal office. OCIG provides legal advice and representation for OIG in all its activities; pursues administrative enforcement through civil monetary penalties, exclusions and information blocking cases; represents HHS in False Claims Act cases and implements and monitors compliance measures; implements all OIG exclusions of health care providers; provides guidance to the health care industry on the Federal anti-kickback statute and other fraud and abuse authorities; and processes all OIG Freedom of Information Act requests. OCIG staff works closely with professionals across OIG to support legally-sound, high-impact work that protects HHS programs and the people touched by those programs.

OCIG is hiring multiple attorneys to support its mission, with a specific emphasis on information blocking enforcement. The position(s) will be as an Associate Counsel (GS-11 to GS-13) and Senior Counsel (GS-14 to GS-15). The duties of the position(s) will include:

# Contact Information

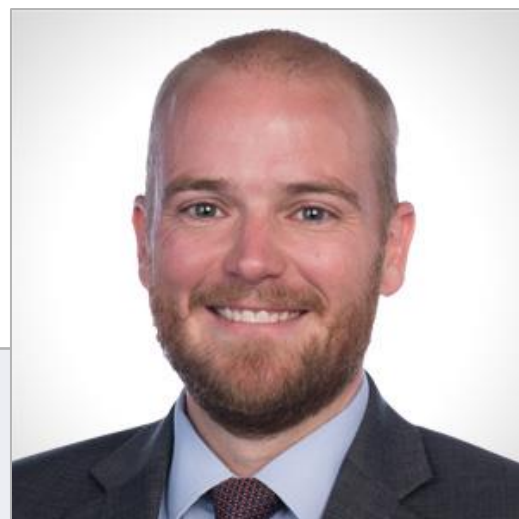


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## RESOURCES:

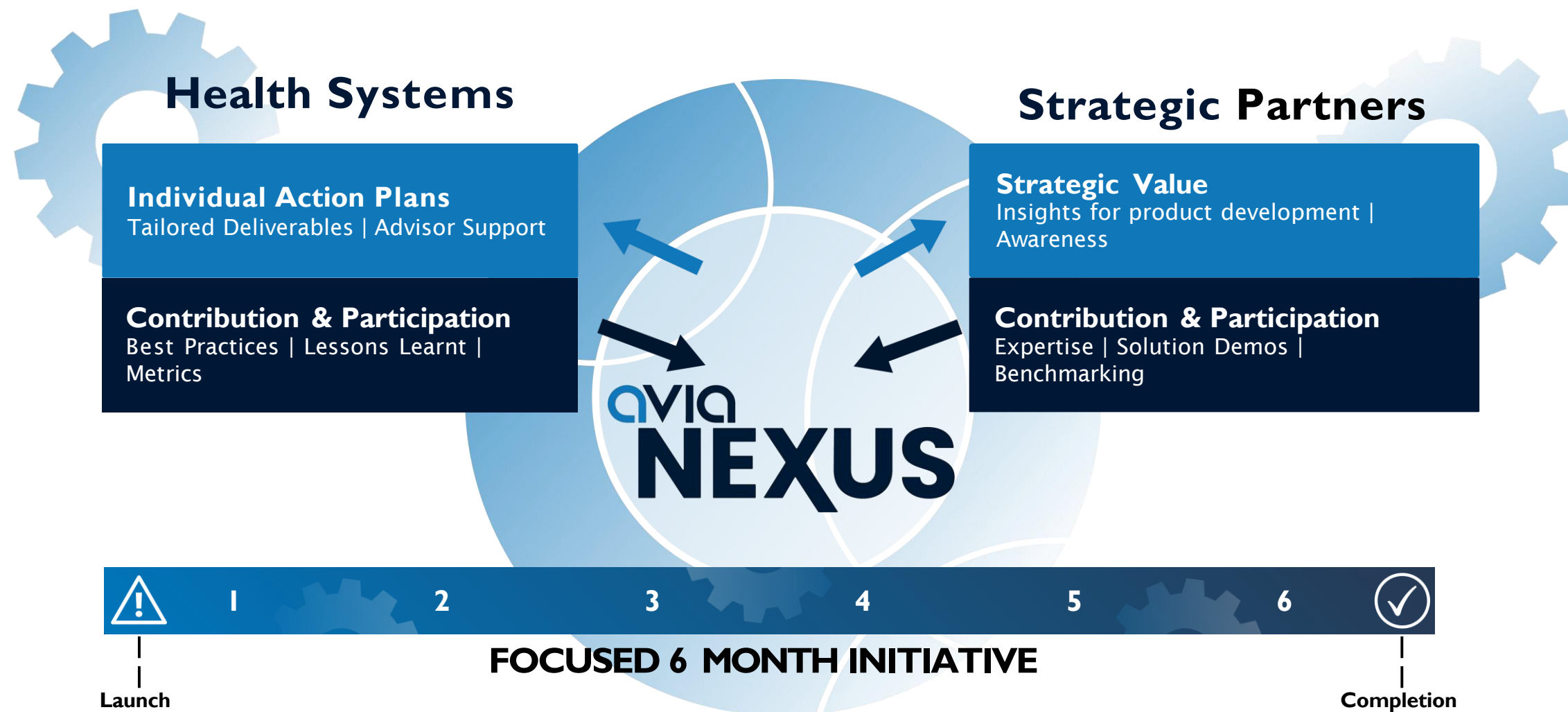
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# About Leavitt Partners



Leavitt Partners helps clients thrive at the intersection of health care and the Federal government.



We partner with health care and human services organizations to understand and shape the policy, political, stakeholder, and other dynamics impacting health care.



And we help our clients drive successful, effective health policy efforts.



# Leavitt Center for Alliances

## HOW WE CAN HELP

- **Convening:** We assess the stakeholders critical to success and bring the right people to the table to engage in the consensus-development process.
- **Facilitation:** An independent but informed voice, we guide stakeholders through the difficult conversations needed to move the alliance forward.
- **Consensus Development:** As a trusted neutral in the alliance process, we help identify and move stakeholders to agreement on creative solutions to the most difficult challenges.
- **Strategy execution:** We help drive a strategy that puts the alliance's consensus into action.
- **Alliance Management:** We provide best-in-class infrastructure and manage all aspects of alliance administration so you can focus on the substance of the alliance's work.
- **Health Care and Policy Expertise:** Our team has been involved in developing most of the major health care legislation over the last two decades.



The Leavitt Center for Alliances is an initiative of Health Management Associates and Leavitt Partners, an HMA Company. The Center aims to elevate the national discourse on health care and help health care organizations solve their most complex challenges through consensus-based alliances.