

FAQ: What Hospitals and Health Systems Need to Know about Reviews from the Office of the Inspector General (OIG)



As part of their 2017 work plan, the Office of the Inspector General (OIG)—an organization within the U.S. Department of Health and Human Services—is speaking with pharma supply chain companies to learn about their early experiences complying with DSCSA.

For this review, the OIG has been contacting health systems since late 2016, asking particular questions about data exchange and requesting specific transaction documentation. Their goal is to identify what’s gone smoothly for dispensers with DSCSA, and where there may be bumps in the road.

What can you expect if you’re contacted? This FAQ answers that question and more, based on our experience helping TraceLink customers respond to OIG requests.

What is the Office of the Inspector General (OIG)?

The OIG is part of the U.S. Department of Health and Human Services (HHS). It ensures the integrity of U.S. healthcare programs, looks for areas of improvement and efficiency in those programs, and fights waste, fraud, and abuse. The OIG is the largest office of its kind in the Federal Government, with more than 1,600 employees, led by Inspector General Daniel R. Levinson, a lawyer and certified fraud examiner.

Why is the OIG interested in DSCSA?

The OIG has oversight over a variety of healthcare-related programs including those from the FDA. As part of their FDA-related public health reviews for 2017 (DSCSA is an FDA initiative), the OIG has included a “Review of Information Exchange in the Drug Supply Chain.”

Through this program, the OIG will gather information on drug supply chain companies’ experiences with DSCSA and the law’s information exchange requirements, to see how they have “successfully exchanged this information and what, if any, obstacles they have faced.”

How are dispensers selected?

The OIG is contacting organizations randomly.

What is the OIG asking from dispensers?

Based on our experience with health system customers, the OIG is requesting:

- An hour-long interview.
- T3 documentation for different product transactions on a particular date.
- Process details and procedures for T3, such as where TI (Transaction Information), TH (Transaction History), and TS (Transaction Statement) appear on documents, and how T3 is transmitted.
- How transaction information is being stored and accessed.
- How trade partner verification is occurring.

What takes place during the interview?

The OIG will likely ask about your DSCSA product tracing processes and implementation – what's gone well, where there have been hurdles or problems, and any best practices you've identified.

If contacted by the OIG, what can dispensers expect in terms of timing?

Based on our customers' experiences, the timeline looks like this:

- After the OIG sends a request, a response is expected within roughly two weeks.
- A 1-hour interview is scheduled for a date about 3-6 weeks from the request.
- Keep in mind: The OIG will select a specific date on which your T3 documentation would be executed – in our experience, that selected date is in the past, having occurred before the OIG's initial request.

What can hospitals and health systems do to prepare?

1. Make sure you have your T3 documentation located in a central repository that is readily accessible at all times, and can produce it for the OIG. They will likely ask you to send it along ahead of your scheduled conversation.
2. Jot down notes regarding how DSCSA implementation went at your organization. What went smoothly? Did you encounter any issues? What practices can you share with peers?
3. Ask your solution provider to provide any necessary support in the event you are contacted by the OIG. TraceLink has consulted in several of these reviews thus far, and is ready to assist all our hospital, health system, and pharmacy customers in similar situations.

Is this an inspection?

No, this is not an inspection. The OIG considers this an interview-based study, a collaborative learning process for them to understand early DSCSA track and trace experiences.

What will the OIG do with the information they collect?

It is our understanding that the OIG will publish a report that includes recommendations and best practices for DSCSA implementation, as well as any potential pitfalls.

The World's Largest Track and Trace Network for the life sciences supply chain, TraceLink connects more than 320 dispensers to their supply chain ecosystems. To learn how we can keep your hospital or pharmacy continuously compliant and connected to trade partners, [contact a TraceLink compliance expert today.](#)