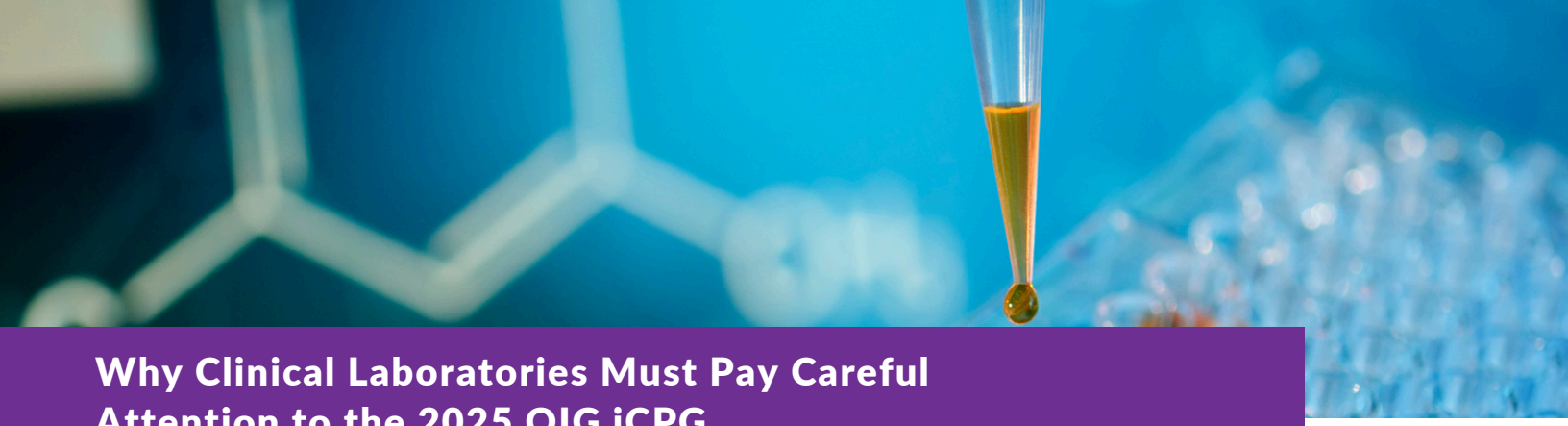

Why Clinical Laboratories Must Pay Careful Attention to the 2025 OIG iCPG

The following whitepaper was authored by Dr. Andrew Fletcher of Eutologic Consulting, a partner of LW Consulting, Inc. (LWCI).

Introduction

For more than two decades, clinical laboratories have been under the scrutiny of the U.S. Department of Health and Human Services Office of Inspector General (HHS -OIG). With the upcoming release of the 2025 General Compliance Program Guidance (iCPG) specific to clinical laboratories, the stakes have never been higher. Laboratories—whether hospital-based, physician office, or independent—must recognize that stewardship and compliance are no longer optional "best practices." They are regulatory expectations, and the updated iCPG will renew and strengthen those requirements.

This paper provides an overview of why laboratories must pay careful attention to the 2025 OIG iCPG. It offers background on the OIG's history and its impact on the laboratory industry, highlights areas of laboratory stewardship already embedded in OIG guidance, and examines why renewed attention to compliance will be essential in the years ahead.

The Origins and Role of the OIG in Healthcare

Congress established the OIG in 1976 to safeguard the integrity of federal healthcare programs. Its mission: fight waste, fraud, and abuse while improving efficiency across Medicare, Medicaid, and other HHS programs.

For laboratories, the OIG's influence became concrete in the late 1990s. On March 3, 1997, the OIG published the Compliance Program Guidance for Clinical Laboratories in the Federal Register. That document laid out, for the first time, expectations for labs to implement compliance programs that addressed billing accuracy, test utilization, medical necessity, and fraud prevention. A supplementary update followed in August 1998, reinforcing compliance expectations not only for labs but also for hospitals and home health agencies.

These early documents placed laboratories at the forefront of compliance activity, making clear that Medicare would only pay for tests deemed "covered, reasonable, and necessary." The guidance also made laboratories responsible for monitoring test utilization and ensuring physicians did not abuse standing orders or over-order inappropriate tests.

In short, since the 1990s, compliance—and by extension, laboratory stewardship—has been an OIG-mandated function for every clinical laboratory serving Medicare and Medicaid patients.

Laboratory Stewardship as Compliance

Over the past decade, "laboratory stewardship" has become a familiar phrase across health systems. Stewardship initiatives typically focus on improving test utilization, reducing inappropriate or duplicate orders, and aligning testing with clinical best practices. For many institutions, these programs are framed as quality improvement or cost-saving efforts.

However, stewardship is more than a voluntary activity. The OIG has long made clear that elements of stewardship—such as ensuring medical necessity, reviewing test volumes, and monitoring standing orders—are fundamental components of a required compliance program. Failure to meet these expectations can expose laboratories to civil monetary penalties, exclusion from Medicare participation, or even criminal liability.

As such, laboratory stewardship should be seen not as an optional enhancement but as a compliance imperative. The upcoming 2025 iCPG will only reinforce this reality.

Why the 2025 iCPG Matters

The OIG's 1998 laboratory compliance guidance has stood for more than 25 years. But healthcare has changed dramatically. Electronic health records, molecular and genetic testing, complex payer rules, and increasing regulatory oversight have all created new risks and opportunities.

The 2025 OIG iCPG for clinical laboratories is expected to:

1. **Update outdated provisions** – The 1998 guidance referenced "standing orders," but predated the widespread use of electronic order sets, preference lists, and clinical decision support. The 2025 iCPG is likely to extend compliance expectations to these newer technologies.
2. **Expand focus on high-cost testing** – With the explosion of genetic and molecular diagnostics, the OIG will likely emphasize medical necessity and utilization management for these costly tests.
3. **Reinforce data-driven monitoring** – Expect stronger requirements for laboratories to monitor test volumes, analyze ordering patterns, and investigate outlier growth trends.
4. **Address provider behavior** – The OIG has consistently noted that ignorance or misunderstanding among ordering providers does not excuse inappropriate billing. The 2025 iCPG may require more robust provider education and feedback mechanisms.
5. **Tie stewardship to compliance risk** – By framing stewardship not only as a quality activity but as a compliance mandate, the OIG will make clear that failure to engage in stewardship can create direct liability.

Key Elements of OIG Expectations for Laboratories

1. Medical Necessity

The OIG requires that laboratories only submit claims for tests that are "reasonable and necessary." While physicians may order any test they believe appropriate, Medicare will only reimburse for those meeting coverage requirements. Laboratories must take reasonable steps to prevent billing for unnecessary services.

In practice, this means tracking commonly misordered tests—such as 1,25 Dihydroxy Vitamin D or RBC Folate—and providing education or feedback to ordering providers. It also applies to expensive genetic tests, where prevalence of clinically actionable results may be very low. Identifying and correcting overuse is both a stewardship and compliance activity.

2. Utilization Monitoring

The OIG has recommended that laboratories analyze utilization by CPT/HCPCS code, identify their top 30 tests, and flag any that grow by more than 10% year over year. While growth may reflect legitimate changes, laboratories must investigate aberrant trends to rule out misuse or fraud.
To meet this expectation, the OIG outlines two acceptable strategies:

1. Engage an outside consultant to analyze utilization patterns and identify potential problems or aberrancies.
2. Perform internal monitoring by reviewing year-to-year trends and investigating unusual growth in test volumes.

The inclusion of consultants is significant. The OIG recognizes that not all laboratories have the internal resources or expertise to perform detailed utilization analysis. Independent consultants bring fresh perspective, benchmarking knowledge, and impartiality—qualities that can strengthen a compliance program and demonstrate good faith to regulators. For laboratories, engaging a qualified consultant can therefore be a practical and defensible way to satisfy OIG expectations while adding technical depth to stewardship efforts.
This requirement dovetails with stewardship practices such as monitoring order volumes, identifying duplicates, and standardizing test menus. But unlike internal monitoring alone, the consultant option provides additional assurance that laboratories are meeting compliance obligations with independence and rigor.

3. Standing Orders and Order Sets

Although the OIG guidance predates electronic health records, it warned that reliance on standing orders could lead to abuse. In today's environment, electronic order sets and provider "favorites" present similar risks. Without laboratory oversight, these tools can perpetuate unnecessary or duplicative testing.

The OIG expects laboratories to monitor, review, and enforce expiration dates on standing orders. By extension, the 2025 iCPG will almost certainly expect laboratories to review and maintain order sets to ensure compliance and medical necessity.

4. Education and Corrective Action

When laboratories identify patterns of inappropriate test ordering, the OIG places a duty on them to notify physicians and recommend corrective action. Ignoring such patterns risks compliance penalties. A structured stewardship program creates the infrastructure to deliver that feedback, track interventions, and document corrective action.

Practical Implications for Laboratories in 2025

The updated iCPG is more than a compliance document—it will shape how laboratories justify resources, engage leadership, and structure stewardship programs. Laboratories should prepare by:

- Building or strengthening stewardship committees that integrate compliance, quality, and clinical stakeholders.
- Documenting stewardship activities as part of the compliance program, ensuring they can be presented during audits.
- Investing in data infrastructure to monitor ordering patterns, volumes, and provider-level utilization.
- Engaging providers through education, feedback, and policy support to address ordering behavior.
- Aligning with hospital leadership to secure resources and emphasize that stewardship is not optional, but a regulatory mandate.

Conclusion

The OIG has long required clinical laboratories to integrate stewardship activities into compliance programs. Medical necessity reviews, utilization monitoring, oversight of standing orders, and corrective feedback are not just best practices—they are regulatory expectations.

With the release of the 2025 OIG iCPG for clinical laboratories, the compliance landscape will become sharper and more prescriptive. Laboratories that treat stewardship as optional will face increased regulatory, financial, and reputational risk. Those that proactively align stewardship with compliance will not only reduce liability but also enhance patient care, reduce unnecessary costs, and strengthen their role within healthcare organizations.

In short, laboratory stewardship is not a voluntary initiative. It is a compliance mandate, and the 2025 OIG iCPG will make that clearer than ever.

Sources

Axios. (2025, August 6). Illinois blocks AI from being your therapist under sweeping mental health regulation. Retrieved from https://www.axios.com/local/chicago/2025/08/06/illinois-ai-therapy-ban-mental-health-regulation

Curana Health. (2025). Integrated behavioral health services in senior care: 2025. Retrieved from https://curanahealth.com

HHS Office for Civil Rights. (2025, May). Enforcement priorities under the HIPAA Security Rule – FY25 notice. Washington, DC.

Illinois General Assembly. (2025). Wellness and Oversight for Psychological Resources (WOPR) Act, Public Act 103-0974. Springfield, IL.

Relias. (2025). Behavioral health compliance trends to watch in 2025. Retrieved from https://www.relias.com

Reuters. (2025, April 7). New legal developments herald big changes for HIPAA compliance in 2025. Retrieved from https://www.reuters.com

Washington Post. (2025, August 12). States move to restrict AI-powered therapy as use surges. from https://www.washingtonpost.com

LW Consulting, Inc

About LW Consulting, Inc.

For two decades, LWCI has delivered operational and compliance improvements to acute, post-acute, and sub-acute healthcare providers and government entities. This expertise is also applied to compliance actions and legal proceedings, with a specialty in serving as an independent review organization (IRO).

Whether the goal is proactive compliance, improved clinical and financial outcomes, or navigating regulatory changes, LWCI brings deep industry expertise to support strategic decision-making and operational success.

Our experienced team delivers actionable insights that help healthcare organizations, including hospitals, long-term care, physician practices, rehabilitation and senior living providers, government programs, and payers, maintain compliance, enhance performance, and minimize risk.

eutilogic consulting

About Eutologic Consulting

Eutologic Consulting is a comprehensive laboratory consulting company led by a pathologist with 25 years of experience.

Their expertise brings frontline insight into how laboratories impact patient care with solutions that are not only operationally sound but also clinically aligned—bridging the gap between compliance, stewardship, and real-world care delivery.

Their experts can assist in strategic consulting, compliance and accreditation readiness, laboratory stewardship, supply chain management, and mergers and acquisition advisory.