Like all entities that bill Medicare, Medicaid, and Tricare, clinical laboratories are subject to a host of legal and regulatory obligations. Lab owners and executives need to make legal and regulatory compliance a priority, as failure to meet these obligations can lead to recoupments, prepayment review, program exclusion, and other penalties.

The U.S. Department of Health and Human Services (DHHS) has published a Model Compliance Plan for Clinical Laboratories (the “Model Plan”). However, despite its name, the Model Plan is not a document that clinical labs can use as the foundation for their compliance programs, nor is it even necessarily a roadmap to compliance. As DHHS states, the Model Plan is, “supplied to assist laboratory providers in crafting and refining their own compliance plans. . . . these guidelines represent the government's suggestions on how to correct and prevent fraudulent activity . . . .” DHHS goes on to clarify that, “each company bears the responsibility for determining the appropriate topic areas and measures to be included in its compliance program.”

With these provisions in mind, DHHS’s Model Plan nonetheless provides practical guidance for developing a custom-tailored clinical laboratory compliance program, and labs should certainly take DHHS’s recommendations into account. Although DHHS states that it does not, “suggest that a laboratory that does not incorporate
all of the[] elements [of the Model Plan] will be at a disadvantage when under the scrutiny of the OIG,” those that fail to follow DHHS’s guidance will certainly face questions as to why they have chosen not to follow the guidance that DHHS has made publicly available.

“DHHS compliance is a key concern for clinical laboratories that bill Medicare, Medicaid, and Tricare. Labs must adopt comprehensive and custom-tailored compliance programs, and they must effectively implement these programs in all aspects of their operations.” – Dr. Nick Oberheiden, Founding Attorney of Oberheiden P.C.

Key Elements of a Clinical Laboratory Compliance Program

The DHHS Model Compliance Plan for Clinical Laboratories addresses many areas of compliance that need to be areas of emphasis for clinical labs. While DHHS advises that it is, “not suggesting that all laboratories must implement all of the compliance elements discussed in [the Model Plan],” from a practical perspective, there are very few circumstances in which a laboratory would not need to address all elements of the Model Plan. With this in mind, here are some (but not all) of the key elements of a clinical laboratory compliance program:

1. Standards of Conduct and Employee Performance

DHHS advises that clinical laboratories, “should develop standards of conduct for all employees which clearly delineate the policies of the laboratory with regard to fraud, waste and abuse and adherence to all guidelines and regulations governing federally funded health care programs.” It also recommends that labs “require that the promotion of and adherence to compliance be an element in evaluating the performance of managers and supervisors.” Clinical laboratories should ensure that all personnel have access to the lab’s standards of conduct, and they should make clear that employees will face adverse employment consequences if they are responsible for compliance failures.

2. Designated Compliance Officer (or Equivalent)

“Every laboratory compliance plan should require the designation of a chief compliance officer or an equivalent (e.g., committee).” The compliance officer or committee should hold primary responsibility for overseeing and enforcing the lab’s compliance program; and, if the officer or members of the committee have other job responsibilities, they should have time set aside for fulfilling their compliance functions.

3. Internal Communication Channels

DHHS emphasizes the importance of internal communication when it comes to maintaining Medicare, Medicaid, and Tricare compliance. This includes ensuring that personnel have access to the lab’s compliance officer and/or legal department so that they can ask questions when necessary, as well as establishing a confidential hotline so that employees can report known or suspected compliance issues. DHHS also emphasizes that labs should take all questions and reports
seriously, and should investigate “immediately” in order to prevent and remedy compliance failures.

4. Employee Education and Training

“Laboratory compliance programs should require compliance and ethics training for all employees, especially personnel involved in billing, sales, marketing and specimen collection and/or test ordering.” Clinical laboratories (like other Medicare, Medicaid, and Tricare participants) will generally need to provide different training programs to different employees. For example, employees in the lab’s billing department should receive different training from those who work with specimens. Laboratories should maintain documentation of each employee’s successful completion of all training programs—including both initial training programs and refresher training programs provided on a periodic basis.

5. Medical Necessity Compliance

Medical necessity presents some of the greatest challenges and greatest risks for clinical laboratories when it comes to Medicare, Medicaid, and Tricare compliance. While DHHS acknowledges that, “physicians must be able to order any tests, including screening tests, that they believe are appropriate for the treatment of their patients,” it also takes the position that laboratories are in a “unique position” to ensure that, “physicians [are] made aware that Medicare will only pay for tests that meet the Medicare definition of ‘medical necessity.’”

As a result, DHHS advises that laboratories should have policies and procedures in place to ensure that they do not bill for medically-unnecessary tests—even if those tests are ordered by a licensed and qualified physician. This is one area where DHHS provides fairly specific guidance about how clinical laboratories can meet their compliance obligations.

6. Billing Compliance

Of course, billing compliance is a central component of any Medicare, Medicaid, or Tricare compliance program. Clinical laboratories must adopt policies and procedures that are effective not only with regard to preventing improper (or “false and fraudulent”) billings, but also with regard to identifying and remedying any billing mistakes. This includes ensuring the proper selection of CPT, HCPCS, and ICD-9CM codes, as well as preventing unbundling, double-billing, and other common billing mistakes.

7. Standing Order Compliance

Clinical laboratories must be very careful when relying on standing orders. DHHS carefully scrutinizes standing orders, as they “often . . . [lead] to fraudulent and abusive practices.” This is particularly true with regard to standing orders that have been in place for extended periods of time, and when a clinical laboratory has a large number of standing orders or relies heavily on standing orders from individual facilities. DHHS writes: “while laboratory compliance plans can permit the use of
standing orders executed in connection with an extended course of treatment, the compliance plan should require the laboratory to monitor existing standing orders to ensure their continuing validity.”

8. Marketing Compliance

“Laboratory compliance plans should require honest, straightforward, fully informative and non-deceptive marketing.” Marketing compliance has taken on a heightened profile with DHHS and other federal law enforcement agencies in recent years, with particular attention being paid to social media and other online solicitations. The U.S. Federal Trade Commission (FTC) shares primary responsibility with DHHS for enforcing clinical laboratories’ (and other healthcare entities’) marketing compliance obligations.

9. Pricing Compliance

In addition to Medicare, Medicaid, and Tricare billing compliance, DHHS also enforces clinical laboratories obligations with respect to other payors. In particular, DHHS emphasizes the importance of pricing compliance with regard to physician profiles. For example, the Model Plan indicates that laboratories’ compliance programs, “should ensure that as tests are included in or added to profiles, the price for the enhanced profile increases and the overall price for the profile is never below cost.”

10. DHHS OIG Fraud Alert Compliance

From time to time, DHHS’s Office of Inspector General (OIG) issues Special Fraud Alerts. The Model Plan advises that clinical laboratories’ compliance programs should, “require that any and all fraud alerts issued by the OIG are carefully considered by the legal staff, chief compliance officer, or other appropriate personnel . . . [and] require that [the] laboratory cease and correct any conduct criticized in such a fraud alert . . . and take reasonable action to prevent such conduct from recurring in the future.”

11. Record Retention

Record retention is a critical aspect of compliance. Not only does DHHS require clinical laboratories to retain compliance-related documentation, but retaining this documentation is also essential for demonstrating compliance during an OIG audit or investigation.

12. Auditing, Monitoring, and Corrective Action

In addition to establishing and implementing policies and procedures focused on Medicare, Medicaid, and Tricare compliance, clinical laboratories must also audit and monitor their compliance efforts on an ongoing basis. When an audit or report uncovers a compliance failure, labs must be prepared to take corrective action quickly—and to appropriately self-disclose the failure to DHHS (or other relevant authorities) if necessary.
Keep in mind, clinical laboratories have many compliance obligations outside of the Medicare, Medicaid, and Tricare billing realm. When developing, reviewing, and updating their compliance programs, clinical laboratory owners and executives must take all pertinent legal and regulatory requirements into account. By taking a comprehensive and proactive approach to compliance, clinical laboratories can substantially reduce their risk of facing federal audits and investigations; and, when they face these inquiries, they will be in a favorable position to avoid costly penalties.

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