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What is Compliance?

Sometimes the concept of compliance can feel abstract, but it essentially means doing the right thing all the time.

More specifically, healthcare compliance programs are created to protect the institution. It is a system of policies, procedures and processes developed to assure compliance and conformity to all applicable federal and state laws governing the organization. ¹

The Seven Fundamental Elements

The [Office of the Inspector General](#) (OIG) believes that healthcare compliance programs need these



What Compliance is Not

It might be clearer to look instead at a few examples of what compliance is not, especially in clinical research billing:

- Billing for services not rendered

- Billing for services that are already paid by the sponsor
- Billing for services promised as free in the informed consent
- Billing for services that are part of a non-qualifying clinical trial (see [volume #8](#) of the Research Billing Buzz)
- Billing Medicare for device trials without CMS approval
- Billing Medicare Advantage for claims that should be billed to Medicare (see [volume #9](#) of the Research Billing Buzz)
- Billing for services without medical necessity or proper documentation ²

False Claims Act

The False Claims Act (FCA) is a federal law that makes it a crime for any person or organization to knowingly make a false record or to file a false claim regarding any federal health care program, including Medicare and Medicaid.

Financial penalties to the person or organization includes recovery of three times the amount of the false claim(s), plus an additional penalty of \$5,500.00 to \$11,000.00 per claim.

Consequences of Non-compliant Billing

- Staff time lost on correcting billing errors
- Lost revenue both on payer side and in research
- Fines and penalties
- Potential loss of federal grant funding

- Potential loss of participation in Medicare/Medicaid
- Enforcement actions and fines
- Loss of community trust and reputation ²

Conclusion

It takes a lot of effort to create an effective compliance program. Johns Hopkins has a robust compliance and ethics infrastructure which includes the Office of Clinical Research Compliance to help researchers navigate the complexities of billing, protect participants and the institution.

References:

¹ Troklus, D., & Vacca, S. (2016). What's in a Name? *Compliance 101*. (p. 10). HCCA.

² Hurtado, K., & Longspaugh, C. Billing Compliance Fundamentals for Successful Clinical Trial Operations. Available:

http://globalresearchtoolkit.srainternational.org/wp-content/uploads/2017/12/Billing-Compliance-Fundamentals_Clinical-Trials.pdf

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