

# Outdated and/or Ineffective Laws and Regulations

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# Outdated and ineffective laws and regulations

- Shifting from Volume to Value
- The healthcare system is embracing change, but can only advance so far with the current regulatory infrastructure
- Stakeholders want to create new solutions for patients embracing change, but can only advance so far with the current infrastructure



# Stark self-referral

- The Stark Law prohibits physicians from referring Medicare patients for certain services to an entity with which the physician (or an immediate family member) has a financial relationship. The Stark Law also prohibits healthcare organizations from billing Medicare for services provided pursuant to an improper referral.
- The Stark Law is a law of strict liability, meaning that no intent to violate the law is required.



# Anti-kickback Statute

- The Anti-Kickback Statute prohibits any individual from knowingly and willfully offering, paying, soliciting, or receiving anything of value in return for a referral or to induce the generation of business reimbursable by a federal healthcare program.
- The Anti-Kickback Statute is a criminal law and intent is required for liability to attach; penalties for violating the statute include imprisonment and substantial fines.



# Civil Monetary Penalties

- Civil monetary penalties may be levied for violations of the Anti-Kickback Statute and the Stark Law, and entities that violate either may be excluded from participation in federal healthcare programs.



# Medicare payment waivers

- There are exceptions to each law (referred to as “safe harbors” for the Anti-Kickback Statute and “exceptions” for the Stark Law) that protect certain types of business arrangements and transactions that are considered to present a minimal risk of fraud or abuse when structured appropriately
- Waivers have been implemented by the Center for Medicare and Medicaid Innovation (CMMI) to ensure the success of several alternative payment demonstration programs.



# NDHI recommendations

- *Create Federal Anti-Kickback Statute and Stark Law waivers for all Accountable Care Organizations that meet certain conditions and extend existing exemptions for interoperability-enabling technologies and training beyond 2021.*
- *Eliminate the “one-purpose” test for Anti-Kickback Statute liability and replace with a balancing test that would require the HHS Office of Inspector General (OIG) to prove either increased costs or actual harm to patients.*
- *Consider related changes to the Civil Monetary Penalties (CMP) Law, where appropriate, to ensure consistency in interpretation and application across both laws to encourage patient engagement and improved outcomes.*
- *Require the Department of Health and Human Services Secretary to review and assess these laws in the context of health system transformation.*
- *Grant OIG and CMS broader flexibility and discretion to develop exceptions and safe harbors to the Federal Anti-Kickback Statute and the Stark Law consistent with current health policy objectives (e.g., increased efficiency and quality, decreased cost).*



# Anti-kickback statutes don't always take into account current healthcare payment and delivery models

How can we all think and work more creatively for the benefit of improved healthcare outcomes?

How do we step out of our silos and work across the system?

How can manufacturers work more directly with ACOs or other integrated care entities?

**NDHI Recommendation**  
**Greater flexibility and new anti-kickback statute safe harbors to achieve increased quality and lower costs**

