



an informational series for hospital leaders

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## WAIVER OF FRAUD & ABUSE LAWS UNDER MEDICARE SHARED SAVINGS PROGRAM

Hospitals developing innovative integrated-care models for Accountable Care Organization (ACO) participation in the Medicare Shared Savings Program may discover that certain financial arrangements are at odds with laws governing fraud and abuse. New models of health care delivery and greater care coordination across the spectrum of care could be stymied or even blocked because of existing laws.

The Affordable Care Act authorizes the Secretary of Health and Human Services (HHS) to waive certain fraud and abuse laws to carry out provisions of the Medicare Shared Savings Program. But, hospitals should be aware that the [proposed waivers](#) recently released by the Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG) may not cover all possible financial arrangements between hospitals, ACO participants, and other providers.

### PROPOSED WAIVERS

Under the proposed ACO rules, Medicare would continue to pay individual providers and suppliers as it currently does under the fee-for-service payment systems. The waivers would apply only to the distribution of ACO shared savings.

As a threshold matter, the waivers will only apply to ACOs that are in compliance with their three year agreement with CMS and ACO regulations.

1. The Secretary of HHS would waive application of the Physician Self-referral and the Anti-Kickback laws to protect:
  - a. Financial arrangements created by the distribution of shared savings *within* the ACO, and
  - b. Financial arrangements created by a distribution of shared savings *outside* the ACO, *but only if* the distribution outside the ACO is for activities necessary for and directly related to the ACO's participation in and operation under the Shared Savings Program.
2. The Secretary would waive application of the Anti-Kickback Statute with respect to *any financial relationship* between or among the ACO, ACO participants and ACO providers/suppliers that is necessary for and directly related to the ACO's operations, *but only if* the relationship implicates the Physician Self-Referral Law and fits squarely within an exception.
3. The Secretary would waive the prohibition on hospital payments to physicians to induce reduction or limitation of services (Gainsharing CMP) for:
  - a. Distributions of shared savings to ACO participating physicians, if the payments *are not knowingly* made to induce the physician to reduce or limit *medically necessary* items or services; and

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- b. Any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers necessary for and directly related to the ACO's participation in and operation under the Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception.

### WAIVERS THAT WILL NOT BE GRANTED

CMS/OIG do not intend to protect distributions of shared savings dollars to referral sources *outside* the ACO, unless those referral sources are being compensated (using shared savings) for activities necessary for and directly related to the ACO's participation in and operation under the Shared Savings Program.

Similarly, CMS/OIG will not extend waiver protections to ACO participants that have independent financial arrangements with potential referral sources that are unrelated to the ACO, its operations, or the Shared Savings Program. Those arrangements would still need to meet an existing exception under the Stark Law, and an existing safe harbor under the Anti-Kickback Statute.

### NEXT STEPS

As hospitals plan for specific integration arrangements, the following questions should be asked, to address the key concerns behind the fraud and abuse laws:

- Does the arrangement shift costs to a federal health care program?
- Is there a risk of underutilization or overutilization of services?
- Can the arrangement withstand accusations of cherry picking?
- Does the arrangement produce cost savings?
- Does the arrangement enhance the quality of care?

The agencies have issued a joint [request](#) for public comments regarding the scope of waivers of the Physician Self-Referral Law, the Anti-Kickback Statute, and prohibited Gainsharing CMP. Can you suggest improvements to the proposed waivers that IHA should advocate for on your behalf?

- Particularly, if you are forming an ACO, are the proposed waivers broad enough to cover the arrangements you are contemplating?
- If you are not considering an ACO at this time, would the proposed waivers cover any future integration arrangements that you may be considering? (Note that the proposed waivers only apply to the ACO Shared Savings Program, but the waivers that are ultimately adopted may guide future decisions by the agencies.)

CMS and OIG recognize that not all possible financial arrangements involved with setting up and operating an ACO are covered by the proposed waivers. **IHA encourages hospitals to send comments to CMS to urge CMS and OIG to adopt waivers that are broad enough to cover their own ACO plans for integrated care. Hospitals should send their comments to CMS by June 6, 2011.**

To send comments to IHA for inclusion in IHA's comment letter to CMS or for questions regarding the content of this memo, please contact IHA Legal Department at 630-276-5464.

*The above information is not to be construed as legal advice. Any questions regarding specific integration models should be directed to hospital counsel.*