

Application & Implementation of ACO Waivers and Ongoing Compliance Issues

Presenter

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Presenter Bio

Todd A. Zigrang, MBA, MHA, FACHE, ASA is the President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 20 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 1,000 transactions and joint ventures involving acute care hospitals and health systems; physician practices; ambulatory surgery centers; diagnostic imaging centers; accountable care organizations, managed care organizations, and other third-party payors; dialysis centers; home health agencies; long-term care facilities; and, numerous other ancillary healthcare service businesses. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.



Mr. Zigrang is the co-author of the soon-to-be released “*Adviser’s Guide to Healthcare – 2nd Edition*” [2015 – AICPA], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Accountant’s Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies*; *Business Appraisal Practice*; and, *NACVA QuickRead*. Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the *American Bar Association* (ABA); *National Association of Certified Valuators and Analysts* (NACVA); *Physician Hospitals of America* (PHA); *Institute of Business Appraisers* (IBA); *Healthcare Financial Management Association* (HFMA); and, *CPA Leadership Institute*.



Overview of Presentation

- Overview of MSSP Waivers
- Ongoing Compliance Issues
- Avoiding Waiver Pitfalls
- Questions & Answers

MSSP Waivers

- Intended to enable ACOs to align performance (clinical and cost) with financial models to change the way care is delivered
- Types of Waivers:
 - ACO Pre-Participation Waiver
 - ACO Participation Waiver
 - Shared Savings Distributions Waiver
 - Compliance with Stark Law Waiver
 - Patient Incentive Waiver



MSSP ACO Pre-Participation Waiver

CMS/OIG will waive applicability of *Stark*, *Anti-Kickback*, and *Civil Monetary Penalty* (CMP) laws to certain ACO-related start-up arrangements undertaken in anticipation of (i.e., that pre-date) MSSP participation, so long as:

- Arrangement is undertaken by parties intending in good faith to participate in the MSSP starting in a particular year (“*target year*”)
- Arrangement includes ACO or at least one ACO participant eligible to form an ACO
- Parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for an MSSP participation agreement in the target year



MSSP ACO Pre-Participation Waiver

CMS/OIG will waive applicability of *Stark*, *Anti-Kickback*, and *Civil Monetary Penalty* (CMP) laws to certain ACO-related start-up arrangements undertaken in anticipation of (i.e., that pre-date) MSSP participation, so long as (continued):

- The ACO governing body must make and authorize a *bona fide* determination that the arrangement is reasonably related to one or more of the following purposes of the MSSP:
 - Promoting accountability for the quality, cost and overall care for Medicare beneficiaries
 - Managing and coordinating care for Medicare beneficiaries, or
 - Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries



MSSP ACO Participation Waiver

CMS/OIG will waive the applicability of the Stark, Anti-Kickback and CMP Laws for ACOs participating and in good standing under the MSSP so long as:

- ACO, one or more ACO participants and/or one or more ACO providers/suppliers is a party to the arrangement – but all parties to arrangements covered by the waiver
- ACO has entered into a Program participation agreement and is in good standing under such participation agreement
- ACO satisfies the requirements of the MSSP regulations concerning its governance leadership and management



MSSP ACO Participation Waiver

CMS/OIG will waive the applicability of the Stark, Anti-Kickback and CMP Laws for ACOs participating and in good standing under the MSSP so long as (continued):

- ACO governing body must make a *bona fide* determination that arrangement is reasonably related to one or more MSSP purposes
 - Promoting accountability for the quality, cost and overall care for Medicare beneficiaries
 - Managing and coordinating care for Medicare beneficiaries
 - Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries



MSSP ACO Waivers

- Waivers are not *get-out-of-jail-free* licenses
 - Successful application of waivers requires cautious, ongoing adherence to rule requirements and compliance parameters
- Waivers do not preempt state laws and regulations
 - ACO boards should seek opinion of qualified counsel (but *not* the ACO compliance officer) as to whether a financial arrangement comports with state fraud and abuse laws



Compliance & Avoiding Waiver Pitfalls

- *Good waiver compliance starts with good board compliance*
 - How does an ACO Board review and approve waiver coverage of an arrangement?
 - Example: How does the ACO Board seek the protections of the ACO participation waiver?
 - Knowing the requirements
 - Spotting the pitfalls
 - Knowing the what thresholds may protect the Board's decision (even if it turns out badly for the ACO)



Compliance & Avoiding Waiver Pitfalls

- OIG Joint Guidance on Healthcare Board oversight
 - Published on April 20, 2015
 - Makes board members responsible for knowing both what is happening in the healthcare industry and the risk(s) specific to their organization
 - During settlement negotiations during false claims settlement, prosecutors may take into account the board's role in compliance
 - May search board meeting minutes for words such as "*Stark*" or "*Anti-Kickback*" to assess board's dedication to organizational compliance



Compliance & Avoiding Waiver Pitfalls

- OIG Joint Guidance on Healthcare Board oversight
 - Smaller organizations may need to be more “*hands-on*” boards in regards to compliance
 - Boards may want to employ, or consult, a regulatory, compliance, or legal professional to “*raise its level of substantive expertise*”
 - “*Sends a strong message about the organization’s commitment to compliance, provides a valuable resource to other Board members, and helps the Board better fulfill its oversight obligations*”
 - “*Board members are generally entitled to rely on the advice of experts in fulfilling their duties*”



What if Waiver Application Fails?

Consider a Fair Market Value/ Commercial Reasonableness Backstop

- Waivers are currently in flux
 - CMS has extended the interim final rule, but never finalized it, and has indicated that waivers may be limited in the future
 - In addition, waiver guidance relies significantly on board judgment and interpretation, and is subject to second-guessing by the government



What if Waiver Application Fails?

Consider a Fair Market Value/ Commercial Reasonableness Backstop

- Boards should consider and document what other regulatory *exceptions* and *safe harbors* may apply in the event waiver protection disappears, and secure necessary valuation and commercial reasonableness reports to underpin their conclusions
 - Domino effect of a faulty waiver protection determination could cause significant financial damage

What if Waiver Application Fails?

Consider a Fair Market Value/ Commercial Reasonableness Backstop

- ACOs may want to seek ongoing *fair market value* and *commercial reasonableness* valuations regardless in order to satisfy IRS rules

Before & After the Board Meeting

- Don't leave the ACO Board out of ACO compliance training
 - Training is not just for providers and staff
 - Board members are accountable, and need to be formally apprised of their fiduciary duties to the ACO

Before & After the Board Meeting

- Always consider “*belt-and-suspenders*” compliance
 - The Board may wish to seek legal counsel’s view of other *Safe Harbors* and *Exceptions* that may apply to an arrangement in the event CMS pulls or redefines a waiver, and obtain appropriate valuations as safeguards
 - Especially advisable in arrangements that may be complex to halt or wind-down (such as those with long periods of data collection), or those that implicate tax or antitrust laws



Questions & Answers

