Waivers Under the Medicare Shared Savings Program: An Outline of the Options

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Introduction

The Patient Protection and Affordable Care Act of 2010 (PPACA) fosters the development of new patient care models designed to improve the coordination, quality and efficiency of health care services to Medicare and Medicaid patients. These new programs are intended, in part, to shift the emphasis in government program fee-for-service payments from the volume of services provided to the value of the services provided. One of the primary initiatives for delivery model innovation under PPACA is the Medicare Shared Savings Program (PPACA, Sec. 3022), more commonly referred to as Accountable Care Organizations (ACOs). To facilitate the establishment of ACOs, PPACA grants the Secretary of Health and Human Services the authority to waive certain provisions of the fraud and abuse laws under the Social Security Act or other provisions of the Medicare law (herein "ACO waivers").

Through the development and distribution of this options outline, the AHLA Public Interest Committee is endeavoring to provide both government and industry a description of some of the options available to the Secretary in crafting the ACO waivers and to serve as a public resource on selected healthcare legal issues in furtherance of our public interest mission. There are waiver options other than those described below and the scope and terms of those listed in this outline could be altered in a number of ways. The purpose of this outline is not to provide an exhaustive review of all of the potential choices or to advocate for one approach over another but rather to explore a range of the ACO waiver options and the respective pros and cons of each option presented.

Background

ACOs will be required to accept responsibility for the overall care of at least 5,000 Medicare beneficiaries. In general, ACO providers will be paid on a fee-for-service basis. If the ACO meets quality benchmarks and reduces the cost of providing care to the Medicare enrollees attributed to the ACO (as measured against a benchmarked per enrollee expenditure target), the ACO will receive a percentage of the savings. More detail concerning ACOs' structure and operations will be included in regulations to be promulgated by the Secretary.

While the industry is waiting for guidance, many interested in this new model are struggling with practical questions concerning the funding, formation and operation of ACOs. Some of the questions include: (1) Can a hospital fund the cost of developing the legal and operational infrastructure of an ACO if physicians who refer to that hospital will be members of the ACO, have an active role in governance and are entitled to a

portion of the ACO's shared savings? (2) Can the ACO pay primary care physician members a per patient per month management fee for overseeing the delivery of care to the beneficiaries attributed to that ACO? (3) Can the ACO offer Medicare beneficiaries cash or other remuneration to induce the beneficiaries to seek care from providers affiliated with the ACO?

Applicable Fraud and Abuse Laws

Section 3022(f) grants the Secretary the authority to waive those requirements of Sections 1128A and B and Title XVIII of the Social Security Act as may be required to carry out the Shared Savings Program provisions. These provisions include:

- Civil Money Penalty Law Prohibition on Payments to Reduce or Limit Care, 42 U.S.C. 1320a–7a(b). A hospital or critical access hospital may not knowingly make a payment, directly or indirectly to a physician as an inducement to reduce or limit services provided to a Medicare or Medicaid beneficiary under the direct care of the physician.

- Beneficiary Inducement Prohibition, 42 U.S.C. 1320a–7a(a)(5). Persons may not provide remuneration to a Medicare or Medicaid beneficiary where the person knows or should know that the remuneration is likely to influence the beneficiary to order or receive a service from a particular provider, practitioner or supplier where the item may be covered in whole or in part under the Medicare or Medicaid program.

- The Stark Law, 42 U.S.C. 1395nn. A physician may not refer Medicare patients for certain designated health services to an entity with which the physician or an immediate family member has a financial relationship, unless an exception applies. An entity receiving a prohibited referral may not bill the Medicare program for the resulting items and services.

- The Anti-Kickback Statute, 42 U.S.C. 1320a–7b(b)(1) and (2). Persons may not knowingly offer or receive, directly or indirectly, overtly or covertly, in cash or in kind, any remuneration to induce or influence the furnishing, arrangement, purchase, leasing, or ordering of items or services for which payment may be made in whole or in part under a federal health care program.

- Prohibitions Against Charging or Collecting More Than the Medicare Allowable, 42 U.S.C.1320a-7a(a)(2). Assignment occurs when a beneficiary asks that a Medicare payment be made directly to the provider. If a provider accepts assignment, Medicare will directly pay the fee schedule amount for the services, and the beneficiary will be responsible for paying the coinsurance and any remaining deductible. Collectively, the fee schedule payment and coinsurance/deductible are referred to as the "allowed amount." By accepting assignment, the provider agrees to accept the "allowed amount" as "payment in full" for the services.

In crafting the ACO waivers, the Secretary will face a familiar challenge. On the one hand, a liberal approach would send a positive signal to the industry, encourage the private sector to invest in ACO development, and provide the predictability and stability needed for the private sector to make long term investments. On the other hand, a narrow approach with more specific safeguards would better preserve Program protections and potentially protect the patients that might be harmed by over or under-treatment. Some will argue that the bigger risk is that the regulatory burdens will stifle ACO development; others will argue that the bigger risk is the Program or patient abuse that could result from giving ACOs a "free pass." The waivers, however, need not be set in stone. As ACOs develop, the Secretary should be able to make appropriate adjustments.

This outline examines the ACO waiver options, focusing first on a global approach and then on separate waivers for each of the laws referenced above.

1. The Global Approaches

Waiver Option 1. Maintain the Status Quo.

Pros

- Preserves the protections afforded by the existing fraud & abuse laws, permitting parties to rely on existing safe harbors, if applicable, advisory opinions, and government discretion in enforcement

Cons:

- Fails to address concerns about the legality of ACO shared savings distributions and other aspects of ACO formation and operation
- Discourages the formation of ACOs because of legal risks
- Discourages the formation of ACOs because some risk adverse providers will incur the costs and suffer the delays associated with obtaining one or more advisory opinions
- Imposes a burden on the OIG and/or CMS to review and process individual requests for advisory opinions
- Arguably is inconsistent with Congress' intent when it granted the Secretary waiver authority

Waiver Option 2: Establish a process for providers to apply for an ACO waiver. The Secretary would grant such waivers if, based on a review of the specific arrangement, the benefits outweigh the risks or other specified criteria are satisfied.[1]

[1] This option could vary from a single application per ACO that addresses all of the relevant statutory prohibitions to individual applications for each statutory prohibition for which the ACO sponsor wishes to obtain a waiver. The process for seeking an ACO waiver could be patterned after the OIG Advisory Opinion process and the Secretary could either make it more streamlined to encourage prompt development of ACOs or more detailed to ensure that there are adequate safeguards to address the full range of issues raised by the ACO waiver application.

Pros

- Permits individualized assessment of the risks of Program and patient abuse created by the proposed ACO and allows the Secretary to structure or limit the ACO waiver accordingly
- Preserves protections of existing fraud and abuse laws under appropriate circumstances

Cons:

- Processing the ACO waiver applications would likely require significant resources and highly trained personnel
- Depending on how the process is structured, preparation of the ACO waiver application could well be costly for the applicant, and review of the waiver applications could require significant government resources
- The time required to administer the waiver process would likely delay ACO formation
- It may be difficult to ensure consistency in the ACO waiver determinations

2. Prohibition on Hospital Payments to Physicians to Reduce or Limit Care

Waiver Option 1: Maintain the Status Quo.

Pros:

- Preserves protections against inappropriate inducements to limit services

Cons:

- Fails to address concerns about the legality of both ACO shared savings distributions and patient management fees to ACO physicians
- Discourages formation of ACOs because of legal risks
- May impair ACO's ability to control costs and improve outcomes because it will be more difficult to link the incentives to desired physician conduct

Waiver Option 2: Issue a blanket waiver stating that ACO shared savings distributions and patient management fees are not payments by a hospital to physicians to reduce or limit care within the meaning of the statute.

Pros:

- Encourages ACO formation by reducing legal risks
- Waiver is limited to ACOs and thus not likely to affect the application of the statute in other contexts
- CMS could limit risks of inappropriate limitations on care through the ACO performance standards

Cons:

- Narrows the statute's protections against inappropriate inducements to limit services

Waiver Option 3: Issue a waiver stating that the statutory prohibition is only triggered if the payment is made to reduce or limit "medically necessary" care.

Pros:

- Narrows prohibition to focus on what some contend is the real moral hazard that prompted Congress to enact the statute
- Encourages ACO formation by reducing legal risks
- CMS could further limit risks of inappropriate limitations on care through the ACO performance standards

Cons:

- May significantly narrow the protections afforded by the statute
- Whether care is "medically necessary" is not always clear and, at least partially, a subjective determination[2]
- May not be sufficiently explicit to eliminate legal risk associated with ACO shared savings distributions or patient management fees because critics could assert either that the management fee inherently encourages limiting medically necessary care or assert after the fact that the shared savings were achieved by limiting medically necessary care

Waiver Option 4: Issue a waiver stating that ACO patient management fees and shared savings payments are subject to the Health Plan Physician Incentive Plan regulations[3] rather than the statute prohibiting hospital payments to physicians to reduce or limit care.

Pros:

- Narrows prohibition on limiting care while retaining some safeguards
- Treats ACOs in the same manner as managed care plans
- Encourages ACO formation by reducing legal risks
- CMS could further limit risks of inappropriate limitations on care through the ACO performance standards
- Health plan physician incentive plan safe harbor could be tweaked if necessary

Cons:

- May significantly limit the protections against hospital incentives to reduce or limit care

[2] PPACA acknowledges the difficulty of making medical necessity determinations and the need to develop "evidence-based" standards.

[3] 42 CFR 422.208; 42 CFR 422.210.

- Arguably inappropriate to treat an ACO like a managed care plan given that ACO providers are paid on a fee-for-service basis and patients do not voluntarily enroll
- Some health plan physician incentive safeguards (i.e., stop loss insurance) are not appropriate in the ACO context

3. Beneficiary Inducement Prohibition

Waiver Option 1: Maintain the Status Quo.

Pros:

- Preserves protections afforded by the statute
- Prevents ACOs from buying patient loyalty/cooperation
- Encourages beneficiaries to select the best qualified providers regardless of ACO affiliation

Cons:

- Decreases ability of ACO to coordinate patient care, achieve better outcomes, or decrease costs
- Undermines clinical integration and quality initiatives among ACO participants
- May increases pressure on ACO-affiliated physicians to steer patients to other providers in the same ACO

Waiver Option 2: Issue a waiver that states that if an ACO incorporates certain safeguards it may offer remuneration to encourage beneficiaries to seek care from ACO-affiliated providers. The safeguards might include: (1) limitations on the types and amount of remuneration that may be offered; (2) requiring disclosure to beneficiaries of the ACOs internal financial incentives; (3) requiring ACO providers to identify other providers who could treat the beneficiary; and/or (4) imposing quality of care process or outcome standards.

Pros:

- Increases ability of ACO to coordinate care and/or achieve savings
- Encourages clinical integration and quality initiatives among ACO participants
- Safeguards reduce risk of undue influence on beneficiaries
- CMS could further limit risks of inappropriate incentives through the ACO performance standards

Cons:

- May erode protections afforded by the statute, such as maintaining a level playing field among competing providers
- Arguably allows ACOs to buy patient loyalty/cooperation based on factors other than quality of care
- May discourage selection of best qualified providers

- Limiting the types of permitted compensation may stifle innovation
- Not clear that payments to beneficiaries are necessary to fulfill objectives of ACOs
- The alternative of using full notice and rule making to amend the anti-inducement regulations would permit more deliberation regarding financial arrangements that are not essential to the immediate rollout of ACOs

Waiver Option 3: Issue a waiver that states that an ACO may offer remuneration to encourage beneficiaries to seek care from ACO-affiliated providers but do not require safeguards such as those listed in the preceding option

Pros:

- Increases ability of ACO to coordinate care and/or achieve savings
- Encourages clinical integration and quality initiatives among ACO participants
- CMS could limit risks of inappropriate incentives through the ACO performance standards

Cons:

- Erodes protections afforded by the statute such as maintaining a level playing field among competing providers
- Arguably allows ACOs to buy patient loyalty/cooperation based on factors other than quality of care
- May discourage selection of best qualified providers
- Not clear payments to patient are necessary to fulfill objectives of ACOs
- The alternative of using full notice and rule making to amend the anti-inducement regulations would permit more deliberation regarding financial arrangements that are not essential to the immediate rollout of ACOs

4. The Stark Law

Waiver Option 1: Maintain the Status Quo.

Pros:

- Preserves the protections afforded by the statute
- Prevents ACOs from making payments based on the volume or value of the physician's referrals for designated health services

Cons:

- Fails to address concerns about Stark law issues raised by potential financial relationships arising out of ACO formation, funding and shared savings distributions or other compensation arrangements
- Discourages formation of ACOs because of legal risks

- Forces ACOs to be structured with an eye toward Stark compliance even if that structure is not the best from either a cost or quality of care perspective
- Increases the cost and complexity of ACOs because of need for expert advice on Stark law compliance and ongoing monitoring
- May increase CMS' workload as parties seek advisory opinions addressing individual ACO structures
- Applies a law premised on limiting the influence of financial incentives on physicians' referral patterns to a new model expressly intended by Congress to incentivize physicians to reduce the cost of care

Waiver Option 2: Issue a waiver that states that if an ACO incorporates specific safeguards, any remuneration arising out of the funding, formation and governance of the ACO[4] and distribution of either patient management fees or shared savings would not create a financial relationship as that term is defined under Stark. The specific safeguards could include: (1) imposing limits on the amount of shared savings or other payments that may be paid to an ACO provider; (2) requiring disclosure to beneficiaries of the ACOs internal financial incentives; (3) requiring ACO providers to provide beneficiaries a list of non-ACO providers who could treat the beneficiary or notice that a referral could be made to non-ACO providers; and /or (4) imposing quality of care process or outcome standards.

Pros:

- Establishes means for ACO participants to address Stark risks
- Encourages ACO formation by reducing legal risks
- Scope of waiver clear and sufficiently broad to address the full range of issues
- Safeguards reduce risk of inappropriate incentives and/or harm to beneficiaries
- CMS could further limit risks of inappropriate incentives through the ACO performance standards

Cons:

- Undermines the protections afforded by the statute by allowing payments to physicians arguably based at least in part on the volume or value of the physicians' referrals
- Potentially discourages ACO formation because of complexity of requirements for qualifying for waiver

[4] The Secretary could refine the scope of the waiver addressing remuneration relating to the funding, formation and governance of the ACO in this and the other options in this outline. Focusing on governance, for example, the waiver could provide that if the party forming an ACO grants other ACO members governance rights that would not constitute remuneration under either the Stark law or the anti-kickback statute. Taking a similar tact, the Secretary could provide that if one party pays the legal and infrastructure costs of establishing an ACO that neither constitutes remuneration to the other members of the ACO nor creates an unexpected financial relationship between the party who provided the funding and the other ACO members.

- Increases costs because of need for expert advice and monitoring to fulfill requirements for waiver
- Scope of waiver as applied to ACO formation and governance could have unintended consequences

Waiver Option 3: Issue a waiver that amends the special rules on compensation in the Stark regulations[5] to provide that payment of patient management fees and distributions of shared savings from an ACO are deemed not to be based on the volume or value of referrals or other business generated between the parties.

Pros

- Establishes a means for ACO participants to address key risks under the Stark law
- Encourages ACO formation by reducing legal risks
- Scope of waiver clear
- CMS could limit risks of inappropriate incentives through the ACO performance standards

Cons:

- Undermines the protections afforded by the statute by allowing payments to physicians arguably based at least in part on the volume or value of the physicians' referrals
- Potentially discourages ACO formation because waiver fails to address Stark issues arising out of the funding, formation and governance of an ACO
- Potentially discourages innovation or more effective ACO models by not addressing the permissibility of other compensation arrangements within ACOs

Waiver Option 4. Issue a waiver amending the Stark shared risk exception[6] to state that remuneration arising out of or relating to the funding, formation and governance of an ACO and the payment of patient management fees or distribution of shared savings will not create a financial relationship under the Stark law.

Pros

- Encourages ACO formation by reducing legal risks
- Scope of waiver clear and sufficiently broad to address the full range of issues
- CMS could further limit risks of inappropriate incentives through the ACO performance standards

[5] 42 CFR 411.354(d).
[6] 42 CFR 411.357(n).

Cons:

- Undermines the protections afforded by the statute by allowing payments to physicians arguably based at least in part on the volume or value of the physicians' referrals
- Scope of waiver very broad, particularly as applied to ACO formation and governance, and could have unintended consequences
- It is arguably inappropriate to treat an ACO like a managed care organization given that ACO patients are Medicare fee-for-service beneficiaries and did not voluntarily enroll

Waiver Option 5: Issue a waiver amending the Stark electronic health records (EHR) exception to make it permanent, expand the list of permissible donors, and create greater flexibility for ACO sponsors to fund and implement EHR systems that support ACO operations.

Pros

- Establishes a Stark-compliant means for ACO sponsors to build the infrastructure necessary to coordinate the activities of the participants
- Scope of waiver clear
- CMS could limit risks of inappropriate incentives through the ACO performance standards

Cons:

- Undermines the protections afforded by the statute by expanding the ability of hospitals and other ACO sponsors to subsidize physician practices thereby potentially compromising the physicians' independence and clinical judgment
- Potentially discourages ACO formation because waiver fails to address Stark issues arising out shared savings distributions or other compensation terms as well as the funding, formation and governance of an ACO

5. The Anti-Kickback Statute

Waiver Option 1: Maintain the Status Quo.

Pros:

- Preserves the protections afforded by the statute
- Prevents sham ACOs from forming for the purpose of inducing or influencing referrals
- Builds on existing advisory opinions addressing shared savings programs

Cons:

- Fails to address industry concerns about anti-kickback issues raised by potential financial relationships arising out of ACO formation, funding and shared savings distributions or other compensation terms
- Discourages formation of ACOs because of legal risks
- Forces ACOs to be structured with an eye toward anti-kickback compliance even if that structure is not the best from either a business or quality of care perspective
- Increases the cost and complexity of ACOs because of need for expert advice on anti-kickback compliance and ongoing monitoring
- May increase the OIG's workload as parties seek advisory opinions addressing individual ACO structures

Waiver Option 2: Issue a waiver creating a safe harbor for ACOs that incorporate specific safeguards. The specific safeguards could include: (1) limits on the amount of shared savings or other compensation that may be paid to an ACO provider; (2) requiring disclosure to beneficiaries of the ACO's internal financial incentives; (3) requiring ACO providers to identify other providers who could treat the beneficiary or provide notice regarding availability of referrals to other providers, and/or (4) quality of care process or outcome requirements.

Pros:

- Establishes means for ACO participants to address anti-kickback risks
- Encourages ACO formation by reducing legal risks
- Scope of waiver clear
- Safeguards reduce risk of inappropriate incentives and/or harm to beneficiaries
- CMS could further limit the risk of inappropriate incentives through the ACO performance standards

Cons:

- Undermines the protections afforded by the statute by permitting payments arguably intended to induce referrals of items or services to be paid for by a federal health care benefit program
- Potentially discourages ACO formation because of complexity of requirements for qualifying for waiver
- Increases costs because of need for expert advice and monitoring to fulfill requirements for waiver
- Scope of waiver as applied to ACO formation and governance could have unintended consequences

Waiver Option 3: Issue a waiver expanding the anti-kickback managed care and/or shared risk safe harbors[7] to include all remuneration arising out of or

[7] 42 CFR 1001.952 (k), (l), (m), (t) and (u).

relating to the funding, formation and governance of an ACO and the distribution of shared savings or other compensation.

Pros

- Encourages ACO formation by reducing legal risks
- Scope of waiver clear
- CMS could limit risks of inappropriate incentives through the ACO performance standards

Cons:

- Undermines the protections afforded by the statute by permitting payments arguably intended to induce referrals of items or services to be paid for by a federal health care benefit program
- Scope of waiver as applied to ACO formation and governance could have unintended consequences
- It is arguably inappropriate to treat an ACO like a managed care organization given that ACO patients are Medicare fee-for-service beneficiaries and did not voluntarily enroll

6. Prohibition Against Charging or Collecting More than the Medicare Allowable Amount

Waiver Option 1: Maintain the Status Quo.

Pros:

- Preserves protections of statute

Cons:

- Fails to address concerns about the legality of both ACO shared savings distributions and patient management fees
- Discourages formation of ACOs because of legal risks

Waiver Option 2: Issue a waiver stating that ACO shared savings distributions and patient management fees do not violate prohibitions on charging or accepting more than the Medicare allowable amount for services to beneficiaries.

Pros:

- Encourages ACO formation by reducing legal risks
- Waiver is limited to ACOs and thus not likely to affect application of statute in other contexts
- CMS could further limit the risks through ACO performance standards

Cons:

- Narrows the statute's protections against inappropriate payments to providers

Waiver Option 3: Issue a waiver stating that the statutory prohibition is only triggered if the payments in excess of the allowable amount are in excess of fair market value.

Pros:

- Gives guidance as to the amount of the payments an ACO may make to participants
- Encourages ACO formation by recognizing that payments in excess of Medicare allowable amount are appropriate

Cons:

- It may be difficult to determine whether the amount of either a patient management fee or shared savings distribution is fair market value
- Increases the cost of ACO formation because of the need for valuation data
- Discourages formation of ACOs because of legal risks