COMPLIANCE HANDBOOK

Medicare Shared Savings Program
Accountable Care Organizations

WILEMS resource group

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INTRODUCTION

The regulatory requirements placed on Accountable Care Organizations (ACOs) within the Medicare Shared Savings Program (Shared Savings Program) are extensive and can be overwhelming as ACOs enter the program. This Compliance Handbook is designed to be a quick reference tool to help ACOs more readily understand the operational and compliance requirements placed on them by the Centers for Medicare & Medicaid Services (CMS).

DISCLAIMER

Although prepared by industry experts, this Handbook should not be used as a substitute for seeking legal or other professional services in specific situations. While we believe that this Handbook can serve as a guide for your organization as you work through the implementation and maintenance of your ACO's operational activities and attempt to create processes which will allow your Compliance team to meet their compliance obligations, Wilems Resource Group is not responsible for the manner in which it is used.

The information contained in this Handbook covers only minimum requirements and does not address specific state rules and regulations for health or medical practice. This Handbook does not constitute legal advice, nor is it intended to be a comprehensive solution to every ACO's compliance needs. The ACO is encouraged to make appropriate inquiries regarding additional considerations, including state specific regulations, beyond the scope of this Handbook. No reference tool can ever be completely comprehensive, and use of this tool can never take the place of reading all relevant guidance and regulations from CMS and other state and federal regulatory entities which may have oversight of your organization.

This manual is provided with the understanding that Wilems Resource Group, LLC, including the authors of this manual, are not engaged in rendering legal, medical, or other professional services. If legal, medical, or other expert advice is required, engage the appropriate professional or contact your own Compliance or Legal department for help.

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UNDERSTANDING ACO REQUIREMENTS

As with any government program, there are several requirements outlined for ACOs. These requirements can be found in state and federal regulations, agreements between the ACO and CMS, regulatory guidance such as the Public Reporting Guidance and the Marketing Toolkit, or even in informal CMS communications such as the ACO Spotlight Newsletter.

It is important to note that although the Shared Savings Program is not new, regulatory requirements still change often and CMS guidance and informal communications create new standards and requirements much more frequently. In any regulated industry, it is vital for someone within the organization to continuously monitor all applicable entities for updated information, guidance, and requirements. This is particularly true for ACOs. The ACO should ensure there is a plan in place for disseminating information and reacting to it in a timely manner.

ACO GOVERNANCE

ACOs are required to maintain certain governance requirements to remain in good standing within the Shared Savings Program.

ACO Governance

MSSP Final Rule 42 C.F.R Section 425.106

The Medicare Shared Savings Program Final Rule, released in 2015, updated the governance requirements for ACOs participating in the Shared Savings Program. Under this Final Rule, each Shared Savings Program ACO is required to maintain an identifiable Governing Body with ultimate authority to execute the functions of an ACO, including processes to promote evidence-based medicine and patient engagement, to report on quality and cost measures, and to coordinate care. This Governing Body may be referred to in any number of ways. Most ACOs refer to the Governing Body as a Board of Managers or Management Committee. The name of the entity is irrelevant as long as all the following criteria are met:

1. The Governing Body must be the same as the governing body of the legal entity that is the ACO.
2. The Governing Body must be separate and unique to the ACO and cannot be the same as the Governing Body of any ACO participant (unless the ACO is formed by a single participant TIN).
3. The members of the Governing Body must have a fiduciary duty to the ACO, including the duty of loyalty, and must act consistent with that fiduciary duty.
    - ***Note:*** *CMS has interpreted this to mean that the Governing Body may not represent or make decisions on behalf of any individual or entity that is not an ACO Participant.*

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4. The ACO must establish a mechanism for shared governance among the Participants that formed the ACO. Recently, CMS has interpreted this to mean that all Participants should be represented on the Governing Body.

5. The ACO must provide for meaningful participation in the composition and control of the ACO's governing body of the Participants or their representatives. CMS has interpreted this to mean that no Participant should overwhelmingly outnumber the others in voting authority on the Governing Body.

    a. 75% control of the Governing Body must be maintained by Participants or their designated representatives.

    - ***Note:*** *This does not require participation by a physician and may include other individuals, such as the CEO of a Participant.*

    - ***Note:*** *The Application Reference Manual allows ACOs to include designated representatives of Participants in the 75% threshold calculation. The ACO need not include representatives for each Participant but must ensure meaningful representation in the composition and control of the ACO's Governing Body.*

    - ***Note:*** *In the MPFS CY 2024 Final Rule, CMS removed the ability of an ACO to seek an exception to the 75% Participant control requirement. If your ACO is currently utilizing an exception to that rule, you must plan to meet the requirement before the start of your next Agreement Period.*

6. The Governing Body must include a Medicare Beneficiary Representative who:

    a. Is served by the ACO;

    - ***Note:*** *This does not mean that the beneficiary must be included on the roster received from CMS. CMS has determined that the Beneficiary is served by the ACO as long as he or she has seen an ACO provider in the past year.*

    - Is not an ACO provider/supplier;

    - Does not have a conflict of interest with the ACO; and

    - Does not have an immediate family member who has a conflict of interest with the ACO.

    - ***Note:*** *CMS does still allow for an ACO to deviate from the Medicare Beneficiary Representative requirements under certain circumstances. However, the ACO must provide notice to CMS explaining why it seeks to differ from the requirements and how the ACO will provide meaningful representation in ACO governance by Medicare Beneficiaries.*

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Conflict of Interest

Conflict of Interest

MSSP Final Rule 42 C.F.R Section 425.106(d)

Shared Savings Program ACOs are required to have a Conflict of Interest (COI) policy that applies to members of the Governing Body and subcommittee members, though it may also include any other individuals or entities providing functions or services related to ACO activities. The COI Policy must:

1. Require each member of the Governing Body and subcommittees to disclose relevant financial interests;
2. Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise; and
3. Address remedial actions for members that fail to comply with the policy.
    - ***Note:*** *CMS requires that a COI form be signed annually prior to the start of the next performance year. Newly identified members should complete the COI form prior to appointment.*

Management and Leadership Requirements

Management and Leadership Requirements

MSSP Final Rule 42 C.F.R Section 425.108

The Shared Savings Program also requires the ACO to hire an ACO Executive, whose appointment and removal are under the control of the Governing Body, and a Medical Director. The ACO Executive (and their team) must have demonstrated the ability to influence or direct clinical practice to improve the efficiency of processes and outcomes, though there are no other specific requirements listed.

The Medical Director, on the other hand, is responsible for managing the ACO's clinical management and oversight and must:

1. Be a board-certified physician and licensed in a State in which the ACO operates; and
    - *Note: This does not require the Medical Director to be a practicing physician, only that he or she be certified and licensed. The individual is not required to see patients.*
2. Be physically present on a regular basis at any clinic, office, or other location of the ACO, an ACO Participant, or an ACO Provider/Supplier.

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FIVE ELEMENTS OF AN ACO COMPLIANCE PROGRAM

CMS deviated from the standard seven (7) Element Compliance Program to reduce administrative burdens for ACOs. However, additional requirements have been included in the five (5) Element Program. The ACO should build a Compliance Program focused on the elements required by CMS and include at least the following:

Five Elements of an ACO Compliance Program

MSSP Final Rule 42 C.F.R Section 425.300

Element 1: Designated Compliance Official

The ACO is required to have a designated Compliance Official who is not legal counsel to the ACO and who reports directly to the ACO's Governing Body. This does not prevent the individual from being an attorney. In fact, most Compliance Officials are licensed attorneys.

- ***Note:*** *The responsibilities of a Compliance Official are often at odds with those of an entity's legal counsel; therefore, CMS remains committed to the requirement that these roles not be filled by the same individual.*

Element 2: Mechanisms for Identifying and Addressing Compliance Concerns

The ACO must implement mechanisms for identifying and addressing compliance concerns related to the ACO's operations and performance. CMS does not provide any further insight into what types of mechanisms would meet this requirement. However, there are several best practice standards used throughout the industry.

Identifying Compliance Concerns

The ACO must create mechanisms and processes which will allow for the timely identification of compliance concerns. These include, but are not limited to:

1. Policies and Procedures (P&Ps): P&Ps set expectations for ownership and completion of ACO activities across operational areas and are an excellent source of documentation for audit purposes.
2. Monitoring Activities: These are informal processes by which Compliance ensures that operational areas are meeting requirements.
3. Oversight Activities: These are the formal audit processes completed by Compliance, another operational area (such as Internal Audit), or by an outside entity.

Regardless of how carefully the ACO's Compliance Official creates and implements these mechanisms, the ACO's Compliance Program can only be successful if the ACO's Governing

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Body understands, supports, and fully buys-in to the importance of recognizing and enforcing compliance requirements.

Addressing Compliance Concerns

Once identified, compliance concerns must be addressed, and the ACO should implement processes to ensure that the issue does not recur. To this end, the consequences of non-compliance need to be clearly communicated. Whether this is done through training materials, a Code of Conduct, P&Ps, informal communications, and/or posters in common areas, there are a few tools that an ACO should be ready and willing to utilize to enforce compliance across the ACO.

1. Corrective Action Plans – documentation of how the ACO plans to correct the issue.
2. Remedial Training – should not be used as a disciplinary tool.
3. Disciplinary Actions – should include options other than termination and must be used consistently.

While these tools are extremely useful, and can fit a wide variety of situations, it is vital that they be used consistently and that the Compliance Official has the support of ACO leadership to utilize them as necessary. Without this support, the Compliance Official cannot enforce even the most basic compliance requirements, and the ACO cannot be successful.

Element 3: Method for Anonymous Reporting

The ACO is required to implement a method by which ACO related individuals and Medicare Beneficiaries can anonymously report suspected problems in regard to the ACO. The anonymous portion of this requirement essentially means the ACO must set up a hotline number, a web form, or any method through which individuals can make a formal report without being identified or feeling pressure to reveal their identity. There are no specific requirements for the method. As such, the ACO should consider the following questions:

1. If using a Hotline:
    - How often should the hotline be available?
    - Should the hotline be staffed?
    - Where/How should reports be routed?
2. If using a Web Form:
    - What options should be available to the reporter?
    - Where should reports be routed?

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The ACO should implement a mechanism to ensure that there is oversight in the unlikely event that a report implicates the individual who would ordinarily receive reports. As an example: hotline calls generally routed to the Compliance Official could be routed to the ACO Executive if the Compliance Official is implicated. Alternatively, web form reports are routinely routed to the Compliance Official and the ACO Executive. The Compliance Official would be responsible for follow-up unless he or she is implicated.

No matter how the ACO answers the above questions, how to access the anonymous reporting tool should be included in the ACO's compliance training and communicated through other materials as appropriate. Any time the method is listed, it should include a reminder of the ACO's non-retaliation policy to reassure individuals contemplating a report.

- ◊ **WRG Resource:** Wilems Resource Group offers an online Compliance Reporting Tool to help ACOs meet this requirement. The tool ensures that ACO related individuals can submit a report anytime from anywhere and choose to remain anonymous. If you'd like to learn more, contact Rebecca Cooper at rcooper@wilemsrg.com.

Element 4: Compliance Training

The ACO is also required to provide compliance training for the ACO, its Participants and Preferred Providers. The determination of who needs to complete the training for "the ACO" can be complicated. This is particularly true when you consider the fact that most ACOs do not have many, if any, actual employees. The operational work is usually completed by employees of a Participant or an outside entity. The ACO's Compliance Official should determine what level of training is appropriate for their organization.

Similarly, there is no requirement as to what this training should include. Most ACOs ensure that the appropriate individuals complete Privacy Training, Fraud, Waste and Abuse (FWA) Training, and some ACO specific compliance training.

The ACO may find that most identified individuals already receive HIPAA and FWA training as part of their employment. It is not necessary for the ACO to require duplicative training, though the ACO specific materials should still be required. Documentation of training completion for all elements should be maintained by compliance for audit purposes.

- ◊ **WRG Resource:** Wilems Resource Group offers online Compliance Training to help ACOs satisfy this requirement. The training includes the following topics: ACO 101, Compliance Program 5 Elements, ACO Requirements Beyond the Compliance Program, Overview of HIPAA/HITECH/ACO Specific Data Requirements, and Fraud, Waste, and Abuse and Waivers. If you'd like to learn more about this product, contact Rebecca Cooper at rcooper@wilemsrg.com.

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Element 5: Requirement to Report Probable Violations of Law

The ACO's Compliance Plan must include a requirement for the ACO to report probable violations of law to an appropriate law enforcement agency. This does **not** require that the average employee, or ACO related individual, report directly to law enforcement. Many ACOs meet this requirement by implementing processes through which concerns are reported to Compliance and/or Legal. Those departments then work together to determine whether, and to whom, to report.

PRIVACY AND DATA CONSIDERATIONS FOR ACOS

ACOs are required to be compliant with all state and federal privacy laws and regulations. This includes HIPAA and HITECH, and the ACO should absolutely ensure that there are processes and protocols in place to meet those requirements. For purposes of this Handbook, however, the focus is on issues that are unique to ACOs.

The first thing to consider is whether the ACO is structured as a Covered Entity, in which case the ACO will be required by HIPAA to send out an annual Notice of Privacy Practices, or as a Business Associate of each Participant. Most ACOs elect to be Business Associates as it limits administrative burden for the ACO and confusion for Beneficiaries. Under this arrangement, the ACO will sign a Business Associate Agreement (BAA) with each ACO Participant.

In addition, the Data Use Agreement (DUA) that the ACO signs with CMS places additional obligations on the ACO above those required by HIPAA. CMS data cannot be shared outside of the ACO, ACO Participants or ACO Provider/Suppliers even if it has been deidentified.

These requirements need to be addressed by the ACO and properly communicated across all ACO related individuals to ensure compliance. The ACO can document a vendor or subcontractor's obligation to meet these additional requirements by adding these requirements to an existing BAA template, or by having the entity sign a separate document referencing the DUA and the additional requirements found therein. Regardless of how you document downstream compliance with these requirements, the ACO should be prepared to provide CMS with the following information in the event of an audit:

- Full legal name of the entity with whom the ACO is sharing data provided by CMS as part of the program.
- Physical address of the entity.
- The date the ACO began sharing data with the entity.
- The date the ACO stopped sharing data with the entity; and
- Upon termination, certification by the entity that all data received has been destroyed in accordance with the DUA.

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MARKETING MATERIAL COMPLIANCE

Historically, ACO marketing material compliance was an operational area that caused concerns for many ACOs. Until recently, ACOs often avoided distributing Marketing Materials or engaging in Marketing Activities due to the requirements to file and wait for CMS review and approval.

Marketing Material Compliance

MSSP Final Rule 42 C.F.R Section 425.310

ACOs are no longer required to submit Marketing Materials and Activities to CMS for review and approval prior to use. Previously, ACOs had a five (5) day file and use period which often caused delays in ACO operations.

- *Note: CMS can still request and disapprove a material at any time and require the ACO to immediately discontinue use of the material until any issues are corrected and the material is approved by CMS.*

It is important to note that the removal of the CMS approval requirement does not remove the requirement that the ACO meet all requirements regarding ACO Materials and Activities. ACOs are prohibited from distributing materials that are inaccurate or misleading and must meet the requirements found in the *Quick Reference Language Guide*. The ACO should implement an internal review and approval process, along with tracking mechanisms, to ensure continued compliance with all requirements.

Voluntary Alignment is a particularly high-risk area for ACO Marketing. The ACO should be particularly careful in documenting any activities related to Voluntary Alignment.

BENEFICIARY NOTIFICATION REQUIREMENTS

Traditionally, CMS releases an updated Marketing Toolkit prior to the start of a performance year that includes the standardized Beneficiary Notices Templates, ACO Office Posters, and Marketing Guidance. Templates cannot be modified beyond adding ACO-specific content such as name, logo, phone number, website, and brief paragraph on care coordination services. The materials no longer need to be filed with CMS for approval prior to use.

ACOs must retain records at the individual/Beneficiary-level for distribution of the written notice and the follow up communication to meet the CMS Beneficiary Notification requirements.

ACOs are required to notify Beneficiaries in three ways:

1. Standardized written notice: letter that must be distributed to all aligned Beneficiaries within a timeline designated by CMS.
2. Follow Up Communication: verbal or written communication that occurs within 180 days of the initial written notice that provides Beneficiaries an opportunity to ask questions.

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3. ACO Office Poster: sign that must be displayed by ACO participants in all facilities.

Standardized Written Notice

The Beneficiary Notification requirements have undergone many changes since the inception of the Shared Savings Program. In the 2023 MPFS Rule, CMS reduced the frequency with which the standardized written notices are provided to Beneficiaries from annually to a minimum of once per agreement period. The timeline to provide the notification to the Beneficiary is dependent on alignment type:

1. Preliminary Prospective Assignment with Retrospective Reconciliation: The ACO must provide the written notice prior to or at the first primary care visit during the performance year in which the Beneficiary receives primary care service from an ACO participant.

2. Prospective Assignment: The ACO must provide the written notice at least once during an agreement period and during the performance year for which the Beneficiary is prospectively assigned to the ACO.

ACOs can operationalize this requirement in a variety of ways. For example, many ACOs use traditional mailing while others prefer to leverage patient portals, email addresses, or in-office handouts. Regardless of the method chosen, the ACO must also ensure that the standardized written notice is available upon request in all settings in which Beneficiaries receive primary care services. The ACO should consider the following when developing a process for Beneficiary Notices:

- CMS expects the ACO to make at least two attempts to send the notification if the first attempt fails for any reason (e.g. returned mail).
- If the ACO chooses to use a portal for the notification process, the Beneficiary must receive a push notification that the message is available.
- The ACO should train and notify practices on frequently asked questions before the notifications are distributed.
- The ACO should create a process for ‘gap notifications’ to Beneficiaries who are newly aligned throughout the agreement period.

Follow Up Communication

This newer requirement aims to encourage greater opportunity for Beneficiaries to ask questions about the ACO and their physician’s involvement. There is no template or script for this outreach. The Follow-Up Communication can be verbal or written **and must occur within** 180 days from the date the standardized written notice was provided.

- *Note: Wilems Resource Group recommends utilizing different methods for the standardized written notice and the follow-up communication.*

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ACO Office Poster

The ACO poster is a CMS template material that must be used without modification and displayed at all times in ACO Participant facilities. Previously, ACOs were only required to display in facilities delivering primary care services; however, the regulation has been updated to include 'all' facilities. The ACO should regularly monitor offices for posters on display.

PUBLIC DISCLOSURE REQUIREMENTS

CMS views transparency as vital to a Beneficiary-centered approach. As such, ACOs are required to maintain a publicly facing website to report ACO specific information as determined by CMS.

CMS provides a template to ACOs for purposes of public reporting. The direct link to the Public Reporting webpage must be provided to CMS through the ACO-MS. Beginning in Performance Year 2025, a new functionality in ACO-MS should allow ACOs to export a pre-populated public reporting template for the website. ACOs are required to report the following:

1. ACO Name and Location
2. ACO Primary Contact
3. Organizational information, including:
    a. Identification of ACO participants
    b. Identification of participants in joint ventures between ACO professionals and hospitals
    c. Identification of the ACO Governing Body members and voting power
    d. Identification of key clinical and administrative leadership
    e. Identification of associated committees and committee leadership
    f. Identification of the types of ACO participants or combination of participants that formed the ACO
4. Shared Savings and Losses information, including the following:
    a. The amount of any payment of shared savings received or shared losses owed to CMS
    b. The total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim, including the proportion distributed among ACO participants

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5. Quality Performance Results including the ACO quality measure number, name, rate, and ACO mean
6. If applicable, Payment Rule Waivers including:
    a. SNF 3-Day Rule waiver, and a bulleted list of SNF affiliates
    b. Telehealth Services Payment Waiver
7. If applicable, use of the Fraud and Abuse Waivers including:
    a. ACO Pre-Participation Waiver
    b. ACO Participation Waiver
8. If applicable, information about the ACO's operation of a beneficiary incentive program for each performance year
9. If applicable, information, updated annually, about the ACO's use of advance investment payments (AIP) including:
    a. The ACO's spend plan
    b. The total amount of any advance investment payments received from CMS
    c. An itemization of how payments were spent during the year.
10. The number of ACO Participants, Provider/Suppliers and Professionals that meet the MIPS Promoting interoperability performance category requirements.
11. If applicable, information, updated annually, about the ACO's use of prepaid shared savings including:
    a. The total amount of prepaid shared savings received from CMS;
    b. The ACO's spend plan; and
    c. An itemization of how prepaid shared savings were spent during the year, including:
        i. Expenditure categories;
        ii. The dollar amounts spent on the various categories;
        iii. Information about which groups of beneficiaries received direct beneficiary services purchased with prepaid shared savings;
        iv. How these services were provided to beneficiaries;
        v. How these services supported the care of beneficiaries; and

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vi. Any changes to the spend plan.

FRAUD, WASTE AND ABUSE WAIVERS & BENEFIT ENHANCEMENTS

CMS collaborated with the Office of Inspector General (OIG) to develop certain waivers to allow ACOs some flexibility in operationalizing ACO activities and arrangements. In addition to these waivers, the OIG has released an opinion stating that ACOs in good standing with the Shared Savings Program have a presumption of clinical integration for purposes of creating a Clinically Integrated Network. This presumption is useful as ACOs begin to look toward negotiating commercial contracts outside of the Shared Savings Program.

None of these waivers apply to similar state laws! It is important to ensure that compliance and/or legal for the ACO evaluate any new programs for compliance with state laws as well.

FRAUD, WASTE AND ABUSE WAIVERS

There are five (5) fraud, waste, and abuse (FWA) waivers available under the Shared Savings Program.

Pre-Participation Waiver

This waives Stark Law, the Federal Anti-Kickback Statute, and the Gainsharing CMP. This waiver applies to ACO-related start-up arrangements in anticipation of participating in the program, so long as certain conditions are met.

Participation Waiver

This waives Stark Law, the Federal Anti-Kickback Statute, and the Gainsharing CMP. This waiver applies broadly to ACO-related arrangements during the term of the ACO's participation agreement, so long as the following are met:

1. The ACO has entered into a Participation Agreement and remains in good standing;
2. The ACO meets all governance, leadership, and management requirements of the program;
3. The Governing Body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the program; and
4. The ACO meets the documentation & public disclosure requirements.
    a. The arrangement and its authorization by the governing body of the ACO must be documented. Documentation must be contemporaneous with the

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arrangement and retained for 10 years. The arrangement must be posted to the ACOs website within 60 days, and should include the following:

i. A description of arrangement including:

1. All parties involved;
2. Any relevant dates;
3. The purpose of the arrangement and how it is reasonably related to the purpose of the program;
4. All items, services, facilities, or goods covered by the arrangement;
5. The financial & economic terms should be included in the documentation maintained by the ACO, but should not be included in the public disclosure; and
6. Date and manner of the Governing Body's Authorization.

Compliance with Stark Law

This waives the Federal Anti-Kickback Statute and the Gainsharing CMP. This waiver applies to ACO arrangements that implicate the Physician Self-Referral Law and meet an existing exception, so long as the following are met:

1. The ACO has entered into a Participation Agreement and remains in good standing with the program;
2. The financial relationship involved is reasonably related to the purposes of the program; and
3. The relationship fully complies with one of the existing exceptions to the Stark Law listed at 42 CFR 411.355 through 411.357.

Shared Savings Distribution Waiver

This waives Stark Law, the Federal Anti-Kickback Statute, and the Gainsharing CMP. This waiver applies to distributions and uses of shared savings payments earned under the program, so long as the following are met:

1. The ACO has entered into a Participation Agreement and remains in good standing.
2. The shared savings are earned by the ACO during the term of the Participation Agreement, even if distribution occurs after the expiration of the agreement.
3. The shared savings are:

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a. Distributed to ACO participants, preferred providers, providers/suppliers, or individuals/entities who were participants, preferred providers, or provider/suppliers during the year in which savings were earned; or

b. Used for activities that are "reasonably related to the purposes of the Shared Savings Program".

Payments made directly or indirectly from a hospital to a physician cannot be *knowingly* made to induce the physician to reduce or limit *medically necessary* items or services to patients under the direct care of the physician.

Beneficiary Incentives Waiver

This waives the Beneficiary Inducements CMP and the Federal Anti-Kickback Statute for medically related incentives offered by ACOs under the program to encourage preventive care and compliance with treatment regimes, so long as the following are met:

1. The ACO has entered into a Participation Agreement and remains in good standing; and

2. There is a reasonable connection between the items/services provided and the medical care of the beneficiary, and:

    a. the items/services are in-kind (no cash or cash equivalents)

    b. the items/services are:

        i. preventive care items/services; or

        ii. advance one or more of the following clinical goals:

            1. Adherence to a treatment regime.

            2. Adherence to a drug regime.

            3. Adherence to a follow-up care plan.

            4. Management of a chronic disease or condition.

This waiver **cannot** be used to provide inducements as an incentive for the Beneficiary to receive services from, or remain in, the ACO.

BENEFIT ENHANCEMENTS

In addition to the five FWA waivers, Shared Savings Program ACOs participating in down-side risk can also benefit from the SNF 3-Day Rule and Telehealth Services Payment Waivers.

SNF 3-Day Payment Rule Waiver

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The Skilled Nursing Facility (SNF) 3-Day Payment Rule Waiver allows SNF Services furnished by Eligible SNFs to be covered under Medicare Part A for Eligible Beneficiaries who are admitted to the SNF without a prior inpatient hospital stay ("Direct SNF Admission") or who are discharged from a hospital to the SNF after an inpatient hospital stay of fewer than three days, as long as other coverage requirements for such services are satisfied.

This waiver does not change the SNF benefit available under Medicare. It merely removes a requirement for when the benefit is available. Moreover, while it does not restrict the Beneficiary's choice of SNF facilities, the waiver is only available for facilities listed on the ACO's SNF affiliate list. If the Beneficiary elects to use a non-affiliated SNF, then the standard 3-day inpatient hospital stay will still be required for Medicare benefits to be available.

SNF Eligibility

In order to be eligible to submit claims for services furnished to Beneficiaries under the 3-Day Payment Rule Waiver, the entity must be:

1. Medicare Enrolled;
2. A SNF or a hospital or critical access hospital that has CMS approval to provide post hospital SNF care ("Swing-Bed Hospital");
3. Designated on the SNF Affiliate List, as participating in the 3-Day SNF Payment Rule Waiver; **and**
4. Approved by CMS - The SNF must maintain an overall CMS 5-Star Quality Rating of 3 or higher. The ACO is responsible for removing SNFs that fail to meet this requirement. As such, this should be part of the periodic ACO monitoring plan.

ACO Requirements

The ACO must provide an accurate and complete list of eligible SNFs and furnish updated lists as necessary to reflect changes in eligibility. This list must be actively provided to Participants and providers and must be available upon request by any Beneficiary.

Telehealth Services Payment Waiver

The Telehealth Services Payment Waiver allows payment for covered telehealth services furnished by a physician or other practitioner billing through the TIN of an ACO participant without regard to certain geographic requirements.

Payment Eligibility

In order to be eligible to submit claims for services furnished to Beneficiaries under the Telehealth Services Payment Waiver, the following conditions must be met:

1. Services must be furnished on or after January 1, 2020.

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2. Services must be provided by a physician or practitioner billing under the TIN of an ACO participant in the ACO within 90 days following the date CMS delivers the quarterly exclusion list to the ACO.

3. The Beneficiary was prospectively assigned to an ACO participating in a two-sided model at the beginning of the applicable performance year.

4. The Beneficiary was excluded in the most recent quarterly update from the prospective assignment list.

5. CMS would have made payment to the ACO participant for the services if the Beneficiary had not been excluded from the ACO's prospective assignment list.

TERMINATING A BENEFIT ENHANCEMENT

An ACO may discontinue the Benefit Enhancement **at the end of the Performance Year** but must notify all Participants and Providers within 30 days prior to the start of the subsequent Performance Year.

The ACO must obtain consent before voluntarily discontinuing the Benefit Enhancement **during a Performance Year**. The effective date of the termination will be provided by CMS in their notice to the ACO. Within 30 days of effective date, the ACO must send notice in writing to affected Beneficiaries stating that:

1. 90 days after the effective date (or the end of the Performance Year, whichever is sooner) the Benefit Enhancement will no longer be covered by Medicare and the Beneficiary may be responsible for payment; and

2. CMS will cease coverage of claims 90 days after the effective date.

BENEFICIARY INCENTIVE PROGRAM

An ACO that elects to implement a Beneficiary Incentive Program may provide cash payments (up to $20) to Aligned Beneficiaries who receive qualifying primary care services. The ACO must be prepared to operate this program beginning on the first day of the Performance Year, including the ability to provide each payment within 30 days of the date when the service was furnished to the Beneficiary.

- ***Note:*** *Aside from the required Beneficiary Notification, the ACO is prohibited from including reference to the Beneficiary Incentive Program in any marketing materials and activities.*

The ACO must meet Public Disclosure and strict documentation requirements, which include:

1. Identification of each Beneficiary to receive a payment;

2. The type and amount of each payment;

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3. The date and HCPCS code of the service provider, and the provider who furnished the qualifying service; and

4. The date the ACO provided the incentive payment to the Beneficiary.

- ***Note:*** *This information can be documented in a simple log but must be maintained for 10 years.*

ADVANCE INVESTMENT PAYMENTS

ACOs must apply to receive Advance Investment Payments (AIP) from CMS. If approved, the ACO must be prepared to meet a number of administrative reporting responsibilities. Including:

- Documentation of all spending. Documentation must be sufficient to prove AIP are not used for any of the prohibited uses, including repayment of any shared losses.
- Public Reporting requirements.
- Requirement to report to CMS.
- Segregation of AIP from all other revenues. The ACO is required to establish and maintain a separate account for all AIP activity.

In addition, the ACO must be sure to monitor eligibility requirements as new Participants are added to the ACO. Failure to pay attention to the eligibility requirements could lead to the ACO being required to pay back all funds received within 90 days.

PREPAID SHARED SAVINGS

ACOs must apply to receive Prepaid Shared Savings from CMS. If approved, the ACO must be prepared to meet a number of administrative reporting responsibilities. Including:

- Documentation of all spending. Documentation must be sufficient to prove Prepaid Shared Savings are used only for approved purposes, and to ensure the ACO's ability to report on spending as required.
- Public Reporting Requirements.
- Implementation of processes to ensure spend plan categories are met. The ACO must spend at least 50 percent of Prepaid Shared Savings on direct beneficiary services in each Performance Year.

Maintenance of a repayment mechanism sufficient to repay any outstanding Prepaid Shared Savings within 90 days of notification from CMS.

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RED FLAG AREAS FOR ACOS

There are a few red flag areas for CMS, and the ACO should actively avoid activities which might suggest inappropriate tactics in operational activities, marketing materials, or creation of new incentive programs in the ACO.

LIMITING BENEFICIARY FREEDOM OF CHOICE

A major criticism in the early days of ACOs was that the program would end up being another version of managed care; an extension of the Health Maintenance Organization (HMO) model or the Medicare Advantage (MA) model that most beneficiaries were actively trying to avoid. ACOs are not allowed to limit a beneficiary's ability to receive services from providers who are not participating in the ACO. More than that, however, the ACO must be sure not to provide any information which might be construed as suggesting that this might be the case.

- ***Note:*** *Beneficiaries should never be referred to as "members" or "patients" of the ACO. They are not a part of the ACO, only the Participants and Provider/Suppliers are participating in the ACO.*

ACOs may communicate with Beneficiaries regarding their ability to complete Voluntary Alignment online at MyMedicare.gov but should be careful not to say anything which might be construed to limit freedom of choice. The ACO cannot offer any inducements for completing Voluntary Alignment and may not complete the process on behalf of the Beneficiary.

CHERRY PICKING

Critics have felt that ACOs would take steps to avoid at-risk and/or high-cost patients in an effort to lower costs and thus achieve shared savings, also known as "cherry picking." In simpler terms, cherry picking refers to programs or activities that target healthy, presumably low cost, Beneficiaries to remain assigned or receive services from the ACO or that discourage high risk/cost beneficiaries. In response to these concerns, CMS agreed to monitor ACOs to identify trends and patterns suggesting that an ACO has avoided at-risk beneficiaries.

- ***Note:*** *It is important to remember that cherry-picking may be intentional but could also be an unintended outcome of a program designed to help the ACO. The ACO must explore potential side effects prior to the launch of any new program or activity to determine whether it could create an appearance of impropriety. Documenting the intent and details of any new program prior to implementation can help the ACO answer any questions which might be raised because of unintended consequences.*

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ABOUT WILEMS RESOURCE GROUP, LLC

Wilems Resource Group, LLC is a boutique consulting firm specializing in Compliance and Engagement solutions for the CMS Value-Based programs and models. Kimberly Wilems-Busenbark founded Wilems Resource Group in 2015 after serving as the acting Compliance Officer for 35 ACOs. Since then, WRG has served as a resource for more than 100 ACOs.

Our team has helped clients navigate compliance in the Shared Savings Program, Next Generation ACO Model, Global & Professional Direct Contracting Model, and the ACO Realizing Equity, Access, and Community Health (REACH) Model. Wilems Resource Group has a proven track record of helping value-based care organizations meet regulatory requirements and educating providers, practice managers, and Medicare Beneficiaries on respective CMS programs and models.

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