ACO Audit Readiness Handbook

Prepared by Wilems Resource Group, LLC.

WILEMS resource group

February, 2018

Table of Contents

Introduction 1

History of CMS ACO Audits 2

Public Disclosure & Website Audits 2

Participant List Audits 2

Quality Measure Validation Audits 3

Red Flag Areas 3

Audit Readiness 4

Governance 5

Compliance Program 6

Compliance Program Monitoring & Oversight 7

Corrective Actions 8

ACO Operations 9

Surviving a CMS Audit 12

Data Collection & Review 13

Responding to the CMS Audit Report 13

Resources 14

Introduction

The Medicare Shared Savings Program Final Rule Section 425.314 (a) and the Next Generation ACO Model Participation Agreement Section XVIII.A require participating Accountable Care Organizations (ACOs) to agree that the Government, including the Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS) and the Comptroller General or their designess, has the right to audit, inspect investigate, and evaluate any books, contracts, records, documents and other evidence of the ACO in order to ensure:

1. The ACO's compliance with program requirements;
2. The quality of services performed under the program; and
3. In risk bearing models, the ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

While many ACOs have begun to prepare for Quality Measure Validation Audits, it seems few have taken the necessary steps to prepare for a general program audit. This Audit Readiness Handbook is designed to provide guidance to ACOs as they work to ensure their organization is prepared to successfully respond to an audit request. This Handbook is not intended to be a comprehensive solution to every audit, as the individual circumstances of each ACO, its compliance processes, and the requests made by CMS can raise specific issues, concerns, and opportunities. Nor does this Handbook establish an attorney/client privilege or relationship between NAACOS, Wilems Resource Group and any ACO, Participant, Preferred Provider, or Provider or Supplier. However, this Handbook will give an ACO the tools necessary to prepare for, and successfully respond to, a CMS audit.

History of CMS ACO Audits

While every Next Generation ACO undergoes a CMS audit, this is not a hard and fast rule for Shared Savings Program ACOs. Still, ACOs under both programs will likely face a CMS program audit at some point. It is important to ensure that your ACO is prepared for an audit request. In order to understand what CMS might ask in the future, it may be helpful to understand what audits have already been completed within the Shared Savings Program.

Public Reporting & Website Audits

CMS reviews each ACO's webpage to ensure compliance with public reporting requirements. In doing so, they may also review any optional web content to ensure that the material has been submitted to CMS for approval as is required by the marketing guidelines. Issues identified as part of these audits have not typically led to serious consequences. Rather, CMS simply requires the ACO to make the necessary corrections. However, the CMS response will largely depend on the severity of the issue identified. If, for instance, your ACO does not submit a marketing website for review, you will likely face more severe consequences than an ACO who has a typo on their public reporting webpage.

It is also worth mentioning that ACOs utilizing the Pre-Participation or Participation Waiver must post documentation related to that use on the ACO's website. As a result, a CMS website audit could open the door to a review of activities being undertaken as part of waiver protections. Your ACO should be prepared to provide any additional documentation around the use of the waiver, and to address any red flags that your waiver usage might raise.

Participant List Audits

In the early days of the program, CMS would do audits to ensure that the ACO was maintaining the Participant List on the ACO's public reporting webpage. This audit raised issues related to timing of additions and terminations and the thirty-day window that the ACO had to post updates. As a result, CMS has moved to the bi-annual public reporting

template process currently in place for the Shared Savings Program. CMS may still do an audit of the ACO's Participant List, but they seem to rely more on the ACO's Annual Certification of the Participant List and allow the ACO to make updates twice per year. Your ACO should ensure you are prepared to respond to the Annual Certification Process in a timely manner.

Quality Measure Validation Audits

The Quality Measure Validation (QMV) Audit measures the accuracy of the ACO's reporting during the quality reporting process. It does **not** measure whether the ACO is meeting the quality standards. As an example, when CMS reviews the flu shot measure during this audit, the question is not whether the flu shot was received, but whether or not the ACO accurately reported whether the flu shot was received. If the ACO reports that a flu shot was **not** received, and the QMV Audit shows the flu shot **was** given, the ACO will fail that record. This is true even though the ACO reported a lower quality standard than was actually achieved for this Medicare Fee-For-Service Beneficiary (beneficiary).

Failure to pass the QMV Audit will almost certainly end in a Corrective Action Plan, but may also lead to an ACO being unble to receive any attained shared savings. Although the possible consequences of a failed QMV Audit are daunting, with a little foresight, ACOs can easily prepare for the QMV Audit. This preparation will help ensure the ACO can respond to a QMV Audit Notice successfully and within the time allotted by CMS. For more information regarding this audit and how to prepare to respond successfully, please see our previously released Quality Measure Validation Audit Resource.

Red Flag Areas

There are a few red flag areas for CMS, and ACOs should keep these in mind when building a Compliance Program. The ACO should always consider whether any activity will raise one of these flags, and ensure there is adequate documentation to reassure CMS that the ACO is acting within the goals of the program. The two most concerning redflags for CMS are anything that suggests that an ACO is limiting beneficiary freedom of choice or engaged in cherry picking.

Limiting Beneficiary Freedom of Choice

CMS strictly governs ACO marketing materials, and the regulatory requirements make it clear that ACOs are not permitted to undertake any action which might limit any beneficiary's freedom of choice as to where they receive health care services. CMS template materials explicitly reinforce the beneficiary's freedom of choice: "Your Medicare benefits are not chaning in any way. You may still go to any doctor, hospital, or other healthcare provider you choose." ACOs should ensure that all ACO related materials are drafted in such a way as to avoid any suggestion of limitation. This includes using terms such as "network" in reference to the ACO, or referring to beneficiaries as "members" or "patients" of the ACO. This standard goes beyong marketing materials, however, and should be considered in all ACO activities.

Cherry Picking

Cherry Picking refers to activities undertaken in an effort to improve an ACO's outcomes through beneficiary assignment gaming. This may include efforts to attract and retain healthy, presumably low-cost, beneficiaries or to avoid high-risk or high-cost beneficiaries. In order to prevent this, CMS has agreed to monitor ACOs in an attempt to identify trends and patterns which may suggest that an ACO is Cherry Picking.

It is important for ACOs to recognize that Cherry Picking may happen intentionally, but may also be an unintended result of an otherwise stellar program. ACOs should discuss and thoroughly examine any potential outcomes for the appearance of impropriety before implementing any new program or initiatives. The ACO should clearly document the intent and details of the program prior to implementation. This documentation may be useful in defending the ACO's intent in the event of an audit.

Audit Readiness

An effective ACO Compliance Program is designed to ensure that the organization is meeting all requirements. This can be overwhelming, particularly for those who are new to ACOs and are not accustomed to the heightened level of oversight associated with

CMS programs. One yardstick for determining the effectiveness of your Compliance Program is to think of your documentation in terms of audit response. Each requirement must not only be met, but must be documented sufficiently that the ACO can prove to CMS that the requirement is being met consistently. The following section breaks down a handful of regulatory requirements and provides examples of documentation ACOs can use to demonstrate compliance during an audit.

It's easy to be compliant. The trick is proving it.

Governance

The Medicare Shared Savings Program Final Rule and the Next Generation ACO Model Participation Agreement list specific requirements for the ACO Governing Body. Most of these requirements focus on the composition of the Governing Body – the requirement to have a Medicare Beneficiary Representative, a Consumer Advocate, and 75% of the voting authority held by Participant representatives. These straight-forward requirments are both easy to meet and to document. The ACO must include this information on the ACO's public reporting webpage.

Governance Action Items:

- ✓ Include Governing Body composition on ACO Public Diclosure Webpage
- ✓ Document & retain Meeting Minutes for ACO Committee & Sub-Committee Meetings
- ✓ Report Sub-Committee Activities to the Governing Body
- ✓ Invite ACO Participants to engage in meetings
- ✓ Consider Townhalls or Bootcamps to engage providers & complete training

The more complicated requirements are related to the role of the Governing Body. The ACO must consider how it would defend an accusation that Participants do not have "meaningful participation" in the governance of the ACO. Or, equally as complicated, how to prove that the Governing Body has "ultimate authority" over the operations and activities of the ACO.

A simple step to document governance is through Meeting Minutes. The ACO should document and maintain Meeting Minutes for all ACO committees and sub-committees. Reports of committee and sub-committee activities should be delivered consistently to

the ACO's Governing Body, whether that be a Board of Managers, Board of Directors, or Management Committee. This activity will speak to the oversight that the Governing Body has over the sub-committees, and will ultimately help the ACO demonstrate the requirement for "ultimate authority".

ACO meetings should be announced and open to all Participants, whenever practical. In many cases it is inappropriate, if not impossible, to give all ACO Participants equal voting authority on the Governing Body. However, the ACO must still ensure that all Participants have "meaningful participation" in ACO governance. Providing all Participants an opportunity to be involved in the discussions and decision-making process, if not in the final vote, can help alleviate concerns arising from a lack of voting power. Many ACOs utilize regular Townhall Meetings, whether in person or virtually, to keep providers engaged in ACO initiatives. Others plan annual or bi-annual provider bootcamps as a way to capture the attention of providers while offering an in-depth look at the ACOs progress, goals, and operational activities. Not only can these meetings be utilized to demonstrate that Participants have "meaningful participation" in the ACO, but can also provide a method for completing required trainings and gaining feedback and buy-in from those on the front lines of your ACO initiatives.

Compliance Program

ACOs participating in the Shared Savings Program and in the Next Generation ACO Model are required to implement a Compliance Program which meets at least the following five (5) elements:

(1) A designated Compliance Official who reports directly to the ACO's Governing Body and is not legal counsel to the ACO;

(2) An effective training program;

(3) A method for anonymous reporting of compliance concerns;

(4) Mechanisms for identifying and addressing potential concerns related to the operations of the ACO; and

(5) A requirement to report probable violations of law to an appropriate law enforcement agency.

In a program audit, CMS will require an ACO to demonstrate effective implementation of each of these elements. Your Compliance Officer should have the expertise and the resources necessary to monitor the ACO's compliance with these, and all, regulatory requirements.

Compliance Program Monitoring & Oversight

Compliance Program Action Items:

- ✓ Build & Implement Compliance P&Ps
- ✓ Launch a Monitoring & Oversight Program
- ✓ Document and follow-up on reports of non-compliance
- ✓ Report Compliance activities to the Governing Body

The first step in implementing and documenting an effective Compliance Program is the development of policies and procedures. These policies will not only serve as documentary evidence during an audit, but create a basis by which the ACO departments can work together to be successful in all areas. These policies will also provide the standards against which your Compliance Officer can develop an effective Monitoring & Oversight Program. This is critical to the ability of the ACO to identify and address potential compliance concerns prior to a CMS audit, and to document this process. If your ACO does not currently have policies and procedures in place, NAACOS has worked with Wilems Resource Group to develop a set of policies and procedures that ACOs can use as a starting point.

Your ACO should be engaged in proactive monitoring to ensure that you are not only checking boxes, but are meeting the intent behind the requirements. This monitoring may involve a variety of activities including submission of test reports to the ACO's anonymous reporting tool, review of training completions, or annual collection of the Compliance Officer's and Medical Director's resumes. The Monitoring & Oversight Program should also be utilized to follow-up on any reported issues of non-compliance. The Compliance Officer should deliver regular monitoring reports to the ACO's Governing Body, or appropriate sub-committee. This reporting can be utilized to prove the ACO's compliance

with the five elements of an ACO Compliance Program, as well as the ACO's overall commitment to ensuring and enforcing compliance.

Corrective Actions

Corrective Action Items:

- ✓ Create iCAPs for issues of non-compliance

The ACO cannot merely identify concerns without taking the appropriate steps to ensure the issue is corrected. The ACO's Compliance Officer should work with the Business Owner to document any identified opportunities for improvement and implement internal Corrective Action Plans (iCAPs) as necessary. It is important to note that iCAPs are not disciplinary tools, and should not be viewed as such. The iCAPs are simply tools to document the steps by which the ACO is working to improve processes and ensure that any issues of non-compliance do not recur. Any effective iCAP should:

- Identify the root cause of the identified issue: This could be as simple as human error or a failure of internal control processes.
- Offer solutions based on the root case: The solutions should be directly related to the root cause of the error, and should be measurable and specific. As an example, if the ACO identifies the issue to be the result of inadequate training, then the ACO should provide remedial training to address the concern.
- Include an ongoing monitoring plan: The iCAP should include a plan for ensuring that the recommended corrective actions are effective. In the training example above, the ACO should also consider completing additional monitoring throughout the year to ensure that the training was effective in correcting the identified issue.

ACO Operations

Operations Action Items:

- ✓ Build & Implement Operations P&Ps
- ✓ Launch a Monitoring & Oversight Program

ACOs are required to implement processes related to improving care and lowering costs. In the Next Generation ACO Model, this requirement is noted under Section VII.A Care Improvement Objectives. However, under section 425.112 of the Medicare Shared Savings Program Final Rule, ACOs are specifically required to have written plans to address individualized care programs, identify target populations, promote the use of enabling technologies for improving care coordination, and how the ACO will partner with long-term and post-acute care providers, both inside and outside the ACO. ACOs in all programs realistically need policies to provide direction in each of these areas. These policies can be used to ensure you are meeting the regulatory specifications, but can also create standards and expectations across the care team and ACO operations to help increase the likelihood of ACO success.

Regardless of the specific processes your ACO chooses to implement, you must work to ensure you are meeting the requirements of the regulations as well as the ACO's own policies and procedures. These policies should be specific and allow the Compliance Officer to create measurable systems to monitor compliance. If your ACO does not currently have a policy covering each of these areas, the narratives submitted during the application processes are a great place to start. In the event that an audit identifies a red flag concern, demonstrable compliance with the ACO's policies related to care improvement activities can help support an ACO's claim that the identified activity was undertaken in good faith. This good-faith understanding can mitigate the potential consequences from CMS.

Marketing Requirements

The Shared Savings Program and the Next Generation ACO Model place strict requirements on what ACOs may say in ACO related materials. While the definitions of marketing materials vary slightly, CMS requires ACOs in both programs to submit certain materials for approval prior to distribution. Whether a material must be submitted for approval or not, the ACO should ensure that all materials meet the CMS standards, are not misleading nor discriminatory. To ensure compliance with these requirements, the ACO should establish a formal internal review procedure. This procedure should include a review for compliance with the marketing guidelines as well as a determination of whether the material meets the definition of a marketing or descriptive material requiring CMS/CMMI approval.

Marketing Requirement Action Items:

- ✓ Submit materials to CMS for review
- ✓ Document & Implement Marketing Material Review Process
- ✓ Archive Marketing Materials

Documentation of this review process should be maintained by the ACO. This documentation can be utilized in an audit to show how the ACO ensures compliance with the marketing guidelines. It can also be used as a mitigating factor in the event that an issue is identified with a material. A formal review process would show that an identified issue was an error, and not a systemic issue with the ACO's material creation process.

CMS Template Materials

ACO marketing materials and CMS Template Materials go hand-in-hand. The ACO should have a process to ensure that template materials are updated in a timely manner any time CMS releases updates. It is important to note that Template Materials are still required to be submitted to CMS, but are automatically approved. In other words, while they must be submitted, you do not have to wait the five or ten days for CMS/CMMI to approve the material prior to distribution.

The ACO should also include monitoring of template materials in the Monitoring & Oversight process to ensure the templates are being utilized as required. For instance, in

the Shared Savings Program, a double check to verify that ACO Posters are visible and the Beneficiary Notification Handout is available in offices where primary care services are delivered. For Next Generation ACOs, verify that reasonable steps were taken to ensure beneficiaries received the Beneficiary Notification letter. ACOs should work to ensure that the mailing process includes documentation sufficient to prove that the letters were mailed. During an audit, CMS would likely provide a sample of Beneficiaries and require the ACO to prove that letters were mailed to those individuals. You should ensure your records allow you to confirm completion at the individual level. Your records should also indicate when letters are returned as undeliverable, and the steps the ACO took in an attempt to meet the notification requirement in those instances.

CMS Template Material Action Items:

- ✓ Monitor Template Material distribution and filings
- ✓ Document & track distribution and mailings

Waivers

The waivers are an incredible tool ACOs can use to be creative and effectuate change in the way beneficiaries think about, and care teams deliver, health care services. Yet, waiver implementation is a large grey area that many ACOs tend to avoid. They are often unsure of how to leverage waivers without taking on additional risk. Your ACO Compliance Officer should work closely with the leadership team and the Governing Body to discuss and analyze the potential risks associated with any new initiative. When the ACO elects to utilize one of the waivers, the Compliance Officer should work closely with operations and the legal team to clearly document the details and the intent of the program. This documentation should specify each of the requirements of the waiver being utilized and how the ACO is ensuring compliance with them. You should also consider adding information regarding Governing Body approval

Waiver Action Items:

- ✓ Clearly document the intent of waiver initiatives
- ✓ Collaborate across departments on waiver implementation
- ✓ Receive and document Governing Body approval
- ✓ Publicly disclosure waiver, if applicable

of the waiver utilization. While this may not be a specific requirement of the waiver you are using (it **is** required for use of the Pre-Participation and Participation waivers), it can also provide evidence of the "ultimate authority" of the Governing Body over the activities of the ACO.

Waiver documentation prior to implementation of the initiative is a requirement under the Pre-Participation and Participation waivers, but is key to successful audit preparations when using any of the available waivers. Should a waiver create unintended consequences, documentation of the processes related to the waiver and the ACO's intentions in utilizing it can go a long way towards alleviating concerns from CMS. In an audit scenario, the ACO's level of documentation could be the difference between CMS implementing a Corrective Action Plan, issuing a sanction, or even terminating the ACO's participation in the Shared Savings Program or Next Generation Model.

Surviving a CMS Audit

Once the audit notice is received from CMS, the ACO will not likely have long to respond. In some cases, organizations are given as little as 48 hours to prepare a response to a request. The tight timeline can cause panic. The first step in managing the successful audit response is to identify key individuals and available resources. The following individuals should be included in the audit project plan:

- Audit Owner: this individual may be in Compliance or Operations, but ideally would not be the individual who oversees the day to day operations of the area being audited. The Audit Owner should have project management experience.
- Business Owner: this is the individual who has ultimate responsibility for the day to day oversight and management of the area being audited.
- Reporting Staff: these individuals will actually pull documentation related to each request being made by CMS, and are likely the same individuals who perform the day to day tasks in the area being audited.

- Quality Assurance (QA) Team: these individuals complete the QA review of the documentation pulled in response to the CMS audit notice. Ideally, these individuals are not involved in the day to day activities of the area being audited, though this may be difficult to accomplish in practice.
- Technical Support: this is a key IT Contact who can be available throughout the audit for resolution of technical issues, such as remote access concerns, or difficulty in uploading files to CMS.

Data Collection & Review

It can be tempting to start at the top of the audit list provided by CMS, and work your way down. However, this can create significant delays through bottlenecks in the QA Review process and make it more difficult for the ACO to meet the tight audit deadline. It is best for the ACO to use the 80/20 Rule, whereby you work to get the easy 80 percent as quickly as possible and start putting that documentation through the QA Review process while you work to locate the more difficult information.

As soon as documentation has been collected, the QA Review can begin. QA Review can be completed as documents are located, or completed once all documents have been located for a particular section. This will depend largely on the specifics of the audit notice received by your ACO. Either way, the QA review should focus on ensuring the documentation pulled is sufficient to support the CMS request. If completed timely, this review can provide the ACO an opportunity to perform additional clean-up on the documentation before submission, and allows for early identification of opportunities for improvement. Your ACO can then begin to work through implementation of iCAPs and a Monitoring & Oversight Program to correct those issues and prevent them from recurring.

Responding to the CMS Audit Report

Hopefully, by the time your ACO receives the CMS Audit Report, you will already be working through any identified deficiencies through the use of internal CAPs. These iCAPs will provide the basis of your response to the CMS Audit Report, and allow the ACO to respond quickly. The ACO should review the CMS Audit Report and highlight:

- Opportunities for improvement based on identified deficiencies: pull internal CAPs and documentation created as a result of the ACO's internal QA Review.
- Areas of disagreement or concern. CMS will most likely set up a call to discuss your audit results. This is a great time to seek clarification on audit results or point out discrepancies between the CMS findings and the ACO's internal QA Review.

Once this is complete, the ACO should draft a response to the CMS Audit Report which addresses each finding and/or deficiency noted by CMS. The ACO should have documented iCAPs and ongoing monitoring to support the effectiveness of those plans. This will go a long way in reassuring CMS that the ACO is acting in good faith and is working to ensure compliance with all program requirements. The ACO's drafted response must be demonstrative of the ACO's ongoing commitment to compliance.

Resources

Although it's easy to be compliant, ACOs may wish to leverage resources to build and document complaint programs. NAACOS offers a variety of helpful resources on their member website to assist ACOs in building policies and procedures, preparing for QMV audits, and more. [Insert access instructions].