COMPLIANCE HANDBOOK

global and professional direct contracting model

Wilems Resource Group, LLC
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RAISING OUR LEGACY

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INTRODUCTION

The regulatory requirements placed on Direct Contracting Entities (DCEs) within the Global and Professional Direct Contracting (GPDC) Model are extensive and can be overwhelming as DCEs shift from the Medicare Shared Savings Program (Shared Savings Program) or the Next Generation ACO Model. This Compliance Handbook is designed to be a quick reference tool to help organizations more readily understand the operational and compliance requirements placed on them by the Centers for Medicare & Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI).

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 DCE'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 DCE's compliance needs. The DCE 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 handbook is provided with the understanding that Wilems Resource Group, LLC, including the authors of this handbook, 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.

UNDERSTANDING DCE REQUIREMENTS

As with any government program, there are a number of requirements outlined for DCEs participating in the GPDC Model. These requirements can be found in state and federal regulations, agreements between the DCE and CMS/CMMI, regulatory guidance, and informal CMS communications (such as the *News You Can Use* updates from CMS). This section of the Compliance Handbook will discuss the requirements as they currently stand in the following areas:

1. DCE Governance
2. Five Elements of a DCE Compliance Program
3. Privacy and Data Considerations for DCEs
4. Marketing Material Compliance
5. Beneficiary Notification Requirements
6. Public Disclosure Requirements

It is important to note that regulatory requirements change often for the GPDC Model 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 DCEs. The DCE should ensure there is a plan in place for disseminating information and reacting to it in a timely manner.

DCE Governance

DCEs are required to maintain certain governance requirements in order to remain in good standing within the GPDC Model.

Governance Requirements

Under the GPDC Model, the DCE is required to maintain an identifiable Governing Body with sole and exclusive authority to execute the functions of the DCE and make final decisions on behalf of the DCE. The DCE can call the Governing Body by any number of names, as long as the following requirements are met:

Governance

GPDC Model Participation Agreement Section 3.02

1. The Governing Body must have responsibility for oversight and strategic direction of the DCE and is responsible for holding DCE management accountable for the DCE's activities.

2. The Governing Body must be separate and unique to the DCE and cannot be the same as the Governing Body of the legal entity of any DC Participant or Preferred Provider (unless the DCE is formed by a single DC Participant).

3. The Governing Body must have a transparent governing process.

4. When acting as a member of the Governing Body, each member has a fiduciary duty to the DCE, including the duty of loyalty, and shall act consistent with that duty.

5. The Governing Body must receive regular reports from the designated compliance official of the DCE.

6. At least 25% control of the DCE Governing Body must be held by DC Participants or their designated representatives.

7. The Governing Body must include at least one Beneficiary served by the DCE who:

    a. Does not have a conflict of interest with the DCE;

    b. Has no immediate family member with a conflict of interest with the DCE;

    c. Is not a DC Participant or Preferred Provider; and

    d. Does not have a direct or indirect financial relationship with the DCE, a DC Participant, or a Preferred Provider.

        - *Note: this requirement does not prevent the Beneficiary from being compensated by the DCE for his or her duties as a member of the Governing Body.*

8. The Governing Body must include at least one person with training or professional experience in advocating for the rights of consumers. This individual may be the same person as the Beneficiary Representative, but must:

    a. Not have a conflict of interest with the DCE;

    b. Have no immediate family member with a conflict of interest with the DCE;

    c. Not be a DC Participant or Preferred Provider; and

    d. Not have a direct or indirect financial relationship with the DCE, a DC Participant, or a Preferred Provider.

        - *Note: this requirement does not prevent the Consumer Advocate from being compensated by the DCE for his or her duties as a member of the Governing Body.*

        ◊ Resource: Wilems Resource Group offers an online DC Consumer Advocate Training to help DCEs satisfy this requirement. This training provides background information on the GPDC Model and the

expectations for the Consumer Advocate within that Model. Interested parties can contact mshort@wilemsrg.com for more information.

9. Each member of the Governing Body must receive a copy of the GPDC Model Participation Agreement signed by the DCE. We recommend emailing the document so that you will be able to prove compliance with this requirement in the event of an audit.

CMS does allow for a DCE to deviate from these specific requirements under certain circumstances. However, the DCE must provide notice to CMS explaining why it seeks to differ from the requirements and how the DCE's policies involve DC Participants and reflect consumer and patient perspectives.

Conflict of Interest

The GPDC Model requires the DCE to have a Conflict of Interest policy that applies to members of the Governing Body, though it may also include any other individuals or entities providing functions or services related to DCE Activities. This Conflict of Interest Policy must:

Conflict of Interest

GPDC Model Participation Agreement Section 3.02(C)

1. Require each member of the Governing Body 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.

Management and Leadership Requirements

The DCE is required to hire a DCE Executive and a Medical Director, whose appointment and removal are under the control of the Governing Body. The DCE Executive (and his or her 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.

Management and Leadership Requirements

GPDC Model Participation Agreement Section 3.03

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

1. Be a board-certified physician, licensed in a State in which the DCE operates.
2. Be physically present on a regular basis at any clinic, office or other location participating in the DCE.

3. Be a DC Participant.

Participant and Preferred Provider Additions

Participants and Preferred Providers

GPDC Model Participation Agreement Section 4.05

GPDC PY2021 Ad Hoc Provider Guidance

The DCE is required to meet certain requirements before submitting any new DC Participant or Preferred Provider to CMS. This is true for the Initial DC Participant or Preferred Provider List, as well as for additions during the Performance Year. In our experience, many DCEs fail to meet the deadlines for these requirements, as they are specified in Article IV of the GPDC Model Participation Agreement. This is particularly problematic as this is likely to be heavily audited by CMS. As such, while these are not strictly part of the implementation of the DCE's Compliance Program, we wanted to take a moment to highlight them.

1. The DCE must have a written agreement in place with each DC Participant or Preferred Provider prior to submission of the individual or entity. This agreement must meet the requirements detailed in Section 3.04.G of the GPDC Model Participation Agreement.

   The DCE *may* obtain entity level agreements on behalf of the individual Participants or Preferred Providers **if and only if**, all of the following conditions are met:

   a. The arrangement between the DCE and the Contracting Entity identifies each individual DC Participant Provider or Preferred Provider who has agreed to comply with the agreement.

      - *Note: In practice, this means you need to include a method for updating this list throughout the year. You should discuss with your legal teams how best to document this.*

   b. The arrangement between the DCE and the Contracting Entity satisfies the requirement that the entity agree on its own behalf, and on behal of each individual provider, to participate in the Model, to engage in DCE Activities, to comply the the applicable terms of the Model, and to comply with all applicable laws and regulations.

   c. Each individual identified in the arrangement between the DCE and the Contracting Entity is employed by, or under contract with, the Contracting Entity and has reassigned their Medicare billing rights to the Contracting Entity.

   d. The Contracting Entity is legally authorized to bind each individual DC Participant Provider or Preferred Provider identified in the arrangement.

   e. The Contracting Entity is the same participant type as the individuals on whose behalf it is contracting (i.e., DC Participant Provider Contracting Entities can only contract on behalf of individual DC Participant Providers).

- *Note: This means that the entity leval TIN and ONPI must be included on your Participant or Preferred Provider List as well as the individual TIN/NPI combinations for the individual providers.*

2. DC Participants and Preferred Providers may be added using the ad hoc additions process. The details of this process are not well documented in the GPDC Model Participation Agreement. DCEs should review the GPDC Model Policy and Operating Procedures: PY2021 Ad Hoc Provider Policy. Under this Policy, additions must be submitted to CMS at least five (5) business days prior to the last Friday of the month. In addition, CMS releases information on when these gates will be open as part of the calendar found in the GPDC Model *News You Can Use* weekly newsletter.

    - *Note: There will be no window for Participant or Preferred Provider submissions during the month of December. The latest effective date of an addition to a DCE during a Performance Year is December 1st.*

3. The DCE must submit written notice of the DCE's intent to include the DC Participant or Preferred Provider on the DCE's Participant or Preferred Provider List. This notice must be submitted to the DC Participant or Preferred Provider, as well as the executive of the TIN through which the individual or entity bills Medicare. This notice must meet all of the requirements specified in Section 4.05.C-E, as applicable.

    - *Note: Starting with additions for PY2022 CMS is no longer requiring an executed Legacy TIN Acknowledgement Form when including a Legacy TIN on the DCE Roster. However, your DCE is now required to submit written notice to the TIN Executive of the Legacy TIN prior to submission. There are no specific requirements as to the content of this notice. Your DCE should use a template document and maintain records that the notice was sent.*

4. The DCE must submit a certification attesting to compliance with all requirements outlined in Section 4.05 of the GPDC PA.

    - *Note: Unlike the NextGen Model, this certification is built into the 4i additions process and does not require an additional upload.*

Participants and Preferred Providers added during the Performance Year can be included in any active Benefit Enhancements and Beneficiary Engagement Incentives **but cannot participate in the DCE's alternative payment mechanisms** until the subsequent Performance Year.

Five Elements of a DCE Compliance Program

Five Elements of an DCE Compliance Program

GPDC Model Participation Agreement Section 11.01

If you are moving to the Global & Professional Direct Contracting Model from a Medicare ACO, your organization will be familiar with the five (5) element Compliance Program favored by CMS in this area. For those who are jumping straight into the GPDC Model, CMS has deviated from the standard seven (7) Element Compliance Program under Medicare Advantage. Many administrative burdens have been reduced for the DCE based on this intentional departure from the standard requirements; however, additional requirements have been included in the five (5) element program.

Element 1: Designated Compliance Official

The DCE is required to have a designated Compliance Official who is not legal counsel to the DCE and who reports directly to the DCE's Governing Body. This does not prevent this individual from being an attorney. In fact, many Compliance Officials are licensed attorneys. However, the responsibilities of a Compliance Official are often at odds with those of an entity's legal counsel. An effective Compliance Official cannot wear both hats.

Element 2: Mechanisms for Identifying and Addressing Compliance Concerns

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

Identifying Compliance Concerns

First, the DCE 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 DCE 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 their 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 DCE's Compliance Official creates and implements these mechanisms, the DCE's Compliance Program can only be successful if the Governing 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 DCE should implement processes to ensure that the issue does not recur. As such, the consequences of non-compliance need to be clearly communicated and consistently utilized. No matter how the DCE choses to communicate these consequences, there are a few tools that a DCE should be ready and willing to utilize to enforce compliance across the DCE.

1. Corrective Action Plans – documentation of how the DCE 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.
4. Termination – while the DCE should have other disciplinary actions available to enforce smaller compliance requirements, DCE related individuals must understand that termination of their participation or contract may occur for severe or repeat offenses.

It is vital that all consequences be used consistently and that the Compliance Official has the support of DCE leadership to utilize them as necessary. Without this support, the Compliance Official cannot enforce even the most basic compliance requirements, and the DCE cannot be successful.

Element 3: Method for Anonymous Reporting

The DCE is required to implement a method by which DCE related individuals can anonymously report suspected problems related to the DCE. The anonymous portion of this requirement essentially means the DCE must set up a hotline number or a web form. There are no specific requirements for the hotline or web form. As such, the DCE 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?

The DCE 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 DCE Executive if the Compliance Official is implicated. Alternatively, web form reports are routinely routed to the Compliance Official and the DCE Executive. The Compliance Official would be responsible for follow-up unless he or she is implicated.

No matter how the DCE answers the above questions, the hotline number or web form link should be included in the DCE's compliance training and communicated through other materials as appropriate. Any time the number or link is listed, it should include a reminder of the DCE's non-retaliation policy to reassure individuals contemplating a report.

◊ Resource: Wilems Resource Group offers an online Compliance Reporting Tool to help DCEs satisfy this requirement. The Tool ensures that DCE related individuals can submit a report anytime from anywhere and choose to remain anonymous. Interested parties can contact mshort@wilemsrg.com for more information.

Element 4: Compliance Training

The DCE is also required to provide compliance training for the DCE, its DC Participants and Preferred Providers. Determining who needs to complete the training for "the DCE" can be complicated. This is particularly true when you consider the fact that most DCEs do not have many, if any, actual employees. The operational work is usually completed by employees of a DC Participant or an outside entity. The DCE'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 DCEs ensure that the appropriate individuals complete Privacy Training, Fraud, Waste and Abuse (FWA) Training, and some DCE specific Compliance Training.

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

◊ Resource: Wilems Resource Group offers online DC Compliance Training to help DCEs satisfy this requirement. The online training is comprised of three modules: DCE Overview Training, HIPAA/Privacy Training, and Fraud, Waste, & Abuse Training. Interested parties can contact mshort@wilemsrg.com for more information.

Element 5: Requirement to Report Probable Violations of Law

The DCE's Compliance Plan must include a requirement for the DCE to report probable violations of law to an appropriate law enforcement agency. This does **not** require that the average employee, or DCE related individual, report directly to law enforcement. Many DCEs 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 DCEs

DCEs are required to be compliant with all state and federal privacy laws and regulations. This includes HIPAA and HITECH, and the DCE 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 those issues that are unique to DCEs. The first thing to consider is whether the DCE is structured as a Covered Entity, in which case the DCE will be required by HIPAA to send out an annual Notice of Privacy Practices; or as a Business Associate of each DC Participant. Most DCEs elect to be Business Associates as it limits administrative burden for the DCE and confusion for Beneficiaries. Under this arrangement, the DCE will sign a Business Associate Agreement (BAA) with each DC Participant.

In addition, Article VI of the GPDC Model Participation Agreement references the HIPAA-Covered Data Disclosure Request Form which places additional obligations above those required by HIPAA in order for the DCE to share data. These requirements need to be addressed by the DCE and properly communicated across all DCE-related individuals to ensure compliance. The DCE 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 HIPAA-Covered Data Disclosure Request Form and the additional requirements found therein. Regardless of how you document downstream compliance with these requirements, the DCE 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 DCE is sharing data provided by CMS as part of the DC Model;
- Physical address of the entity;
- The date the DCE began sharing data with the entity;
- The date the DCE stopped sharing data with the entity; and
- Certification by the entity that all data received has been destroyed in accordance with the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet.

Marketing Activities and Materials Compliance

Marketing Material Compliance

GPDC Model Participation Agreement Section 5.04

DCE Marketing Compliance is an operational area that causes concerns for many DCE's early in their participation. The DCE is required to submit a Marketing Plan that details the strategy for outreach. This plan must be approved by CMS. In addition, any materials that are deemed to meet the definition of a Marketing Material, Activity or Event within the GPDC Model Participation Agreement must be submitted to CMS for review and approval. There is a ten (10) day file and use period, meaning that as long as the material is not disapproved the DCE can distribute 10 days after filing.

CMS can disapprove a material at any time, even after the expiration of the file and use period. If a material is disapproved for any reason, the DCE must immediately discontinue use of the material until any issues are corrected and the material is approved by CMS.

The DCE should maintain records for all marketing materials, events and activities.

Under the GPDC Model, Marketing Materials include, but are not limited to, general audience materials or activities conducted by or on behalf of the DCE or its DC Participants or Preferred Providers, when used to educate, notify, or contact Beneficiaries regarding the DCE's participation in the Model. *Note: Provider facing materials are **not** included in this definition.*

1. Materials may not include any misleading information. This includes, but is not limited to, language suggesting Beneficiaries must see providers only within the DCE or are prohibited in any way from seeing providers outside of the DCE or that CMS endorses one DCE over another.

2. Materials and Activities may not discriminate or selectively target Beneficiaries on the basis of race, ethnicity, national origin, religion, gender, sex, age, mental or physical disability, health status, receipt of health care, claims experience, medical history, genetic information, evidence of insurability, geographic location, or income.

3. Similar to the above requirement, DCEs are required to translate Marketing Materials into any non-English language that is the primary language of at least 5 percent of the individuals in the DCE Service Area.

4. DCEs are strictly prohibited from conducting any Marketing Activities or Events outside of the DCE Service Area.

Beneficiary Notification Requirements

Prior to the start of each program year, CMS releases a template Beneficiary Notification letter. CMS indicates variable fields in the letter where the DCE is allowed to insert its own original content such as DCE phone number, website, and overview of care coordination services. Final content must be approved by CMS prior to use by the DCE. CMS sets the deadline for release

of this notice each year. Notices can be sent via any method, as long as the DCE can provide evidence of distribution at the Beneficiary level. If using a portal or e-Mail service, the DCE should consider using a paper mailing to close any gaps for undeliverable messages. If the DCE uses a paper mailing to deliver the Notifications, then a Paper-Based Voluntary Alignment Form may be included as well.

- *Note: If your DCE is leveraging Paper-Based Voluntary Alignment, CMS must approve your Paper-Based Voluntary Alignment Plan and materials prior to the DCE releasing communication to Beneficiaries.*
- *Note: Your DCE can only use a portal system to send this message if the Beneficiary receives a notification (via email or otherwise) that there is a new message in the portal.*
- *Note: Your DCE should consider how to identify and track those Beneficiaries who have "unsubscribed" from any e-mail notifications, either from the practice or the portal itself. The Notifications will need to be sent through an alternative method in these instances.*

Public Disclosure Requirements

CMS views transparency as vital to a Beneficiary-centered approach as well as Beneficiary engagement. As a result, DCEs are required to maintain a publicly-facing website to report DCE specific information as determined by CMS.

The GPDC Model Participant Agreement Section 10.01 requires the DCE report the following on a publicly facing website maintained by the DCE:

1. Organizational information including all of the following:
    a. Name and location of the DCE;
    b. Primary contact information for the DCE;
    c. Identification of all DC Participants and Preferred Providers;
    d. Identification of all joint ventures between or among the DCE and any of its DC Participants and Preferred Providers;
    e. Identification of the DCE's key clinical and administrative leaders and the name of any company by which they are employed;
    f. Identification of members of the DCE's Governing Body and the name of any entity by which they are employed;
    g. Shared Savings and Shared Losses information; and
    h. The DCE's performance on the quality measures.

FRAUD, WASTE AND ABUSE SAFEHARBORS

In November 2020, the Department of Health and Humans Services (HHS) Office of Inspector General (OIG) issued the final rule "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," and the CMS issued the final rule "Modernizing and Clarifying the Physician Self-Referral Regulations." These waivers do not replace the waivers available to Shared Savings Program or NextGen ACOs. As such, many ACOs have not given them the attention they may deserve. In the GPDC Model Participation Agreement, CMS has chosen to rely on these Safe Harbors rather than work with OIG to develop waivers specific to the GPDC Model. One thing has not changed - **none of these waivers apply to similar State laws!** It is important to ensure that Compliance and/or Legal for the DCE evaluate any new programs for compliance with state laws as well.

DCE Financial Arrangements Safe Harbor

DCE Financial Arrangements

GPDC Model Participation Agreement Section 3.04

CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements is available to protect DCE financial arrangements reasonably related to the provision of DCE Activities. As such, while ACOs may be accustomed to developing initiatives under the requirements of the Participation Waiver, that language will not be seen in the GPDC Model. The DCE will still need to document the details of the arrangement, in advance of or contemporaneous with the commencement of activity. While the regulations only require documentation of the financial aspects of the arrangement, we recommend the DCE ensure all of the following elements are documented:

- How the arrangement is reasonably related to the provision of DCE Activities as defined by the GPDC Model PA;
- How the DCE has reasonably determined that the arrangement advances one or more goals of the GPDC Model;
- Confirmation that the arrangement does not induce providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient;
- Confirmation that the DCE has not, and the arrangement does not, offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care

program referrals or other Federal health care program business generated outside of the GPDC Model; and

- Confirmation that the arrangement complies with Section 3.04(A)-(E) and (I) of the GPDC PA, all safe harbor requirements set forth in 42 CFR §1001.952(ii)(1), and any applicable requirements for PCC, APO and TCC Payment Arrangements.

Beneficiary Incentives Safe Harbor

As in the Shared Savings Program and the Next Generation ACO Model, DCEs are generally prohibited from providing gifts or other remuneration to Beneficiaries unless certain requirements are met.

If the remuneration is not being provided under the Part B Cost-Sharing Support or the Chronic Disease Management Reward Beneficiary Engagement Incentives (BEI), then it must meet all of the following requirements from 42 CFR §1001.952(ii)(2):

- The DCE must reasonably determine that the incentive will advance one or more goals of the GPDC Model.
- The incentive must have a direct connection to the patient's health care.
- The incentive must be furnished by the DCE, a DC Participant or Preferred Provider.
- The incentive must meet any additional program requirements imposed by CMS.
- The DCE must maintain, and make available, records sufficient to establish compliance with these conditions.

If the DCE is utilizing the Part B Cost-Sharing Support or the Chronic Disease Management Reward BEI, all requirements of the applicable GPDC Model PA Appendix must be met. These elements will be reviewed when the DCE submits an Implementation Plan to CMS.

Beneficiary Incentives - Additional Program Requirements

While these requirements are not referred to as a Beneficiary Inducement Waiver, the additional program requirements for Beneficiary Incentives will be very familiar to any organization with experience under the Shared Savings Program or Next Generation ACO Model. The GPDC Model PA allows DCEs to provide certain in-kind items or services to Beneficiaries in conjunction with any DCE Activities if the following conditions are satisfied:

- The in-kind items or services are preventive care items or will advance one or more of the following clinical goals for the Beneficiary:
    - Adherence to a treatment regime,

    - Adherence to a drug regime,
    - Adherence to a follow-up care plan, or
    - Management of a chronic disease or condition.
- The in-kind item or service has a reasonable connection to the Beneficiary's health care;
- The in-kind item or service is not a Medicare-covered item or service for the Beneficiary on the date it is furnished;
- The in-kind item or service is not furnished in whole or in part to reward the Beneficiary for completing or agreeing to complete Voluntary Alignment; and
- The in-kind item or services is furnished directly by the DCE, a DC Participant or a Preferred Provider.

It is important to remember, the DCE must meet all of the requirements of the Safe Harbor from 42 CFR §1001.952(ii)(2) as well as the additional requirements from the GPDC Model PA.

Beneficiary Incentives – Documentation

The DCE is required to maintain, and make available, documentation sufficient to prove compliance with all of the above listed requirements. Similar to Next Generation ACOs, DCEs are required to maintain records regarding, at a minimum, the following information related to any incentives provided:

- The nature of the in-kind item or service;
- The identity of each Beneficiary that received the in-kind item or service;
- The identity of the individual or entity that furnished the in-kind item or service; and
- The date the in-kind item or service was furnished to the Beneficiary.

Benefit Enhancements and Beneficiary Engagement Incentives

In addition to the Safe Harbors, DCEs can also utilize any of these Benefit Enhancements and Beneficiary Engagement Incentives (BEIs) as long as the DCE timely elects to participate in the program for the next Performance Year and submits an Implementation Plan to CMS detailing how the DCE will compliantly implement the requirements of the applicable GPDC Model PA Appendix.

Available Benefit Enhancements

- 3-Day SNF Rule Waiver
- Telehealth
- Post-Discharge Home Visits,
- Care Management Home Visits

- Home Health Homebound Waiver
- Concurrent Care for Beneficiaries that Elect Medicare Hospice

Available Beneficiary Engagement Incentives

- Part B Cost-Sharing Support
- Chronic Disease Management Reward

Beneficiary Eligibility

In order to be eligible to receive services under these Benefit Enhancements and BEIs, the Beneficiary must be aligned to the DCE at the time or be an Originally Aligned Beneficiary excluded from alignment to the DCE within the 90 days prior.

The DCE should be aware the 90 day grace period does not apply to the BEIs. For Benefit Enhancements, the grace period does not apply when exclusion occurs for any of the following reasons:

- Transition to Medicare Advantage or other Medicare managed care plan;
- Medicare is no longer the primary payer;
- Loss of Medicare coverage for Part A, when the furnished service would have been reimbursed under Medicare Part A; or
- Loss of Medicare coverage for Part B, when the furnished service would have been reimbursed under Medicare Part B.

DC Participants and Preferred Providers must be able to access the most current information regarding beneficiary alignment, in order to ensure a Benefit Enhancement or BEI is not furnished inappropriately. The DCE must consider how to disseminate roster updates to providers in a timely manner.

DCE Requirements

Use of a Benefit Enhancement or BEI requires sophisticated operational processes and a robust compliance monitoring program to ensure that all elements of the selected program are met. The DCE must be prepared, not only to meet those requirements, but to maintain documentation sufficient to prove compliance. In many cases, the implementation of processes and internal control measures prohibits organizations from implementing otherwise useful programs. Talk to your compliance officer and build internal protocols that make sense, avoid bottlenecks and create documentation throughout the process to ensure the ability to implement these programs efficiently and compliantly.

Terminating a Benefit Enhancement or Beneficiary Engagement Incentive

The DCE may discontinue any Benefit Enhancement or BEI **at the end of the Performance Year** but must notify all DC Participants, Preferred Providers and affected beneficiaries within 30 days prior to the start of the subsequent Performance Year.

The DCE must obtain consent before voluntarily discontinuing any Benefit Enhancement or BEI **during a Performance Year**. The DCE must provide written notice of termination to CMS at least 30 days in advance. If CMS consents to termination, the effective date of the termination will be provided by CMS. In this case, the DCE must notify all DC Participants, Preferred Providers and affected beneficiaries within 30 days after the effective date of the termination.

BENEFICIARY VOLUNTARY ALIGNMENT

Generally, alignment is determined by the CMS claims-based process. However, Beneficiaries may choose to be aligned to the DCE through either Paper-Based or Electronic Voluntary Alignment. GPDC Model Beneficiaries are aligned prospectively, prior to the start of the relevant Performance Year. A DCE may elect Prospective Plus alignment, wherein CMS will update the DCE's Alignment Roster each quarter to account for additions through Voluntary Alignment.

DCEs may communicate orally with Beneficiaries regarding their ability to complete voluntary alignment online at MyMedicare.gov or through the use of a Voluntary Alignment Form but should be careful not to say anything which might be construed to limit freedom of choice. The DCE cannot offer any inducements for completing voluntary alignment and may not complete the process on behalf of the Beneficiary. Your DCE should ensure Beneficiaries are instructed to contact the DCE with questions about how to make changes to the Voluntary Alignment Form.

Paper-Based Voluntary Alignment

If the DCE elects to participate in Paper-Based Voluntary Alignment, the DCE may conduct targeted outreach by providing the Voluntary Alignment Form and cover letter to eligible Beneficiaries. CMS provides a template Voluntary Alignment Form and cover letter and the DCE is not allowed to make changes to these materials. The DCE may also provide the Voluntary Alignment Form at the point of care in the offices of DC Participants, but must notify CMS of the intention to do so. The DCE should also ensure that all Beneficiaries who receive care from a DC Participant are provided a Voluntary Alignment Form upon request. This is true even if the Beneficiary has already completed a form and wishes to make a change.

If conducting Paper-Based Voluntary Alignment activities, the DCE must:

1. Submit a plan to CMS for approval and maintain a list of Beneficiaries included in the outreach, as well as the forms and letters sent to Beneficiaries;

2. Maintain records related to Voluntary Alignment, including all materials returned to the DCE from Beneficiaries; and

3. Submit a Paper-Based Voluntary Alignment list to CMS, as required.

CMS provides specific deadlines for when the DCE is required to submit the Paper-Based Voluntary Alignment list. As such, the DCE should consider their internal processes and capabilities in order to set a reasonable internal timeline for submission to CMS. In an audit, CMS may request executed Voluntary Alignment Forms and/or envelopes received from Beneficiaries to verify that the Paper-Based Voluntary Alignment list is complete and accurate.

Electronic Voluntary Alignment

Under Electronic Voluntary Alignment, a Beneficiary may select to align with the DCE by designating a DC Participant as their primary clinician on MyMedicare.gov. CMS provides information on how to complete Voluntary Alignment online. The DCE may share this information with eligible Beneficiaries but must first submit a document to CMS describing the process the DCE will use for distribution and identification of Beneficiaries. This is intended to help prevent cherry picking. As such, the DCE should be careful to avoid plans which may unintentionally lead to cherry picking.

RED FLAG AREAS FOR DCES

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

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. As a result, a major component of the GPDC Model is the ability of assigned and aligned Beneficiaries to maintain freedom of choice in their provider. DCEs are not allowed to limit a Beneficiary's ability to receive services from providers who are not participating in the DCE. More than that, however, the DCE must be sure not to provide any information which might be construed as suggesting that this might be the case.

QUICK TIP: Beneficiaries should never be referred to as "members" or "patients" of the DCE. They are not a part of the DCE, only the DC Participants and Preferred Providers are participating in the DCE.

Cherry Picking - Keeping the Healthy, Avoiding the Sick

Another early concern revolved around the idea that ACOs were “death-panels” designed to determine which individuals were young and/or healthy enough to receive services. Critics 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 DCE or that discourage high risk/cost Beneficiaries. In response to these concerns, CMS agreed to monitor DCEs to identify trends and patterns suggesting that a DCE has avoided at-risk Beneficiaries.

The DCE should also consider the risks involved when participating in Voluntary Alignment Outreach. When sending Voluntary Alignment outreach, the DCE can target certain Beneficiary populations, but must include the process for identification of these populations as part of the Voluntary Alignment Plan to be approved by CMS. You should ensure that your selected populations cannot create the appearance of cherry-picking. For example, the DCE should not restrict targeted outreach to eligible Beneficiaries who have not been in to see a provider in over 12 months. This is, inherently, a lower cost population. In addition, you create the risk of Voluntarily Aligning Beneficiaries who do not have recent claims history with your DC Participants. CMS may view this as an inappropriate alignment and restrict your DCE’s ability to participate in Voluntary Alignment moving forward.

QUICK TIP: 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 DCE. The DCE 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 DCE answer any questions which might be raised as a result of unintended consequences.

ABOUT WILEMS RESOURCE GROUP, LLC

Wilems Resource Group, LLC is a boutique consulting firm specializing in Compliance and Engagement solutions for the Medicare Shared Savings Program, Next Generation Accountable Care Organization (ACO) Model, and Global and Professional Direct Contracting Model. We measure success on our ability to help our clients understand program requirements, determine the appropriate level of acceptable compliance risk, and create programming that meets all regulatory requirements. We first take the time to understand the client's company culture and business goals. Working alongside the client's team, we build customized compliance and engagement programs for the ACO, DCE, physicians, practice managers, and Beneficiaries. We are #raisingourlegacy.

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