Direct Contracting Model Welcome Packet

July 15, 2020

Welcome to the Direct Contracting Model! CMS looks forward to working with your organization to improve quality of care, enhance outcomes, and lower cost of care for Medicare beneficiaries.

This welcome packet provides you with general information regarding your participation in the Implementation Period of the Direct Contracting Model and important documents for you to review. Please review the documents enclosed carefully. If you have any questions on the contents of this packet, please do not hesitate to contact the Direct Contracting team through the following means:

Phone Inquiries: Direct Contracting Entities can contact the Accountable Care Organization Information Center by calling 1-888-734-6433, Option 1 for ACO and then option 3 for Direct Contracting Model, between the hours of 8:30 a.m. to 7:30 p.m. Eastern Time Monday through Friday.

Electronic Inquiries: Direct Contracting Entities can email DPC@cms.hhs.gov and will receive confirmation that their email was received within 24 hours.

Sincerely,

The Direct Contracting Model Team

Direct Contracting Model Welcome Packet

1. **Welcome Letter**

2. **Content Explanation** (This document)

3. **Direct Contracting Model Timeline**
   - This timeline shows important deadlines for the Direct Contracting Model Implementation Period (IP) participants, including the IP Welcome and 4i Introduction webinars.
   - **Onboarding Webinar Invitation**

4. **CMMI Incidence Response Processes and Template (found in separate attachment)**
   - This document details important information about protecting CMS data and responding to potential violations of Federal security/privacy laws and/or CMS security/privacy policies.

5. **Direct Contracting Model Learning System Introduction**
   - This document provides an introduction to the Direct Contracting Model Learning System and details some of the upcoming activities.

6. **Beneficiary Notification Template (found in separate attachment)**
   - This document provides a beneficiary notification letter template to alert beneficiaries of your participation in the Direct Contracting Model. Additional guidance will be forthcoming, but IP participants will be expected to send their beneficiary notification letters by November 30, 2020 after signing of the participation agreement.

7. **Financial Methodology Resources**
   - This document provides an overview of important financial terms.

8. **Marketing Guidelines**
   - This document highlights the requirements and restrictions regarding marketing to beneficiaries.

9. **Voluntary Alignment Overview**
   - This document provides an overview on the voluntary alignment process.

10. **MyMedicare.gov Fact Sheet (found in separate attachment)**
    - This document provides information on how beneficiaries use MyMedicare.gov to electronically voluntary align.

11. Voluntary Alignment Template Letter (found in separate attachment)

- This document is edited with the Direct Contracting Entity (DCE) information and provided to the beneficiaries to voluntarily align.

12. Data Overview

- This document provides an overview of the data to be received in the Implementation Period.

13. Introduction to 4i

- 4i is a technology platform in which the DCE will manage many aspects of the model, for example: provider list processing, accessing reports, and submitting benefit enhancements.

Model Timeline – Implementation Period (IP)		
Task	**Date**	**Notes**
CMS Onboarding Webinar	July 22nd 2PM, ET	Please see following page for call in information
4i Training Videos will be made available as well as a Live Virtual Demonstration	Week of July 27, 2020	4i is a technology platform in which Direct Contracting Entity (DCE) will manage many aspects of the model, for example: provider list processing, accessing reports, and submitting benefit enhancements.
4i Access and Onboarding	August 3, 2020	Participants will receive access to the 4i system.
DC Participant Provider and Preferred Provider List revisions due in 4i	August 3-August 10, 2020	The DCE will have the opportunity to update and finalize the provider list submitted with the IP application.
Participation Agreement (PA) available for review	September 1, 2020	
Deadline to sign PA	September 27, 2020	
Financial Methodology Papers to be published	September-November, 2020	
Initial DC Participant Provider and Preferred Provider Lists due for Performance Year (PY1)	September 28, 2020	
IP Begins	October 1, 2020	
Data Disclosure Form available in 4i	September 28, 2020	No beneficiary identifiable data may be shared with the DCEs until this is signed.
Beneficiary Alignment Lists sent to DCEs	Early October, 2020	The above Disclosure form must be signed before this data can be released to the DCE.
Final DC Participant Provider and Preferred Provider List due for PY1	October 23, 2020	
Beneficiary Notification Letters deadline	November 30, 2020	The DCE sends these letters to its beneficiaries as notification that they have been aligned to your DCE. All DCEs are required to send these letters once the Participation Agreement is signed.
CMS to produce and send Historical Claim and Claim Line Feeds (CCLFs) to DCEs	Mid to late November	Please note that DCEs should set up their own IT systems to store CCLFs (or any reports) prior to this date. More information on these reports is provided in the Data Sharing Overview
Benefit Enhancement, Implementation Plans, and Payment Selections for PY1 Providers due in 4i	November 23, 2020	

Direct Contracting Model Welcome Packet

Please join CMS for the onboarding webinar scheduled for

July 22nd from 2-3:30 PM Eastern Time.

Access Information

To join the audio portion of the meeting

1. Please call the following number:

   WebEx: 1-877-267-1577

2. Follow the instructions you hear on the phone.

   Your WebEx Meeting Number: 998 016 176

To view this meeting

1. Go to
https://meetings.cms.gov/orion/joinmeeting.do?MTID=d1db83c3520bb19cc9d37de10a7fca62

2. If requested, enter your name and email address.

3. Click "Join".

4. Follow the instructions that appear on your screen.

The Direct Contracting Model Learning System

Welcome to the Direct Contracting Model learning system! We look forward to meeting you and working with you to provide educational programs, collaboration settings, and tools that help you achieve your goals and the goals of the Model. Below is an overview of the Learning and Diffusion Group (LDG) at The Innovation Center, the goals of the Direct Contracting Model learning system, and how the learning system will be supporting your organization:

The overarching LDG goals for all Innovation Centermodel learning systems:

- Identify and disseminate new knowledge and practice
- Leverage data and participant input to guide change / improvement
- Use learning communities and networks to share and spread new knowledge and practice

Within the Direct Contracting Model learning system, we will learn with and from you to:

- Make the model successful (achieve savings, improve quality)
- Help you achieve success within the model (provide high quality care and shared savings)
- Learn what it takes to make the Direct Contracting Model work for CMS beneficiaries, for providers, and for CMS

The Direct Contracting Model learning system will provide opportunities for continuous, collaborative learning and data-driven decision-making through a variety of activities, such as:

- An infrastructure, both virtual and in-person, for encouraging collaboration, sharing, and problem solving
- Learning activities that address the needs of participants
    - Examples include technical assistance, benefit enhancement implementation support, webinars, and affinity groups
- The capability to create and efficiently deploy tools that support learning and improvement, including, but not limited to, needs assessments, data feedback reports, case studies, webinars, and toolkits
- A process for keeping model participants and CMS up-to-date on promising practices in the areas of care delivery, beneficiary/provider/supplier engagement, risk sharing financial management, payment methodologies, multi-payer alignment, and other areas relevant to the model

To inform learning system activities and resources, the learning system team will stay aligned on the key concerns and objectives through a combination of an annual assessment survey, driver diagrams, planning groups, and other informal data collection activities.

Please stay tuned for the next steps on how to become engaged in the Direct Contracting Model learning system starting fall 2020 and we look forward to working with you!

Financial Methodology

For the Professional and Global Options

The financial methodology is the process by which CMS calculates benchmarks, expenditures, and the other elements used to determine shared savings or shared losses for entities participating in Direct Contracting. It also encompasses the prospective payment mechanisms, financial settlement, and risk mitigation options. Definitions are provided below for a selection of key terms and additional detail on the methodology can be found in the Request for Applications (RFA) and other publications on the CMS Direct Contracting website: https://innovation.cms.gov/innovation-models/direct-contracting-model-options. CMS will be releasing a series of papers with further details on each component of the financial methodology in the coming months. As a reminder, there is no financial responsibility in the Implementation Period (IP).

Benchmark

The benchmark is a Per Beneficiary Per Month (PBPM) dollar amount against which a Direct Contracting Entity (DCE) is held accountable for performance year (PY) Medicare Fee For Services (FFS) expenditures for its aligned beneficiaries. It is determined based on a combination of historical and regional expenditures and reflects the total cost of care for Medicare Parts A and B services. The methodology for determining the benchmark varies based on the DCE type and how beneficiaries are aligned to the entity.

Regional Expenditures

The Direct Contracting model incorporates the regional dynamics in Medicare expenditures through the development of an adjusted Medicare Advantage Rate Book appropriate for the model. The regional expenditures will reflect the weighted average county rates based on the distribution of aligned beneficiaries.

Shared Savings / Shared Losses

A DCE can earn a payment from CMS (shared savings) or be required to repay CMS (shared losses) based on its performance in the model. If the expenditures incurred by a DCE's aligned beneficiaries are less than the PY benchmark, the DCE will earn shared savings from CMS; if the expenditures exceed the benchmark, the DCE will be required to repay shared losses.

Risk Adjustment

Risk adjustment is a method for measuring the health risks of a population and modifying payments to reflect the predicted expenditures of that population. A risk score is assigned to each beneficiary based on demographic characteristics, medical diagnoses (Hierarchical Condition Categories (HCCs)), and other risk factors.

Capitation & Advanced Payments

The Direct Contracting model includes prospective payments mechanisms (Total Care Capitation, Primary Care Capitation, and Advanced Payment Options) in which the DCE is paid directly by CMS for a subset of provider services in lieu of some portion of claims payments to providers (which are reduced). These prospective payments will not be made during the Implementation Period – they will begin on or about April 2021 for Performance Year 1 (PY1) and will be distributed on a monthly basis throughout the performance period. Payments will be made to the DCE's designated bank account by the Innovation

Payment Contractor (IPC), a CMS contractor authorized to issue payments to and recover overpayments from CMMI model participants.

More information regarding the financial methodology and payment mechanisms will be available in the PY1 Participation Agreement and a series of papers to be published in the early Fall, which will cover the following topics, among others, in detail:

- Financial Methodology Overview & Benchmarking Methodology
- Advanced Payment Mechanisms & Capitation
- Risk Adjustment Methodology
- Direct Contracting Adjusted Medicare Advantage Rate Book
- Financial Settlement Process
- Risk Mitigation Options

Marketing Guidelines

In order to allow for more robust outreach to beneficiaries regarding the Direct Contracting Entity (DCE) and its participation in the Direct Contracting Model, CMS will permit DCEs to produce marketing materials and engage in marketing activities during the Implementation Period of the Direct Contracting Model, provided such communications and activities comply with all applicable laws, regulations, and guidance[1] and with the requirements of the Direct Contracting Model Participation Agreement. For example, DCEs will be able to provide marketing materials and hold outreach events to the extent permitted by applicable law. The following marketing guidelines can be referenced when developing marketing materials and when conducting marketing events.

Please note that this guidance is subect to change.

KEY TERMS & DESCRIPTIONS

- **"Marketing Materials"** is defined as general audience materials such as brochures, advertisements, outreach events, letters to Beneficiaries, webpages published on a website, mailings, social media, or other materials sent by or on behalf of the DCE or its DC Participant Providers or Preferred Providers, when used to educate, notify, or contact Beneficiaries regarding the DCE's participation in the Model. Marketing Materials do not include communications that do not directly or indirectly reference the Model (for example, information about care coordination generally would not be considered Marketing Materials); materials that cover Beneficiary-specific billing and claims issues; educational information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of "marketing" under the HIPAA Privacy Rule (45 CFR Part 160 & Part 164, subparts A & E).
- **"Marketing Activities"** is defined as the distribution of Marketing Materials and other activities, including Voluntary Alignment Activities (defined below), conducted by or on behalf of the DCE or its DC Participant Providers or Preferred Providers, when used to educate, notify, or contact Beneficiaries regarding the DCE's participation in the Model.
- **"Voluntary Alignment Activities"** is defined as any marketing activities or other activities conducted by or on behalf of the DCE or its DC Participant Providers or Preferred Providers, when used for purposes of educating, notifying, or contacting Beneficiaries regarding Voluntary Alignment.
- **"Marketing Events"** is defined as Marketing Activities that are events designed to educate Beneficiaries about the DCE's participation in the Model. In conducting Marketing Events, the DCE may engage in activities including, but not limited to:
    - Hosting the Marketing Event in a public venue;
    - Answering Beneficiary-initiated questions regarding the DCE's participation in the Model; or

[1] Applicable laws, regulations, and guidance include, but are not limited to: (a) Federal criminal laws; (b) the False Claims Act (31 U.S.C. § 3729 et seq.); (c) the anti-kickback statute (42 U.S.C. § 1320a-7b(b)); (d) the civil monetary penalties law (42 U.S.C. § 1320a-7a); (e) Health Insurance Portability and Accountability Act of 1996 (HIPAA); and (f) the physician self-referral law (42 U.S.C. § 1395nn).

- Distributing the DCE's, a DC Participant Provider's, or a Preferred Provider's business cards and contact information to Beneficiaries.

REPORTING & REVIEW OF MARKETING MATERIALS AND ACTIVITIES

- The DCE must submit to CMS, in a form and manner and by a date specified by CMS, a plan for implementing the Marketing Activities described in the Participation Agreement ("Marketing Plan") via email at DPC@cms.hhs.gov, subject to CMS review and approval.
- The DCE and its DC Participants, Prefered Providers, and any other individuals or entities performing functions or services related to DCE Activities may not use Marketing Materials or engage in Marketing Activities until such Marketing Materials and Marketing Activities are reviewed and approved by CMS. Any material changes to CMS-approved Marketing Materials and Marketing Activities must be submitted to CMS via email at DPC@cms.hhs.gov to be re-approved.
- Marketing Materials do not include:
  - Communications that do not directly or indirectly reference the Model (for example, information about care coordination generally would not be considered Marketing Materials);
  - Materials that cover Beneficiary-specific billing and claims issues;
  - Educational information on specific medical conditions;
  - Referrals for health care items and services; and
  - Any other materials that are excepted from the definition of "marketing" under the HIPAA Privacy Rule (45 CFR Part 160 & Part 164, subparts A & E).
- There is an initial ten day review period for Marketing Materials and Marketing Activities; however, CMS reserves the right to issue a written notice of disapproval of any Marketing Materials and Marketing Activities at any time. CMS may disapprove Marketing Materials and Marketing Activities that are inaccurate or misleading or that do not comply with the requirements of the Participation Agreement, including because they are discriminatory or used in a manner that is discriminatory, state or imply that alignment to a DCE removes or otherwise affects a beneficiary's freedom to choose a provider or supplier, or are likely to result in program integrity concerns.

LANGUAGE/FORMAT GUIDANCE

- Direct Contracting Marketing Materials and Marketing Activities should indicate that the DCE is participating in the Direct Contracting Model and provide a brief description of the Model, including contact information for CMS, where applicable.
- Any press release that materially and substantially references the DCE's participation in the Direct Contracting Model must be prior approved by CMS and should include correct contact information for the DCE. Both a telephone number with the correct hours of operation, and, if applicable, the DCE's website should also be listed.

PROHIBITED ACTIVITIES

DCEs, DC Participant Providers, Preferred Providers, and other individuals and entities performing functions or services related to DCE Activities are prohibited from conducting Marketing Activities before the start of the Implementation Period.

- The following are prohibited as part of any Marketing Events:

  - Health screenings or any other activity that could be perceived as, or used to avoid treating At-Risk Beneficiaries or to target certain Beneficiaries for services for the purpose of trying to affect alignment to the DCE for a future Performance Year.
  - Requiring attendees to provide their contact information as a prerequisite for attending the Marketing Event; any sign-in sheets used for purposes of the Marketing Event must be clearly labeled as optional.
- Beneficiary contact information provided at a Marketing Event (e.g., for a raffle or other drawing) may not be used for any purpose other than the purpose for which it was solicited.
- The DCE is prohibited and must prohibit its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities from using Marketing Materials or conducting Marketing Activities through the use of:
  - Door-to-door solicitation, including leaving information such as a leaflet or flyer at a residence;
  - Using telephonic solicitation, including text messages and leaving voicemail messages; or
  - Approaching Beneficiaries in common areas, such as parking lots, hallways, lobbies, sidewalks. This restricton does not apply to solicitation in common areas of a health care setting.
- The DCE is prohibited and must prohibit its DC Participant Providers, Preferred Providers, and other individuals and entities performing DCE Activities on behalf of the DCE from conducting Marketing Activities—other than the distribution and display of Marketing Materials—in restricted areas of a health care setting. Restricted areas of a health care setting include, but are not limited to:
  - exam rooms, hospital patient rooms, treatment areas (where patients interact with a health care provider and his/her clinical team and receive treatment, including dialysis treatment facilities); and
  - pharmacy counter areas (where patients interact with pharmacy providers and obtain medications).
- DCEs will not be allowed to engage in activities that discriminate against or selectively target beneficiaries (e.g., based on the anticipated costs of a beneficiary's care).

If you have any questions, please email us at DPC@cms.hhs.gov.

Voluntary Alignment

Voluntary Alignment is the process whereby CMS aligns to a Direct Contracting Entity (DCE) those beneficiaries who have designated a Direct Contracting (DC) Participant Provider as their primary clinician or main source of care. A beneficiary who indicates that a DC Participant Provider is his or her primary clinician or main source of care generally will be aligned to the DCE, even if the beneficiary would not otherwise be aligned to the DCE based on claims-based alignment. There are two ways for a beneficiary to be voluntarily aligned to a DCE—Electronic and Paper-based.

Electronic Voluntary Alignment is the process of a beneficiary going into the MyMedicare portal on Medicare.gov and designating a DC Participant Provider as their primary care clinician, main doctor, main provider, and/or the main place they receive care. Electronic Voluntary Alignment is part of normal Medicare operations and can be done by a beneficiary at any time. Instructions on Electronic Voluntary Alignment are included in this Welcome Packet.

For Paper-based Voluntary Alignment, the DCE will provide the beneficiary with a form to sign electing their primary clinician, main doctor, main provider, and/or the main place they receive care. The DCE can collect this information through the provider's electronic portal, if applicable (though for simplicity will still be referred to as a 'paper-based' election, since it is in lieu of the physical paper form).

Participation in Voluntary Alignment through the paper-based process is optional. In order to participate in paper-based Voluntary Alignment starting in the Implementation Period, the DCE must update the Voluntary Alignment marketing plan and outreach strategy submitted with their application. Once the DCE is onboarded to 4i[1], this will be found as an editable field. When the DCE has updated their plan and is ready for CMS to review, they will send an email which will include their updated Voluntary Alignment Template Letter (found in this packet) to the helpdesk requesting review. CMS will review your outreach strategy and changes to the Voluntary Alignment template letter within two weeks of submission. CMS will also share the template for submitting your Voluntary Alignment List.

Once the Participation Agreement is signed and your DCE has received CMS approval for your Voluntary Alignment template letter and outreach strategy, your DCE may begin reaching out to beneficiaries using the Voluntary Alignment Form, CMS-approved Voluntary Alignment template letter, and the attached instructions on the use of MyMedicare.gov. These may be mailed to eligible beneficiaries and given to beneficiaries at the offices of your DC Participant Providers or Preferred Providers.

More information regarding conducting Voluntary Alignment will be available in the Participation Agreement and in upcoming webinars.

[1] 4Innovation (4i) is a user-friendly system that uses modern cloud technology to support Alternative Payment Models (APMs).

Implementation Period (IP) Data Overview

The exchange of timely, appropriate, and useful data continues to be a top priority for CMS. The Innovation Center will provide a number of reports to assist Direct Contracting Entities (DCEs) in their Implementation Period (IP) activities. All data will be made available to the DCE in their 4Innovation (4i) portal. The following reports will be provided to all entities:

IP Beneficiary Count

At the beginning of the IP, all DCEs will receive a report on the count of the beneficiaries aligned to the DCE. Beneficiaries included in this count are beneficiaries identified as having at least one paid claim for a Qualified Evaluation & Management (QEM) service during the two-year alignment period who were then prospectively aligned to a DCE based on the methodology described in in the Direct Contracting IP Participant Agreement (PA). A beneficiary is generally aligned with a DCE if he or she received the plurality of Primary Care Qualified Evaluation & Management (PQEM) services during the alignment period from the DC Participant Providers. The IP Alignment Report will also include beneficiaries who have been voluntarily aligned to a DCE.

IP Participant List

The Innovation Center will provide the list of DCE's DC Participant Providers and Preferred Providers for the IP who have been approved by CMS to participate in the Direct Contracting Model. The list will be made available to DCEs in The Innovation Center 4i portal at the start of the IP. DCEs will have the ability to view and download the complete list of DC Participant Providers and Preferred Providers that the DCE submitted for the IP, add providers during the specified window, and drop providers from the list.

During the IP, DCEs may request the minimum necessary data for their provisionally aligned beneficiaries to develop and implement care coordination and quality improvement activities. The DCE must attest to its ability to meet the HIPAA requirements for receiving such data. Data that the DCE may request includes:

Claim and Claim Line Feeds (CCLFs)

IP participants of the Direct Contracting Model should expect to receive a one-time set of historical Claim and Claim Line Feeds (CCLFs) for Medicare claims paid for services provided to their beneficiary alignment population. The CCLFs will comprise of 12 zipped files that collectively capture Medicare Part A, Part B, and Prescription Drug claims that had been paid during the 12-month period prior to the start of the IP. In compliance with the Direct Contracting Model's data sharing policy, claims information for beneficiaries who have opted out of medical data sharing or who have received alcohol or substance abuse treatment will not be provided to DCEs. DCEs will have the option to download the historical CCLFs from the Innovation Center 4i portal. Please note that the CCLFs are provided to help Model participants understand cost, utilization, and enrollment, however, these files are not used in PY financial reconciliation and shared savings calculations.

IP Alignment Report

CMS will make available a list of prospectively-aligned beneficiaries for each DCE. The beneficiaries included in the IP Alignment Report are aligned using the methodology described in the *IP Beneficiary Count* report. The beneficiary list will be updated monthly during the IP to capture exclusions.

IP Risk Adjustment Report

The Risk Adjustment Report will provide DCEs bene-level detail on the risk scores for their aligned beneficiaries. More information on the report will provided in the fall.

Introduction to 4i

4Innovation (4i) is a user-friendly system that uses modern cloud technology to support Alternative Payment Models (APMs). The 4i system provides a secured mechanism to verify, validate, and protect users' identifiable information. This allows users to securely login and access sensitive data using a common login ID and password shared across other CMS hosted applications, relieving users of managing multiple user IDs and passwords. All Implementation Period (IP) Direct Contracting Entities (DCEs) will be invited to 4i the first week of August.

4i allows participating DCEs perform the following functions:

- **Manage Users Accessing Entity Details:** Invite users in your organization to manage your Entity's information without CMS Help Desk support.
- **Manage Legal Agreements**: Attest and sign legal agreements between the Model and your organization.
- **Manage Participant List:** Add DC Participant Providers and Preferred Providers participating in the Entities, provide real-time feedback on the provider's Medicare enrollment, and manage the start and end dates of all providers in the organization.
- **Submit Change Request:** Request important changes such as change in Tax Identification Number (TIN) in participating Entities for CMS review and approval, and view the status of the request in real time.
- **Notification:** Get notification on pending actions or completed actions for your Entity.
- **Extract Entity Information:** View and download Entity's report in Excel and csv format.
- **Secure File Delivery**: Provide access to download files that contain PHI/PII details such as Claims and Claim Line Feed (CCLF), beneficiary details, etc.

The week of July 27th, training videos that cover all the functionality and features described above will be provided to the Direct Contracting Entity (DCE). Additionally, a live virtual webinar will occur on July 29th, and Help Desk support will be available to facilitate quick and easy adoption of the 4i system.