

Prospective Contract Components

For Contracts Between a Medicaid Managed Care Organization and a CDC-Recognized Organization

This document is intended to be educational in nature, providing elements to consider when contracting between a Medicaid payer (Payer) and a CDC-recognized organization (Organization). This document does not constitute legal advice and does not substitute for legal advice when crafting an agreement. Entities should consult with an attorney or contract specialist when establishing such an agreement.

The following are examples of contract components that could be included in a contract between a Medicaid payer and a CDC-recognized organization. Each contract component is meant to be illustrative and not to be copied verbatim. The components are listed in sections to help with navigation of this document but are not suggested to be included in any specific order or category.

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Section I. Certification and Conditions of Participation

Organization affirms that it currently holds recognition from the Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) to deliver the National Diabetes Prevention Program (National DPP) lifestyle change program. [The State Medicaid Agency may determine which levels of recognition are required for the Organization to deliver services (e.g., pending, preliminary, or full recognition.)] The Organization will maintain the required recognition status for the duration of the contract and must notify the organization within [X] business days of a change in CDC recognition status.

Organization also affirms that it is a Medicaid-enrolled provider for the National DPP lifestyle change program and has a type 2 National Provider Identifier (NPI). Organization affirms to not have Medicaid exclusions and to remain in good standing in accordance with the requirements of the State. Organization shall comply with Payer's policies and procedures.

Organization and Payer shall adhere to all Federal, State, and local laws, rules, regulations, licensing, procedures, and professional ethics, including if/when those rules change during the course of the contract.

Section II. Program Description

The CDC-recognized National DPP lifestyle change program is a one-year, evidence-based program for individuals with prediabetes and/or at high risk for type 2 diabetes. Through involvement in this program, eligible participants can delay or prevent progression to type 2 diabetes through five (5) to seven (7) percent weight loss and achievement of 150 minutes of exercise each week.

Section III. Definitions

- The CDC/ADA Prediabetes Risk Test. A brief seven-question survey that allows individuals to gauge their risk of having prediabetes. The test can be accessed at: https://www.cdc.gov/prediabetes/takethetest/
- CDC-recognized organization. An organization that offers the National DPP lifestyle change program and has received pending, preliminary, or full recognition from the Diabetes Prevention Recognition Program.
- Diabetes Prevention Recognition Program (DPRP). A CDC-established program to ensure high quality implementation of the National DPP lifestyle change program. It sets standards by which organizations obtain CDC recognition.
- National DPP lifestyle change program. A CDC-recognized, evidence-based program designed to delay or prevent a participant's progression to type 2 diabetes.
- Core sessions. Weekly sessions in which individuals participate during the first six (6) months of the program (sixteen (16) sessions total). The sessions are focused on teaching participants healthy lifestyle choices and assisting them in losing weight.

Core maintenance sessions. Monthly sessions in which individuals participate during the second six (6) months of the program (six (6) sessions total). These sessions are focused on maintaining healthy lifestyle choices and weight loss.

Section IV. Eligibility and Frequency Limits

The Payer shall provide the Organization with a means to access the real-time member enrollment status with the Payer to verify managed care organization (MCO) enrollment on the dates of service.

Eligibility determination for the program shall ultimately be the responsibility of the Organization. Payment for services delivered by the Organization to participants who meet Medicaid and National DPP lifestyle change program eligibility criteria on the dates of service shall not be retroactively denied or recovered. Eligibility criteria, as outlined by CDC, is as follows:

Participants:

- Must be at least 18 years old, and
- Must be overweight (body mass index ≥ 25 ; ≥ 23 if Asian), and
- Have had no previous diagnosis of type 1 or type 2 diabetes, and
- Have a blood test result in the prediabetes range within the past year:
 - o Hemoglobin A1C: 5.7%–6.4%, or
 - o Fasting plasma glucose: 100–125 mg/dL, or
 - Two-hour plasma glucose (after a 75 gm glucose load): 140–199 mg/dL, or
- Be previously diagnosed with gestational diabetes, or
- Score 5 or higher on the CDC/ADA Prediabetes Risk Test [The inclusion of the CDC/ADA Prediabetes Risk Test as a criterion for enrollment may depend on the specifics of your State's benefit. If applicable, please consult your State Medicaid agency for more information.]

Physician referral [shall/shall not] be required for program eligibility. [A physician referral is not required by CDC. These benefit parameters may be determined at the State level. If applicable, please consult your State Medicaid agency for specifics of your State's benefit.]

Organizations must show that a minimum of [X%] of completers in the evaluation cohort are eligible for the National DPP lifestyle change program based on either a blood test indicating prediabetes or a history of gestational diabetes. The remainder must be eligible based on the CDC/ADA Prediabetes Risk Test. [CDC requires 35% of completers in the evaluation cohort to be eligible based on a blood test indicating prediabetes or a history of gestational diabetes. Payers or the State Medicaid agency may require higher or lower participant level eligibility requirements for blood testing for reimbursement purposes.]

The program may be covered up to [X] times per beneficiary per lifetime.

The contract should include details on what happens if a National DPP lifestyle change program participant loses eligibility for the program. Your State or Payer may have specifics on this event. Please consult your State Medicaid agency or Payer for more information.]

Section V. Scope of Services

Organization shall furnish items and services to persons with prediabetes and/or at high risk for type 2 diabetes under a National DPP lifestyle change program that has [pending, preliminary, or full

recognition. The State Medicaid Agency may determine which level of recognition are required for the Organization to deliver services]. Such services include, but are not limited to:

- Sixteen (16) weekly sessions during the first six (6) months (core sessions)
- Six (6) monthly sessions during the second six (6) months (core maintenance sessions)
- A lifestyle coach, meeting CDC DPRP standards, to run each session
- Facility to host the sessions (or acceptable virtual platform in the case of an online or distance learning delivery format)
- National DPP lifestyle change program curriculum, as approved by CDC
- Other items or services as required by the DPRP
- Other additional items as requested in this section by the Payer [Insert here. Examples of additional items could include the following:]
 - o Contact with participants via a portal or text on a weekly basis
 - Offering of one-on-one meetings with each participant three (3) times during the program year
 - Access to an online support group [e.g., Facebook group, etc.]

Section VI. Incentives for Participants

The Organization may issue incentives to participants to encourage retention, and the Payer [shall/shall not] provide the funding to the organization for such incentives. The Organization may issue an incentive after beneficiaries reach certain enrollment and performance milestones according to the schedule below:

- Incentive provided for beneficiaries attending classes at weeks [XX, XX, and XX]
- Incentive provided for beneficiaries achieving [X%] weight loss

[Your State Medicaid agency may have specific rules for the monetary value of incentives provided and the total value of incentives an individual member may receive over a specified period of time. If applicable, please consult your State Medicaid agency for specific parameters on incentives.]

Addendum A provides examples of possible incentives provided to beneficiaries participating in the National DPP lifestyle change program.

Program materials:

The Organization may issue program materials for the participants and the Payer [shall/shall not] provide the funding for the materials. Program materials could include:

- Scale/Wireless Scale
- Gym Membership

Addendum A provides additional examples of possible program materials provided to beneficiaries participating in the National DPP lifestyle change program.

Section VII Incentives for Organization

Payer may issue incentives to the Organization to reward an organization's success at helping participants achieve retention and/or weight loss goals, such as by using an attendance milestone reimbursement

model (the Organization receives a fixed amount after specified attendance milestones have been met) and/or a performance-based reimbursement model (the Organization receives a pre-determined amount if specified outcomes are met). Incentives to the Organization from the Payer for participant retention or weight loss goal achievement can be negotiated. [Specific measurements and/or milestones can be included here].

Section VIII. Participant Identification

Payer shall work with Organization to identify potentially eligible beneficiaries for the program. The Payer shall also include informational materials about the program in its provider onboarding and through provider communication and outreach with participating primary care providers including Federally Qualified Health Centers (FQHCs), or Patient-Centered Medical Homes (PCMH), if applicable, to facilitate identification and referrals of potentially eligible beneficiaries to the program.

Payer shall identify potentially eligible beneficiaries through actions including but not limited to:

- Predictive modeling/analytic reporting from the Payer's claims database
- Referrals by Case/Care Managers who work with beneficiaries screened or assessed for the risk of developing type 2 diabetes
- Referrals by primary care providers or other providers of primary care services who identify National DPP lifestyle change program candidates
- Enrollee self-identification using the CDC/ADA Prediabetes Risk Test [The inclusion of the CDC/ADA Prediabetes Risk Test as a criterion for enrollment may depend on the specifics of your State's benefit. If applicable, please consult your State Medicaid agency for more information.]

Section IX. Promotion, Marketing, and Enrollment

All promotion and marketing campaigns must be conducted in accordance with Federal and State regulations. The Payer shall ensure the Organization is made aware of the Federal and State regulations for promoting and marketing services to Medicaid beneficiaries and the Organization shall comply with those Federal and State regulations.

Payer shall promote the availability of the program to eligible beneficiaries through actions such as, but not limited to, promoting the National DPP lifestyle change program in its member newsletter, member portal, targeted educational literature disseminations, emails, text messaging, provider portal, provider newsletter, at provider orientations and trainings, in collaboration with the Organization at community health fairs, etc.

[This section is applicable only if all parties agree to have the Organization help promote the program.]

Organization [shall be responsible for/shall assist the Payer in] administering campaigns for enrolling eligible beneficiaries into the National DPP lifestyle change program through phone, email, or any other communication channels to which Payer and Organization agree, using beneficiary contact information provided by Payer. Organization shall share marketing materials and existing materials as available and desired by the Payer.

The Payer agrees to give a list of physicians or provider offices/systems that are popular with their members for the Organization to work with to provide materials to encourage physicians to refer their patients to the program.

The Payer shall provide the Organization with a list of potentially eligible National DPP lifestyle change program beneficiaries on a set schedule as identified by their analytic reports, Case/ Care Managers, etc.

- Organization shall partner with the Payer to, at a minimum:
 - o Promote the National DPP lifestyle change program to eligible beneficiaries.
 - Enroll [XX] of the Payer's beneficiaries into the program.
 - o Provide reports on promotional activities at least biannually.
 - o Partner with health care providers to promote the program and refer patients.

Section X. Delivery

Organization may deliver the National DPP lifestyle change program through an [in-person, online, distance learning, and/or combination format. The State Medicaid Agency may determine which modality is permissible for the Organization to use to furnish services]. In-person sessions may be delivered at health or community centers or other appropriate facilities.

[If the Organization delivers the National DPP lifestyle change program through an online, distance learning and/or combination format, the contract may need to include additional details regarding *limitations, liability, and a cyber insurance policy.*]

Section XI. Coding, Billing, and Invoicing

[This section is applicable if the Organization submits claims directly to the payer or to the applicable third-party organization that handles billing and/or network management.]

Organization shall submit claims to the Payer (or the applicable third-party organization) [bi-weekly, monthly, or quarterly]. Organization shall use [HCPCS or CPT] codes to submit claims. [HCPCS and CPT codes for the National DPP lifestyle change program may vary by state. If applicable, please consult your State's Medicaid agency for specifics of your State's benefit.] Below are examples of two National DPP-specific CPT Category III codes:

- 0403T Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day. Used for programs provided in person and is billable once per day.
- 0488T Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting. Used for programs provided online or via electronic technology but may still contain some inperson components and is billable once per 30 days.

[The following is example language regarding claims submission through electronic or paper forms.] Organization shall submit claims to the Payer via electronic submission or paper form. To submit claims electronically, the Organization shall submit the 837-P file to the clearinghouse used by the Payer. To submit claims using the paper format, the Organization shall submit the CMS-1500 form to the clearinghouse used by the Payer. Both the 837-P and CMS-1500 forms can be found on the CMS website.

The Organization shall submit "clean claims"—defined as claims forms with no missing data fields or inaccurate information—to the clearinghouse used by the Payer to avoid rejected claims.

[This section is applicable if the Payer contracts with the Organization to establish an invoicing method for billing.]

Organization shall invoice the Payer (or the applicable third-party organization) [bi-weekly, monthly, or quarterly]. The accuracy of the invoices will be ensured prior to remitting the invoice for payment by [insert processes in place to vet invoices].

Section XII. Payment Schedule

Organization shall be reimbursed by Payer for all National DPP lifestyle change program services provided under this agreement as set forth in schedule [XX]. [Fee schedules may vary across states].

Organization shall be reimbursed by the Payer in accordance with State regulations. [State regulations specify standards for a clean claim, timely filing, timely claims processing, and timely claims payment.]

Section XIII. Reporting and Evaluation

Organization shall provide [monthly, bi-monthly, quarterly] participant status reports to Payer, which shall contain aggregate data on beneficiaries related to [enrollment, attendance, outcomes (e.g., weightloss progress, weekly hours of physical activity, and behavior changes), participant satisfaction, efficiency of budget and timelines, and/or participant learning outcomes.] The Payer will congregate aggregated data on [impact on medical claims (e.g., lower hospital admittance)].

The Organization shall release to Payer, upon request, any additional information necessary for the Payer to perform any of its contractual and regulatory obligations, including, but not limited to, its records, reporting, and quality assurance duties. The Organization's facilities and records shall be open to inspection by the Payer and Medicaid agency, and the Organization is subject to all audits and inspections to the same extent that audits and inspections may be required of the Payer under law or under its contract. Copies of Organization's medical records pertaining to the Payer's participants, if any, shall be furnished to the Payer upon request for transfer to a subsequent provider in the event of a termination of this agreement.

To be considered "successful implementation or execution" of the program, the Payer will: [Insert any *evaluation markers. The following are examples:*]

- Market to at least [XX%] of their members
- Provide a list of at least thirty (30) eligible participants within twelve (12) months of the contract [can include minimum number of participants]

To be considered "successful implementation or execution" of the program, the Organization will: [Insert any evaluation markers. The following are examples:]

- Meet at least a 5% average weight loss across all employee participants that attend at least seventeen (17) sessions (total)
- Keep an attendance average of 70% across all employee participants that attend at least four (4) sessions

Section XIV. Health Insurance Portability and Accountability Act (HIPAA)

All parties must protect the confidentiality of patient protected health information (PHI) and shall use and disclose patient data in accordance with HIPAA and other applicable privacy laws and regulations. All parties must adhere to Federal and State data privacy and confidentiality requirements for the documentation, storage, and transportation of PHI. [Because National DPP lifestyle change program participant data is HIPAA protected, it is considered part of the medical record. State Medicaid agencies have requirements on how long to maintain medical records and how to destroy medical records. Please consult your State's policies on medical record maintenance and destruction.] The [Payer/Organization] shall be the owner of the medical record and shall be responsible for maintaining the medical record for [XXI] period of time in accordance with State rules.

[Payer may also request a Business Associate Agreement or a Data Use Agreement with the Organization. The Business Associate Agreement or Data Use Agreement should specify who is responsible in the event of a data breach. For virtual data collection (e.g., blue tooth scale, recording data in an app, or any other online data collection), Payer and Organization should have a Data Security Agreement. If subdelegates are agreed upon by both parties, then those subdelegates will also have to abide by the same PHI data privacy and confidentiality conditions as the Payer and Organization.]

Section XV. Fraud and Abuse

The Organization must report any possible instances of Medicaid fraud to the Payer immediately upon receipt of information. The Organization must monitor its employees and owners on a [monthly or otherwise agreed upon basis] for suspension or disqualification from government funded health care programs.

Section XVI. Termination

Either party may terminate this agreement at any time for any reason ("without cause"), upon ninety (90) days' prior written notice to the other party. Either party may terminate this agreement "with cause" [immediately or within 30 days] in the event of serious quality of care concerns or fraudulent activity. Either party shall have a [30 day or other agreed upon time period] "cure period" to correct a problem that has caused one party to seek to immediately terminate the contract with cause.

Additional Components That Are Likely to Be Included in a Contract

Contracts between a Payer and an Organization are also likely to have language describing:

- Indemnification
- Dispute resolution, including arbitration (including who pays the cost)
 - Jurisdiction used for arbitration and mediation
- Confidentiality
 - Business confidentiality of the agreement (i.e., parties cannot share the terms of the agreement)
- Data sharing
- Assignment (i.e., parties cannot pass the contract on to another business)
- Exclusivity or non-exclusivity (i.e., Organization is or is not the Payer's only National DPP lifestyle change program provider)
- Risk assessment and security questionnaire
- Force majeure clauses
- Payer credentialing requirements

Addendum A

Addendum A outlines possible incentives and/or program materials the Payer may fund, and the Organization could issue, to beneficiary participants to encourage retention in the National DPP lifestyle change program. Possible incentives include:

- Products related to the National DPP lifestyle change program including:
 - o Pedometer
 - Digital food scale
 - o Fitness tracking gear (e.g., Fitbit)
 - Healthy eating cookbook
 - Measuring cups
 - o Portion control plates and/or bowl
 - Yoga mat
 - Gym membership
 - Online subscriptions to:
 - Workout videos
 - Food tracking apps
 - o Digital/Wireless weight scale
 - Water bottles
 - o Curriculum pages printed/bound
- Gift cards to promote a healthy lifestyle such as:
 - o Gift card to a grocery store
 - o Gift card to athletic wear store
 - O Purchase entrance fee to local walks/runs/ athletic events