



The Diabetes Prevention and Management Initiative Workgroup is tasked with working collaboratively with the Medi-Cal Program and the California Diabetes Program in the development and design of a five-year diabetes initiative for Medi-Cal fee-for-service beneficiaries which will decrease the number of individuals who develop Type II diabetes and reduce the severity of the disease in those who have been diagnosed.

**To effectively meet this task, the goal of the workgroup is to provide expert advice and consultation to department program staff on the following design elements of the diabetes initiative:**

- Screening criteria for pre-diabetes and diabetes
  - Targeted population for the initiative
  - Proven interventions to improve the health status of individuals diagnosed with pre-diabetes and diabetes which will reduce or prevent complications including the use of incentives for beneficiaries and providers
  - Methods to estimate short and long-term cost savings and/or cost avoidance based on risk stratification of screened individuals
  - Evaluation criteria
- I. There are many different models of care that can be used as a foundation in the development of a delivery system in managing chronic diseases. The Chronic Care Model (CCM) identifies essential elements of a health care system that encourages high-quality chronic disease care. These elements are the community, the health system, self-management support, delivery system design, decision support and clinical information systems. The use of evidence-based change concepts under each element in the model works synergistically to foster productive interactions between informed patients who take an active part in their care and providers with resources and expertise. The foundational elements of the CCM model will be used as the basis on which the components of this initiative are developed.

**FRAMEWORK FOR CALIFORNIA'S DIABETES INITIATIVE**

**ADA SCREENING GUIDELINES:**

The following is the most current American Diabetes Association (ADA) criteria for testing diabetes in adult individuals<sup>1</sup>:

1. Testing for diabetes will be considered for those who are:
  - Age ≥45 Years **and**
  - Overweight (Body Mass Index [BMI] ≥25 kg/m<sup>2</sup>)
2. Testing for diabetes should be considered for those at a younger age or carried out more frequently in individuals with a BMI ≥ 25 kg/m<sup>2</sup> **AND** have additional risk factors:
  - Habitually physically inactive
  - First degree relative with diabetes
  - Members of a high risk ethnic population: e.g. African American, Latino, Native American, Asian American, Pacific Islander

- Previously identified impaired fasting glucose or glucose tolerance test
- History of gestational diabetes or delivery of baby weighing >9lbs
- Hypertension ≥ 140/90 mm Hg
- High Density Lipoprotein cholesterol (<35 mg/dl or triglyceride level >250 mg/dl<sup>3</sup>)
- Have other clinical conditions associated with insulin resistance e.g. polycystic ovary syndrome or acanthosis nigricans<sup>4</sup>
- On previous testing, had impaired glucose tolerance test (IGT) or impaired fasting glucose (IFG)
- History of vascular disease

<sup>1</sup> American Diabetes Association, Standards of Medical Care Diabetes-2007: Diabetes Care;30(1), 2007

<sup>2</sup> BMI cutoffs for overweight may be adjusted as follows: Non **AAP**I ≥ 25, Asian American ≥ 23, Pacific Islander ≥26 kg/m<sup>2</sup>)

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**Target Population**

- Must be a full-scope, Medi-Cal-Only<sup>5</sup> fee-for-service beneficiary, between the ages of 18-64, who meet the ADA screening criteria for testing for diabetes in adults; and
- Diagnosed with pre-diabetes, Type 1 diabetes<sup>6</sup> or Type 2 diabetes

**Screening Services**

The following laboratory tests will be used for screening eligible adult individuals for pre-diabetes or diabetes:

- Fasting plasma glucose (FPG)
- Oral glucose tolerance test (OGTT)
- Hemoglobin A1C (A1C)

To be eligible for services ***the appropriate lab tests must have been completed within the last 3 months or less.***

**Interventions**

**Risk Category**

- Individuals who are diagnosed with pre-diabetes or diabetes will be placed in the appropriate risk category and will be eligible for a core set of services as outlined in this matrix.
- Core services will include an initial assessment; case management; enhanced nutrition, health education and psychosocial services; and periodic reassessments.

**PRE-DIABETES**

**Risk Category: Pre-diabetes**

- **A1C 6.1-6.9% - for discussion**
- IFG (FPG 100-125 mg/dl)
- IGT (2-hr plasma glucose 140-199 mg/dl)

- Up to 8 hours of group classes: 2 hours can be administered by a registered dietitian (RD) and 6 hours by a health educator or certified comprehensive diabetes health care worker. Classes will address lifestyle modifications such as nutrition, physical activity, and weight loss.
- In subsequent years, beneficiaries will be eligible for an additional **2 or 4 or more? hours of group classes per 12-month consecutive period – for discussion.**

<sup>3</sup> ADA 2007 Clinical Practice Recommendations

<sup>4</sup> Acanthosis nigricans is a disorder that may begin at any age, causing velvety, light-brown-to-black, markings usually on the neck, under the arms or in the groin; most often associated with obesity; can also be congenital or linked to an endocrine disorder.

<sup>5</sup> A full-scope, Medi-Cal Only eligible is an individual who has Medi-Cal as the only source of health insurance and is entitled to the full range of medically necessary services under the Medi-Cal program without any limitations.

<sup>6</sup> There is no specific pre-screening for Type 1 diabetes

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DIABETES

<p><b>Risk Category 1: Low</b></p> <ul style="list-style-type: none"> <li>○ Type 2 diabetes, A1C &lt; 8% <b>and</b></li> <li>○ LDL Cholesterol &lt; 100 mg/dl <b>and</b></li> <li>○ Blood Pressure &lt; 130/80 mmHg</li> </ul>	<ul style="list-style-type: none"> <li>○ Up to 10 hours of a diabetes self-management class within a continuous 12-month period</li> <li>○ One of the training hours may be given on a 1:1 basis and the rest of the classes in a group format</li> <li>○ For individuals who are blind, deaf or if group classes are not available within a two-month period, individual classes may be provided</li> <li>○ In the subsequent years, beneficiaries will be eligible for a 2-hour self management class, during a 12-month consecutive period</li> <li>○ The diabetes self-management class will include the following content areas as per the National Standards for Diabetes Self Management Education and shall include a written curriculum, with criteria for successful learning outcomes. Assessed needs of the individual will determine which of the content areas below are delivered:             <ul style="list-style-type: none"> <li>▪ Describing the diabetes disease process and treatment options</li> <li>▪ Incorporating appropriate nutritional management</li> <li>▪ Incorporating physical activity into lifestyle</li> <li>▪ Utilizing medications (if applicable) for therapeutic effectiveness</li> <li>▪ Monitoring blood glucose, and using the results to improve control</li> <li>▪ Preventing, detecting, and treating acute complications</li> <li>▪ Preventive (through risk reduction behavior), detecting and treating chronic complications</li> <li>▪ Goal setting to promote health, and problem solving for daily living</li> <li>▪ Integrating psychosocial adjustment to daily life</li> <li>▪ Promoting preconception care, management during pregnancy, and gestational diabetes management (if applicable)</li> </ul> </li> </ul>
<p><b>Risk Category 2: Moderate</b></p> <ul style="list-style-type: none"> <li>○ Type 2 diabetes <b>and any of the following:</b></li> <li>○ A1C ≥ 8%</li> <li>○ LDL Cholesterol ≥ 100 mg/dl</li> <li>○ Systolic blood pressure ≥ 130 mmHg or diastolic pressure ≥ 80 mm Hg.</li> </ul>	<ul style="list-style-type: none"> <li>○ Diabetes self-management classes as defined above (if not already taken)</li> <li>○ Enhanced services for Risk Category 2: Moderate:             <ul style="list-style-type: none"> <li>▪ 4 Certified Diabetes Educator visits (NP, PA, RN, <u>CDE?</u> or RD<sup>7</sup>) – <b><i>what is the frequency?</i></b></li> <li>▪ 4 enhanced nutrition services per <b><i>each?</i></b> 12-month consecutive periods with primary provider/practitioners</li> <li>▪ Enhanced psychosocial visits (for clinical depression or adjustment disorder related to the diagnosis of a chronic medical condition) - 4 maximum within a 12-month consecutive period with the appropriate primary provider/practitioners<sup>8</sup>. <b><i>Individuals presenting with major depression, bipolar disorder, or schizophrenia must be referred to County Mental Health since these conditions would be beyond the scope of these visits.</i></b></li> </ul> </li> </ul>
<p><b>Risk Category 3: High</b></p> <ul style="list-style-type: none"> <li>○ Type 1 diabetes</li> <li>○ Type 2 diabetes <b>with one or more</b> of the following:</li> </ul>	<p>Eligible for all Risk Category 2: Moderate interventions plus the following:</p> <ul style="list-style-type: none"> <li>○ Comprehensive diabetes management protocol (<b><i>to be developed</i></b>).</li> <li>○ Up to 10 face-to-face Certified Diabetes Educator (NP,PA, RN, CDE, or RD) visits per 12-month period</li> <li>○ Up to 10 Certified Diabetes Educator phone consultations per each 12-month consecutive period</li> </ul>

<sup>7</sup> NP=Nurse Practitioner; PA=Physician Assistant; RN=Registered Nurse; CDE, RN, CDE or RD

<sup>8</sup> If the individuals needs more than 4 visits within a 12 month consecutive period, they should be referred to County Mental Health services for more intensive treatment

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- Taking insulin
- Renal Disease<sup>9</sup>
- Congestive Heart Failure
- Hospitalization for preventable diabetes conditions such as hyperglycemia, hypoglycemia, and certain infections e.g. foot ulcers, cellulitis and abscesses. ? ER visits for discussion – for discussion.

- In subsequent years, additional visits may be authorized per 12-month consecutive periods

*Service Delivery*

**Primary Provider**

- Must have an active, unrestricted Medi-Cal Provider number and be in one of the following categories:
- Physician - general practice, family practice, internal medicine, obstetrics/gynecology, pediatrics
    - Relevant specialists will be able to see the clients as referrals (e.g. endocrinology, nephrology, cardiology, ophthalmology, podiatry, dental; and appropriate mental health services for clinical depression or adjustment disorder).
  - Group medical practice, if at least one member is one of the physician types noted above.
  - Preferred Provider Organization
  - Clinic (hospital, community, or county)
  - Comprehensive diabetes management protocols (**to be developed**) and technical assistance will be developed by the California Diabetes Program and the Medi-Cal Program and provided to eligible participating Medi-Cal providers.

**Practitioner**

- The primary provider may employ or contract with any of the following practitioners listed below to render comprehensive diabetes services appropriate to their credentials/skill level and the risk category of the beneficiary:
- |                                |   |
|--------------------------------|---|
| ○ Nurse Practitioners          | ○ Licensed Clinical Social Workers  |
| ○ Physician Assistants         | ○ Psychologists   |
| ○ Registered Nurses            | ○ Marriage, Family, and Child Counselors  |
| ○ Certified Diabetes Educators | ○ Health Educators ( <b>CDE certification? For discussion</b> )   |
| ○ Licensed Vocational Nurses   | ○ Comprehensive Diabetes Health Care Worker – individual must be diabetes certified and can be trained medical assistants and/or promotores |
| ○ Registered Dietitians        |   |
| ○ Pharmacists                  |   |

<sup>9</sup> Renal disease defined as serum creatinine ≥ 2.0 mg/dl.

**FRAMEWORK FOR CALIFORNIA'S DIABETES INITIATIVE**

<p><b>Designated Care Coordinator</b></p>	<ul style="list-style-type: none"> <li>○ Responsibility of the primary provider.</li> <li>○ May delegate to an appropriate practitioner (see above), as specified in the comprehensive diabetes management protocols (<b>to be developed</b>) to oversee and organize the provision of care as per the Individualized Care Plan and as determined by the Risk Category of the individual.</li> </ul>
<p><b>Service Delivery Location</b></p>	<ul style="list-style-type: none"> <li>○ The diabetes initiative will be coordinated by the California Department of Public Health (CDPH), California Diabetes Program in collaboration with the Department of Health Care Services (DHCS), Medi-Cal Program and local health agencies.</li> <li>○ As part of the \$150 million allocated for this initiative under the Governor's health care reform proposal, it is proposed that funding be allocated for the development of regional networks to support the management of pre-diabetes and diabetes.</li> <li>○ The regional network will include diabetes care centers which will be centers of excellence for the program. CDPH, DHCS, and local health agencies will work collaboratively with existing California diabetes care centers of excellence, to determine the number of regional networks and to provide technical assistance to the identified regional networks.</li> <li>○ The California Diabetes Program will serve as the coordinating office for the regional networks.</li> <li>○ Services under this initiative will be delivered in the following <b>accredited? settings</b>:             <ul style="list-style-type: none"> <li>▪ Diabetes Care Centers</li> <li>▪ Private Medical Practice/Office</li> <li>▪ Group Medical Practice/Office</li> <li>▪ Clinics (hospital, community, or county)</li> <li>▪ Hospital/Medical Centers</li> </ul> </li> </ul>

**Program Benefit Structure/Program Incentives**

<p><b>Benefits</b></p>	<p>All eligible participants must meet the targeted population criteria. The Medi-Cal benefit package will be modified to add the following new services for the diabetes initiative:</p> <ul style="list-style-type: none"> <li>○ S9140: Diabetic management program, follow-up visit to non-MD provider</li> <li>○ S9141: Diabetic management program, group session</li> <li>○ S9455: Diabetic management program, nurse visit</li> <li>○ S9465: Diabetic management program, dietician visit</li> </ul> <p>In addition, <b>the following existing Comprehensive Perinatal Services Program (CPSP) Z codes will be modified for the diabetes initiative</b>:</p> <ul style="list-style-type: none"> <li>○ Z1032: Initial comprehensive visit</li> <li>○ Z1-32-ZL and Z1036: Bonuses for early entry and 10<sup>th</sup> office visit respectively</li> <li>○ Z6300, Z 6302, Z6304, and Z 6306: Psychosocial services which include initial psychosocial assessment and development of a care plan, first 30 minutes; initial psychosocial assessment and development of care plan, each subsequent 15 minutes; reassessment/treatment/intervention; and group psychosocial treatment/assessment/intervention, respectively.</li> <li>○ As warranted, adopt CPSP coding for nutrition and health education services, if above S codes inadequate.</li> </ul>
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**FRAMEWORK FOR CALIFORNIA'S DIABETES INITIATIVE**

**Provider Incentives**

- Financial incentives will be provided to participating providers who screen at risk individuals for pre-diabetes or diabetes and follow all specified program requirements including enrollment and management of individuals, data reporting, and making referrals for self-management classes.
- Emphasis will be on promoting quality improvement activities, improvements in the following: blood glucose levels, blood pressure, weight and physical activity levels in eligible beneficiaries.
- ***Further discussion will be necessary to develop and refine both incentives and quality improvement methodology.***

**Beneficiary Incentives**

- Incentives will be provided to participating beneficiaries who adhere to their individualized care plans and follow through with recommended referrals for screening services, group classes, self-management classes or to specialists. Incentives could include glucose meters; strips and medications (not covered by Medi-Cal) and provided through donations or pharmacy assistance programs or occasional gift cards for classes.

***Data Collection***

**Data Elements to be Reported**

- Basic demographic information
- Co-morbid medical conditions
- Clinical data – A1C, blood pressure, BMI, high/low density lipoproteins, cholesterol, creatinine, serum creatinine
- Completion of self management classes – group or individual
- Specialty care received from the following: endocrinology, nephrology, cardiology, ophthalmology, podiatry and appropriate mental health services for clinical depression or adjustment disorder
- **Diabetes related hospitalizations- for further discussion**

***Evaluation***

Evidence of effectiveness of comprehensive care – some clinical models for consideration:

- Evaluation results from CPSP: The cost for providing enhanced care was 5 percent higher than average cost of care under existing Medi-Cal program. For every dollar spent on Obstetrical Access model of services, two to three dollars were saved compared to the Medi-Cal obstetric services alone. Impressed by the results California State legislature enacted AB 2821, Bates, requiring publicly subsidized prenatal care to include nutrition, health education, and psychosocial services in addition to obstetrical care. Further legislation AB 3021 implemented a Medi-Cal reimbursement mechanism for enhanced prenatal care.
- Evaluation results from Project Dulce: Significant improvements in clinical indicators of diabetes control; adherence to standards of care; and self-care activities. Short-term cost study indicates savings in hospital costs and increased pharmacy costs; Simulation model demonstrated cost effective improvements in QALY and decreased incidence of diabetes related complications.
- Diabetic Prevention Program (DPP)

**FRAMEWORK FOR CALIFORNIA'S DIABETES INITIATIVE**

**Evaluation method**

***The following is the suggested evaluation methodology for the diabetes initiative:***

- Insert Ken Babamoto's and Gary He's edits.
- Disease registry/regional network info

***Outcomes***

**Clinical Outcomes**

Proposed target optimum values based on ADA guidelines:

- Hemoglobin A1C < 7%
- ***Weight loss goal of 7% NEED TO DISCUSS***
- ***BMI < 30 kg/m<sup>2</sup>***
- ***HOW DO WE WANT TO APPROACH PHYSICAL ACTIVITY?***
- Low Density Lipoprotein < 100 mg/dl
- High Density Lipoprotein > 45 mg/dl for men; and > 55 mg/dl for women

**Economic Outcomes**

***To be determined based on clinical outcomes and evaluation methodology***