



Center for Medicaid and CHIP Services
State Demonstrations Group

May 13, 2016

Mari Cantwell
Chief Deputy Director
Department of Health Care Services
Director's Office, MS 0000
P.O. Box 997413
Sacramento, CA 95899-7413

Dear Ms. Cantwell:

This letter is to inform you that the following attachments to the Special Terms and Conditions (STCs) for California's section 1115(a) demonstration, entitled "California Medi-Cal 2020 Demonstration" (11-W-00193/9), are approved as submitted by the state and as modified through our discussions.

- Whole Person Care (WPC) Reporting and Evaluation (Attachment GG)
- WPC Pilot Requirements and Application Process (Attachment HH)
- WPC Pilot Requirements and Metrics (Attachment MM)
- WPC Application and Selection Criteria

CMS finds these protocols and documents to be in accordance with the STCs for the demonstration, and has no further questions or comments at this time.

Copies of the approved attachments are enclosed. They will replace the corresponding attachments in the STCs.

We look forward to continuing to work with you and your staff on the California Medi-Cal 2020 Demonstration. If you have any questions, please contact your project officers, Ms. Mehreen Hossain, at either 410-786-0938 or by email at Mehreen.Hossain@cms.hhs.gov, and Ms. Heather Ross, at either 410-786-3666 or by email at Heather.Ross@cms.hhs.gov.

We appreciate your cooperation throughout the review process.

Sincerely,

/s/

Angela D. Garner
Director Division of System Reform Demonstrations

Enclosure

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cc: Henrietta Sam-Louie, Acting ARA Region IX

Attachment GG
WPC Reporting and Evaluation

- a. **Progress Reports.** Each WPC Pilot Lead Entity (“Lead Entity”) shall submit mid-year and annual reports for the duration of the WPC Pilot according to the requirements in this Attachment. The State shall specify the manner and format in which WPC Pilots shall submit data for the mid-year and annual reports.

- b. **Mid-Year Reports.** Lead Entities of WPC Pilots shall submit a mid-year report to the State.
 - i. Reporting requirements shall be specified in guidance set forth by the State, and shall include:
 - 1. A minimum standard required data set for all WPC Pilots. The minimum required data shall include data points from the following categories at a minimum:
 - a. Participant characteristics
 - b. Number of participants
 - c. Type and volume of medical and non-medical services utilized
 - d. Type and volume of emergency department and inpatient services utilized
 - e. Total amount of overall funds spent
 - 2. Additional data and information as specified in Attachment MM WPC Requirements and Metrics and the approved WPC Pilot application.
 - 3. Additional data and information to support measurement of the purpose of the WPC evaluation as set forth in STC 123 including:
 - a. Improve coordination across participating entities including data and information sharing;
 - b. Improve beneficiary health outcomes;
 - c. Reduce avoidable utilization of emergency and inpatient services (ED, hospital and psychiatric inpatient);
 - d. Increase access to social services;
 - e. Improve care coordination across participating entities; and
 - f. Improve housing stability, if applicable.
 - 4. A list of participating entity and/or stakeholder meetings, as applicable, held during the period, including agendas, and a narrative description of program activities during the period including identified barriers, challenges, and successes.
 - 5. Data and other documentation as described in the WPC Pilot application demonstrating progress in the approved activities.
 - 6. The data described in the approved WPC Pilot application demonstrating the progress toward WPC Pilot goals in relation to the infrastructure, services, and other strategies as described in the

approved WPC Pilot application and WPC Pilot Special Terms and Conditions.

- ii. The mid-year report including data and information through June 30 shall be due to the State no later than 60 days after June 30 each year.
 - iii. For Program Year 1, no mid-year report shall be submitted.
 - iv. Upon submission of a complete (as determined by the State) mid-year report, the State will determine whether progress toward the WPC Pilot requirements approved in the WPC Application has been made. To the extent that progress has been made in a manner approved in the Application, notification of such and an interim payment in an amount proportional to the progress toward achievement of the WPC Pilot goals based on the approved annual total computable funding agreed to in the approved WPC Pilot application shall be paid to the WPC Pilot Lead Entity. If the state determines that less than 50% of the annual payment is due, the WPC Pilot will be given 14 days to respond and revise reports as appropriate. At the discretion of the State, a proportional amount of interim funding will be adjusted and paid.
 - v. Within 30 days of the determination of the interim payment due based on the mid-year report, the State will issue requests to the WPC Pilot for the necessary intergovernmental transfer amounts. The WPC Pilot entities will make intergovernmental transfer of funds to the State in the amount specified within 7 days of receiving the State's request. If the intergovernmental transfers are made within the requested timeframe, the payment will be paid within 14 days after the transfers are made.
- c. **Annual Reports.** On an annual basis, Lead Entities shall submit an annual report to the State for the purpose of demonstrating that the WPC Pilot is conducted in compliance with the requirements of the WPC Pilot as set forth in the STCs and attachments, the WPC Pilot approved application, any agreement between the State and the WPC Pilot Lead Entity, and/or policy letters and guidance set forth by the State. Lead Entities will submit their reports using the structured report template provided for this purpose by the State. The annual report will also be used to determine if the interventions were performed in the manner agreed upon in the WPC Pilot approved application and to report on the impact of the WPC Pilot interventions, as applicable and as described in the approved WPC Pilot application.
- i. Annual reporting requirements shall be specified in guidance put forth for WPC Pilot applications by the State and shall include at a minimum:
 - 1. The same data elements included in the minimum standard required data set from the mid-year report.
 - 2. The same additional data elements set forth in Attachment MM WPC Reporting and Requirements and as agreed to in the approved WPC Pilot application.
 - 3. A narrative describing the activities and interventions the WPC Pilot performed during the year for each component as described in the application including barriers, challenges, and successes.

4. A narrative of how the WPC Pilot is making progress toward accomplishing the objectives described in STC 123 (Mid-Point and Final Evaluations) and STC 112 (WPC Strategies)
 5. Progress achieved in the activities and interventions in the approved WPC Pilot application.
 6. For Program Year 1, the annual report shall consist of baseline data and information as set forth in this Attachment and Attachment MM, WPC Requirements and Metrics.
- ii. The annual report shall be due no later than 60 calendar days after the end of the program year unless otherwise specified by the State.
 - iii. Upon submission of a complete (as determined by the State) annual report, the State will determine whether the WPC Pilot requirements approved in the WPC Application have been met. If the requirements for a deliverable have been fully met, the State will notify the WPC Pilot and provide funding in an amount equal to the amount agreed to in the WPC Pilot Application for that deliverable, less any amount already received from the mid-year report. If the required deliverables have been partially met, notification of such partial completion will be sent to the WPC Pilot entity, and the WPC Pilot entity will be given 14 days to respond and revise reports as appropriate. At the discretion of the State, an adjusted amount of proportional funding will be determined. The amount of such proportional payments shall reflect the activities or progress performed as documented in the annual report, less any amounts already received from the mid-year report.
 - iv. Within 30 days of the determination of the end of year payment due based on the annual report, the State will issue requests to the WPC Pilot for the necessary intergovernmental transfer amounts. The WPC Pilot entities will make intergovernmental transfer of funds to the State in the amount specified within 7 days of receiving the State's request. If the intergovernmental transfers are made within the requested timeframe, the payment will be paid within 14 days after the transfers are made.
 - v. The State may impose sanctions, including the recoupment of funds from the WPC Pilot, should it be determined that the WPC Pilot is out of compliance with its requirements as set for in the STCs and attachments, the agreement between the WPC Pilot and the State, and/or policy letters or guidance set forth by the State. In addition to the requirements accompanying recoupment described above, any recoupment imposed as a sanction shall only occur after technical assistance has been provided by the State and failure to comply with corrective action occurs by the WPC site. Prior to initiating any recoupment of WPC Pilot funds, the State shall provide the Lead Entity notice and an opportunity to comment regarding the identified area of non-compliance and the expected amount of recoupment, as appropriate. In the event of such recoupments, the State must return the associated IGT funds to the transferring entities within 14 calendar days of funds being recouped.

- vi. The State shall make the annual reports available to the public on its website.

II. WPC Evaluation

The state will identify an independent entity to conduct a mid-point and final evaluation. The independent entity shall work with the State to draft an evaluation proposal for approval by CMS. The draft will be shared with WPC Pilot sites and the public for comment. The mid-point and final evaluations will meet standards of leading academic institutions and academic peer review, including standards for the evaluation design, conduct, interpretation, and reporting of findings. The purpose of the evaluations will be to understand the extent to which the WPC Pilot interventions:

- i. Improve coordination across participating entities including data and information sharing;
 - ii. Improve beneficiary health outcomes;
 - iii. Reduce avoidable utilization of emergency and inpatient services (ED, hospital and psychiatric inpatient);
 - iv. Increase access to social services;
 - v. Improve care coordination across participating entities; and
 - vi. Improve housing stability, if applicable.
- a. The mid-point evaluation will be due one year prior to the expiration of the demonstration and will include data from program years 1 (as applicable), 2, and (to the extent possible) 3. The final evaluation will be completed no later than six months following the expiration of the demonstration.
 - i. Using the data reported in the annual reports pursuant to Section I(b)(i) above, and other data requested from the WPC Pilot sites as specified by the State, the evaluations shall evaluate the extent to which the WPC Pilots individually and collectively accomplished the objectives described in STC 123 (Mid-Point and Final Evaluations) and STC 112 (WPC Strategies).
 - ii. Evaluators shall interview state staff, each WPC Pilot and participating entities (as appropriate), and other stakeholders, for purposes of conducting the evaluations.
 - b. Data collected for purposes of the evaluation shall not be used by the independent entity for purposes other than the evaluation of the objectives described in STC 123 (Mid-Point and Final Evaluations) and STC 112 (WPC Strategies).
 - c. The mid-point and final evaluations shall be made available to the public on the State's website.

Attachment HH
WPC Pilot Requirements and Application Process

I. Application Process

a. Release of WPC Pilot Application and Guidance

- i. By April 1, 2016, or within 90 days following approval of the WPC Pilot Requirements and Metrics, Attachment MM, WPC Pilot Requirements and Application Process, Attachment HH, and WPC Reporting Evaluation, Attachment GG, whichever is later, the State will publish a WPC Pilot application (including a structured application template), the list of the entities eligible to apply as a Lead WPC Pilot Entity (“Lead Entity”), the application process, detailed timelines, data and reporting requirements, and selection criteria.
- ii. At least 10 calendar days prior to the planned publication date, the State will share a courtesy copy of the draft application with CMS, and consider any timely comments and feedback that CMS may provide.
- iii. Upon release of the application and accompanying materials, the State will conduct a conference call open to all interested applicants to help explain the opportunity and application, and answer prospective applicants’ questions.
- iv. The application shall include a description about the type and quantity of data that WPC Pilots will be required to submit for the mid-year and annual reports, as specified in Attachments GG and MM. It shall also include mid-point and final evaluation requirements as set forth in STC 123 which are to:
 - a. Improve coordination across participating entities including and information sharing;
 - b. Improve beneficiary health outcomes;
 - c. Reduce avoidable utilization of emergency and inpatient services (ED, hospital and psychiatric inpatient);
 - d. Increase access to social services;
 - e. Improve care coordination across participating entities; and
 - f. Improve housing stability, if applicable.
- v. Applicants shall attest that they will report and submit timely and complete data to the State in a format specified by the State. Incomplete and/or non-timely data submissions may lead to a financial penalty after multiple occurrences and technical assistance is provided by the State. Applicants shall also attest that federal funding received shall be returned if the Pilot, or a component of it as determined by the state, is not subsequently implemented. The application shall include information about the State’s role and the role of the Lead Entity with regard to pilot monitoring, provision of technical assistance, and imposition of corrective action and Pilot termination.

- vi. The application shall include the total and maximum amounts of funding available for the WPC Pilots for each program year, and the process the State will use to select and approve WPC Pilots.
The application shall include a structured template for applicants to address the required elements, including those listed in I.b.

b. Required Application Elements

- i. WPC Pilot applicants shall address all elements in STC 117(b).
- ii. WPC Pilot applicants shall identify high-risk, high-utilizing Medi-Cal beneficiaries in the geographic area that they serve and assess their unmet need, as described in WPC Pilot Special Terms and Conditions STC 112. Applications shall identify the target population, the expected number of individuals served or affected by the Pilot, and the number of those individuals that are Medi-Cal beneficiaries.
- iii. Applicants shall list all Universal and Variant metrics that they plan to meet for each program year, how they will document their achievement of metrics, and describe how payments for pilots will comport with STC 113, given the three broad aims of WPC.
- iv. Applicants shall define and describe the services they will provide that are not otherwise covered or directly reimbursed by Medi-Cal. If housing services are to be provided or a housing pool is to be utilized, the applicant must be precise about which services will be funded by Pilot funds, and limited to housing-related activities and services described in the June 26, 2015 CMCS Informational Bulletin. The applicant must describe the relationship between Pilot funding and provision of services broadly, and how federal financial participation will be received only for services provided to Medi-Cal beneficiaries.
- v. Applicants shall identify as Pilot participants at least one Medi-Cal managed care health plan operating in the geographic area of the Pilot, both the health services and specialty mental health agencies or department, at least one other public agency or department, and at least two community partners that have significant experience serving the target population, in accordance with STC 115.
- vi. Applicants shall make an attestation that the WPC Pilot lead entity will enter into an agreement with the State, if necessary (as specified by the State), which specifies the requirements of the WPC Pilot, including data sharing agreement in accordance with STC 118.
- vii. Applicants shall make an attestation that the WPC Pilot lead entity shall agree to help develop and participate in regular learning collaboratives to share best practices among Pilot entities, in accordance with STC 119.
- viii. Applicants shall make attestation that the funds transferred for the IGT qualify for federal financial participating pursuant to 42 CFR 433, subpart B, and are not derived from impermissible sources such as recycled Medicaid payments, federal money excluded from use as state match, impermissible taxes, and non-bona fide provider-related donations in accordance with STC 126.a.

- ix. Applicants shall make attestation that they will respond to general inquiries from the State pertaining to the WPC Pilot initially within one business day after acknowledging receipt and provide requested information within five business days, unless an alternate timeline is approved or determined necessary by the State. The State will consider reasonable timelines that will be dependent on the type and severity of the information when making such requests.
 - x. Applicants shall acknowledge that payments for WPC pilots will be contingent on certain deliverables or achievements, denoted in STC 126(f), and will not be distributed or may be recouped if pilots fail to demonstrate achievement or submission of deliverables.
- c. **Submission of WPC Pilot Applications by Lead Entities**
- i. Applications shall comply with all application processes and requirements as specified by the State, including but not limited to those elements listed in Whole Person Care Special Terms and Conditions STC 117(b).
 - ii. Lead Entities shall submit complete WPC Pilot applications consistent with the application requirements listed in STC 117 and Attachment HH to the State by May 15, 2016, or 45 days after the State issues the WPC Pilot application, whichever is later.
 - iii. As part of the review and approval process described in Section below, funding shall be designated for the applications. In the event that available funding remains within the annual limits of the WPC Pilot, additional funding may be requested by approved WPC Pilot sites or applications may be requested and accepted by the state after the initial application period. Nothing shall preclude an applicant from reapplying with a strengthened application if they were not approved in the first round, following request by the State. All initial application requirements would remain in effect, with the exception of specified dates.

II. State Review Process

- a. Within 60 days after submission of the application, the State will complete its review of the application, respond to the Lead Entity in writing with any questions, concerns or problems identified. Upon receipt, the Lead Entity will respond to questions and concerns in writing within 5 business days.
- b. Within 30 days after submission of the final responses to the State's questions, the State will complete its review of the application and shall take action on the application and notify the applicant. Notification to CMS of recommended approved applications by the State will also occur.
- c. Within 10 days of the State's notification to CMS of the State approval of APC Pilot applications, CMS shall notify the State of any concerns or questions regarding final approval. Within 10 days of final approval, the Lead Entity shall formally accept or decline approval of the application.
- d. In the event that an approved WPC Pilot application is approved for less than 90 percent of its requested funding, the State shall allow the Lead Entity to withdraw its application. The State shall offer the WPC Pilot the opportunity to modify its

application per the reduction in funding during the question and answer process, as determined appropriate by the State.

III. Pilot Funding

- a. The State shall review each WPC Pilot application and consider equal valuation across requests. The State shall consider differences in proposed interventions, target populations, and geographic areas when conducting this review.
- b. The State shall issue no sooner than October 1, 2016 guidance to WPC Pilots specifying when funding may be decreased prospectively and retrospectively as a result of a WPC Pilot not completing a component of the Pilot's intervention(s) as specified in its approved application, and non-progress on universal and/or variant metrics, as determined by the State.

IV. Pilot Termination

- a. The State may suspend or terminate a WPC Pilot if corrective action has been imposed and persistent poor performance continues.
 - i. If a deficiency is identified by the State, the State shall first provide technical assistance to the WPC Pilot.
 - ii. If the WPC Pilot continues to demonstrate poor performance, a corrective action plan (CAP) will be imposed. The CAP will include specific milestones and timelines as approved by the State. The State will work with the WPC Pilot to develop the CAP; however, final issuance of the CAP will be done by the State.
 - iii. If the WPC Pilot does not come into compliance with the CAP, the State may impose penalties, sanctions, or terminate the WPC Pilot.
- b. Should a WPC Pilot be terminated, the State shall provide notice to the Pilot and request a close-out plan due to the State within thirty calendar days unless significant harm to beneficiaries is occurring in which case the State may request a close-out plan within ten business days. The State shall approve the close-out plan upon determining all components are acceptable. The close-out plan shall include:
 - i. A timeline for close-out of the WPC Pilot;
 - ii. A process to notify all Pilot participating entities of termination of the Pilot;
 - iii. A process to notify all participating beneficiaries of termination of the Pilot which will include:
 1. The effective date of the termination;
 2. A description of how the termination will affect the beneficiary's access to services;
 3. Who the beneficiary should call if they need information or have questions about the termination;
 4. A referral to a community resource or entity that can provide any of the terminated services, whenever possible.

Notices shall indicate that disenrollment from the Pilot will be terminated within thirty days of the date of the notice. The State may determine a shorter time frame should it be determined that beneficiary harm is

occurring. Notices shall be approved by the State and must be mailed in the appropriate threshold language.

- iv. A process to call all beneficiaries a minimum of five times prior to the termination. The call script shall include the same information included in the aforementioned notices and shall be approved by the State.
- v. A process for notifying the public in the geographic area where the WPC Pilot operates of its termination.
- vi. A timeline for reporting final data and information to the State as required in Attachments GG and MM in a manner specified by the State.
- vii. A budget to close out the Pilot.

V. Learning Collaboratives

- a. WPC Pilot lead and participating entities shall participate in all WPC learning collaborative activities. Participation of lead and/or participating entities in any specific learning collaborative activity shall be determined by the State.
- b. Learning collaborative activities shall be structured to provide information about and assist with Pilot implementation and close-out; share best practices and learnings across WPC Pilots; and for the State to provide information, discuss requirements, and report data about the Pilots.
- c. A subset of WPC Pilot lead entities shall be identified to assist the State with planning and providing direction about how learning collaboratives will be structured.
- d. The State shall convene a minimum of bi-weekly calls during the first year after approval of Pilot applications to discuss implementation issues, answer Pilot questions, and clarify Pilot requirements. The frequency of these calls shall be decreased following this initial year dependent on the need for them, however, shall be no less than monthly.
- e. The State shall convene a minimum of two in-person learning collaboratives during each WPC program year with the exception of year 1. These meetings shall be focused on the sharing of best practices across WPC pilots; when possible, national policy and practice information will be shared; reporting of WPC Pilot performance; and to help establish working relationships across pilots to promote discussion and sharing of information amongst pilots in between meetings without direction.

Attachment MM
WPC Pilot Requirements and Metrics

- I. WPC Pilot Performance.** All WPC pilots will report universal and variant metrics mid-year and annually, unless otherwise specified below. Universal metrics will be a same set of metrics required of all WPC pilots; Variant metrics will differ between pilots and will be tailored to the unique strategies and target population(s) of each individual WPC Pilot. Data reported during WPC Program Year (PY) 1 shall be for a time period prior to implementation and will establish a baseline. WPC Pilot metric performance may be calculated by the State or WPC Pilot, as specified by the State in a reporting template with instructions.

When utilizing and reporting Plan Do Study Act (PDSA) for purposes of Universal and Variant metrics, WPC pilots shall utilize a template developed by the State, which may be modified as appropriate when reporting on its target population(s) and interventions (as approved by the State). The template shall also demonstrate a change-management plan, including a mechanism for identifying needed adjustments, a process for carrying out the change, a process for observing and learning from the implemented change(s) and their implications, and a process to determine necessary modifications to the change based on the study results and implement them. It shall include requirements pertaining to when new versions of policies and procedures shall be submitted as a result of use of PDSA. The template shall also provide an opportunity for WPC pilots to document when additional changes are not needed based on study results, as approved by the State. The PDSA approach shall be measured within the timelines set forth below for each measure in this Attachment and approved in the application. Reporting including supporting documentation of all measures will be included in and submitted with the mid-year and annual reports as specified in Attachment GG. Health outcomes metrics rates shall be measured annually, however, progress and supporting documentation shall be submitted semi-annually. Administrative Metrics shall include a written description of the structure, barriers and challenges, and activities, if any, relating to the operationalization of them during PY 1; for all other program years PDSA reporting will occur.

- II. Universal Metrics.** Universal metrics will assess the success of all WPC pilots in achieving the WPC goals and strategies as specified in STCs 110 and 112. They will be reported by all WPC Pilots for the duration of the demonstration and shall include:

- i. Health Outcomes: Ambulatory Care – Emergency Department Visits (HEDIS) including utilization of PDSA with measurement and necessary changes a minimum of quarterly.
 - 1. Children (as applicable)
 - 2. Adults (as applicable)
 - 3. Total
- ii. Health Outcomes: Inpatient Utilization-General Hospital/Acute Care (IPU) (HEDIS) including utilization of PDSA with measurement and necessary changes a minimum of quarterly.
 - 1. Children (as applicable)
 - 2. Adults (as applicable)
 - 3. Total
- iii. Health Outcomes: Follow-up After Hospitalization for Mental Illness (FUH) (HEDIS)
 - 1. Children (ages 6 – 17) (as applicable)
 - 2. Adults (as applicable)
 - 3. Total
- iv. Health Outcomes: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET) (HEDIS)
 - 1. Adolescents (ages 13 – 17) (as applicable)
 - 2. Adults (as applicable)
 - 3. Total
- v. Administrative: Proportion of participating beneficiaries with a comprehensive care plan, accessible by the entire care team, within 30 days of:
 - 1. Enrollment into the WPC Pilot
 - 2. The beneficiary’s anniversary of participation in the Pilot (to be conducted annually)

Utilization of PDSA with measurement and necessary changes a minimum of quarterly to determine any necessary changes to meet the timelines and ensure care plans are comprehensive in nature and accessible by the entire care team.
- vi. Administrative: Care coordination, case management, and referral infrastructure.
 - 1. Measured by:
 - a. Submission of documentation demonstrating the establishment of care coordination, case management, and referral policies and procedures across the WPC Pilot lead and all participating entities which provide for streamlined beneficiary case management. Upon completion, and within a timeline approved by the State, the policies and procedures will be submitted to the State for review and approval.

- i. The WPC lead entity may serve as the central communication point across all participating entities. However, all participating entities must have access to and be provided with timely access and updates to beneficiary information for care coordination and case management purposes.
 - ii. The policies and procedures shall establish a communication structure for participating beneficiaries. The number of participating entities for purposes of the Pilot as points of contact for beneficiaries shall be minimalized.
 - b. Monitoring procedures for oversight of how the policies and procedures set forth in iv.1(a) are being operationalized – including a regular review to determine any needed modifications.
 - i. Utilization of PDSA with measurement and necessary changes a minimum of semi-annually.
 - c. A method to compile and analyze information and findings from the monitoring procedures set forth in iv.1(b). And a process to modify the policies and procedures set forth in iv.1(a) in a streamlined manner and within a reasonable timeframe.
- vii. Administrative: Data and information sharing infrastructure
 - 1. Measured by:
 - a. Submission of documentation demonstrating the establishment of data and information sharing policies and procedures across the WPC Pilot lead and all participating entities that provide for streamlined beneficiary care coordination, case management, monitoring, and strategic improvements, to the extent permitted by applicable state and federal law. Upon completion, and within a timeline approved by the State, the policies and procedures will be submitted to the State for review and approval.
 - i. The WPC lead entity may serve as the central data and information sharing entity across all participating entities. However, all participating entities must have access to and be provided with

timely access and updates to necessary beneficiary data and information to the extent permitted by applicable state and federal law for streamlined beneficiary care coordination, case management, monitoring, and strategic improvements.

- b. Monitoring procedures for oversight of how the policies and procedures set forth in v.1(a) are being operationalized – including a regular review to determine any needed modifications.
 - i. Utilization of PDSA with measurement and necessary changes a minimum of semi-annually.
- c. A method to compile and analyze information and findings from the monitoring procedures set forth in v.1(b), and a process to update as appropriate the policies and procedures set forth in v.1(a) in a streamlined manner and within a reasonable timeframe in accordance with PDSA.

III. Variant Metrics. Variant metrics will assess the success of individual WPC pilots in achieving the WPC goals and strategies as specified in STCs 110 and 112. These metrics shall be specific to the WPC Pilot target population(s), strategies, and interventions. Variant metrics may vary by PY, though some metrics shall be consistent across all PYs of the Pilot. The metrics may include process and/or outcome measures and will utilize PDSA as is set forth above in this Attachment. Variant metrics shall be approved by the State in the WPC Pilot application. The State may request modifications or changes be made to proposed application metrics. Additional documentation may be requested and reviewed for approval by the State for Variant Administrative metrics.

1. Each WPC Pilot shall report on a minimum of:
 1. i. Four Variant metrics for each PY, including at a minimum items 1, 2, 3, and 4 below (or for pilots implementing a housing component, five Variant metrics for each PY, including at a minimum items 1, 2, 3, 4, and 5): One administrative metrics in addition to the Universal care coordination and data sharing metrics.
 2. One standard health outcomes metrics (e.g., HEDIS) applicable to the WPC Pilot population across all five program years for each target population.
 3. WPC Pilots utilizing the PHQ-9 shall report the Depression Remission at Twelve Months (NQF 0710)

- metric; all other Pilots shall report one alternative health outcomes metric.
- 4. WPC Pilots including a severely mentally ill (SMI) target population shall report the Adult Major Depression Disorder (MDD): Suicide Risk Assessment (NQF 0104) WPC Pilots; all other Pilots shall report one alternative health outcomes metric.
- 5. WPC Pilots implementing a housing component shall report a fifth metric specific to this intervention.
- 2. Variant metrics must be created through the following standardized process:
 - i. Conduct an assessment of:
 - 1. The target population(s) characteristics and needs (utilizing available data resources); and
 - 2. Gaps in the WPC Pilot service area infrastructure to meet the identified needs of the target population(s).
 - ii. Define specific objectives/strategies that provide for process improvement pertaining to the identified needs and gaps.
 - iii. Conduct the following steps based on the identified objectives/strategies:
 - 1. A literature review including identification of any existing metrics used on a national level to measure outcomes pertaining to the WPC Pilot target population(s)
 - 2. Consider metrics that are already being captured by one or more participating entities for local programs
 - iv. Select metrics that measure progress towards the objectives/strategies, using the following guidelines:
 - 1. Select metrics that measure changes in infrastructure, processes, and/or outcomes

IV. Annual performance accountability. Universal and Variant metric performance may be assessed according to directional change relative to the initial baseline data and assessment. Performance of individual metrics may also be measured and calculated based on established thresholds as compared to other WPC Pilot performance (adjustments for target population(s), structure, geographic area, and other factors, may be made as needed). For health outcomes metrics, the following measurement process shall be used:

- 1. PY 1: Approved WPC Pilots shall gather and report baseline data on their target population(s) against which changes in future years will be assessed. Data should only include time periods prior to the beginning of the WPC Pilot interventions. Partial data for PY 1 shall be reported for time periods after the WPC Pilot is implemented, as applicable.

2. PYs 2-3: WPC Pilots will report on all Universal and Variant metrics, and describe in their mid-year and annual reports early trends, potential explanations, and plans to incorporate lessons into a continual cycle of performance improvement (using a PDSA methodology).
3. PYs 4-5: WPC Pilots will report on all Universal and Variant metrics, including discussing the direction of the changes shown in the data. If changes are in the predicted direction, WPC Pilots shall comment on what they believe contributed to the improvement. If changes are not in the predicted direction, WPC Pilots shall comment on what may be hindering improvement, and how interventions will be adapted to improve performance.

For administrative metrics, the following measurement process shall be used:

- a. PY 1: Approved WPC Pilots shall report on Universal and Variant administrative metrics including activities relating to establishing the infrastructure to implement them. A description of the infrastructure and/or processes for the time period prior to the beginning of the WPC Pilot interventions shall be included.
- b. PYs 2-5: WPC Pilots will report on all Universal and Variant administrative metrics and describe in their mid-year and annual reports early trends, potential explanations, and plans to incorporate lessons into modifications to the supporting infrastructures for the administrative metrics. If the State determines a WPC Pilot does not demonstrate appropriate performance pertaining to administrative metrics as set forth, DHCS may impose corrective action or discontinue operation of the Pilot.



Whole Person Care Pilot Application

Application due July 1, 2016

General Instructions

Thank you for your interest in applying to participate in the Whole Person Care (WPC) pilot program, part of the state of California's Medi-Cal 2020 Section 1115 demonstration. In order to apply, the organization that will serve as the lead entity of the WPC must complete and sign this application. Prior to completing this application, it is strongly suggested that applicants carefully review the documents that govern the Medi-Cal 2020 demonstration, available on the Department of Health Care Services (DHCS) website (<http://www.dhcs.ca.gov/services/Pages/WholePersonCarePilots.aspx>), including:

- [Special Terms and Conditions \(STC\) \(110-126\)](#)
- [STC Attachments GG, HH and MM](#)
- [Frequently Asked Questions](#)

Please complete the WPC pilot application and return it to 115wholepersoncare@dhcs.ca.gov no later than **5 p.m. PT on July 1, 2016**. Incomplete applications will not be considered. In order for this application to be considered complete for the purposes of submission, all components of the application must be completed, the application must be signed, and the first three attachments below must be included:

1. Letters of participation agreements for all participating pilot entities (See Question 1.3)
2. Letters of support from participating providers and relevant stakeholders
3. A funding diagram illustrating how the requested funds would flow from DHCS to the lead entity and how the funds would be distributed among participating entities (See Question 5.2)
4. (Optional) A description of any requested requirement exceptions. For example, if a lead entity cannot reach agreement with a required participating entity. (STC 117b, STC 115)

Applications will be reviewed and selected based on the process outlined in the Appendix. The application review process and timing is as follows:

| Deliverable/Activity | Date |
|---|-------------------|
| 1. DHCS releases WPC pilot RFA, timeline, and selection criteria | May 16, 2016 |
| 2. DHCS conducts webinar for potential applicants/interested entities | May 19, 2016 |
| 3. WPC pilot applications due to DHCS | July 1, 2016 |
| 4. DHCS completes WPC application review; sends written questions to applicants | September 1, 2016 |
| 5. Applicants' written responses due to DHCS | September 8, 2016 |
| 6. DHCS notifies CMS of WPC pilot selection decisions | October 7, 2016 |
| 7. DHCS notifies applicants of WPC pilot selection final decisions | October 24, 2016 |
| 8. Lead entities provide formal acceptance to DHCS | November 3, 2016 |

Section 1: WPC Lead Entity and Participating Entity Information

The purpose of this section is to provide information about the WPC pilot lead entity and the other entities that will be participating in the WPC pilot.

Lead Entity Description

DHCS will accept applications for WPC pilots from the designated lead entity, which must be a county, a city and county, a health or hospital authority, a Designated Public Hospital, District/Municipal Public Hospital, or a consortium of any of the above entities serving a county or region consisting of more than one county.¹ The lead entity will be the single point of contact for DHCS and is responsible for coordinating and monitoring the WPC pilot. (STC 115)

Participating Entity Description

In addition to designating a lead entity, the WPC pilot application must identify other entities that will participate in the WPC pilot. **Participating entities must include:**

- At least one Medi-Cal managed care health plan (MCP) operating in the geographic area of the WPC pilot to work in partnership with the lead entity when implementing the pilot specific to Medi-Cal managed care beneficiaries. Plan participation must include all sub-plans of the prime MCP when full delegation of risk has occurred. See the web link below for a listing of MCPs by county: <http://www.dhcs.ca.gov/individuals/Pages/MMCDHealthPlanDir.aspx>.
- Both the health services and specialty mental health agency or department, and at least one other public agency or department, which may include county alcohol and substance use disorder programs, human services agencies, public health departments, criminal justice/probation entities, and housing authorities (regardless of how many of these fall under the same agency head within a county). If housing services are provided, the public housing authority must be included.
- At least two other WPC community partners (entities or organizations) that have significant experience serving the target population within the pilot's geographic area, including physician groups, community clinics, hospitals, and community-based organizations. Note that the lead entity may not list itself as one of the two required WPC community partners

The WPC pilot application may also identify additional entities that will participate in the pilot beyond the minimum requirements. DHCS encourages pilots to include additional participating entities in order to include as many existing providers to the target population as possible. If a lead entity cannot reach agreement with a required participating entity, it may request an exception. (STC 115)

¹ DHCS's request to the federal Centers for Medicare and Medicaid Services (CMS) to amend the Medi-Cal 2020 demonstration to allow a federally recognized tribe or a tribal health program operated under a Public Law 93-638 contract with the federal Indian Health Services to be considered a "lead entity" will be submitted to CMS for approval with CMS. An application submitted by this type of lead entity will only be considered for a pilot award if the DHCS amendment request is approved by CMS.

1.1 Whole Person Care Pilot Lead Entity and Contact Person (STC 117.b.i)

| | |
|--|--|
| Organization Name | |
| Type of Entity (from lead entity description above) | |
| Contact Person | |
| Contact Person Title | |
| Telephone | |
| Email Address | |
| Mailing Address | |

1.2 Participating Entities

Identify the participating entities in the WPC pilot, describe the entities, and explain their role in the WPC pilot. In the below chart, under "Required Organizations," please provide information for the entities that are required to participate. If you have additional participating entities, please list them under "Optional Organizations." If you are applying for an exception to the participating entities requirements, please explain which requirement you are unable to meet, your reason for seeking an exception, and supporting documentation of communications with the required entities for which an exception is being requested. (STC 117.b.ii)

| Required Organizations | Organization Name | Contact Name and Title | Entity Description and Role in WPC |
|--|--------------------------|-------------------------------|---|
| 1. Medi-Cal managed care health plan | | | |
| 2. Health Services Agency/Department | | | |
| 3. Specialty Mental Health Agency/Department | | | |
| 4. Public Agency/ | | | |

| | | | |
|---|--------------------------|-------------------------------|---|
| Department (if housing services are provided, must include the public housing authority) | | | |
| 5. Community Partner 1 | | | |
| 6. Community Partner 2 | | | |
| Additional Organizations (Optional) | Organization Name | Contact Name and Title | Entity Description and Role in WPC |
| 7. (Insert type of entity from table above- e.g., additional Health Services Agency/Dept., Community partner, etc. Add additional lines as needed.) | | | |
| 8. | | | |
| 9. | | | |
| 10. | | | |
| 11. | | | |

1.3 Letters of Participation and Support

As part of your application submission, attach letters from all of the participating pilot entities that indicate a commitment to participate in the WPC pilot. Attach letters of support from participating providers and other relevant stakeholders in the geographic area where the WPC pilot will operate. (STC 117.b.xv and xvi)

Section 2: General Information and Target Population

The purpose of this section is to provide information on the WPC pilot geographic area, need for the pilot, governance structure, and target population.

WPC Target Population Description

WPC pilots must identify high-risk, high-utilizing Medi-Cal beneficiaries that reside in the geographic area they serve, and assess their unmet need. WPC pilots may focus on one target population or more than one target population. The target population(s) shall be identified through a collaborative data approach to identify common patients who frequently access urgent and emergency services across multiple systems. The target population(s) **may include, but are not limited to**, individuals:

- a. With repeated incidents of avoidable emergency use, hospital admissions, or nursing facility placement.
- b. With two or more chronic conditions.
- c. With mental health and/or substance use disorders.
- d. Who are currently experiencing homelessness.
- e. Who are at risk of homelessness, including individuals who will experience homelessness upon release from institutions (hospital, subacute care facility, skilled nursing facility, rehabilitation facility, Institution for Mental Disease, county jail, state prisons, or other).

Individuals who are not Medi-Cal beneficiaries may participate in approved WPC pilots, but funding in support of services provided to such individuals is not eligible for federal financial participation. The WPC lead entity may propose inclusion of these individuals in the pilot, subject to DHCS approval. (STC 111)

2.1 Geographic Area, Community and Target Population Needs

Describe the geographic area in which the WPC pilot will operate and the need for the WPC pilot. Describe how other participating entities took part in defining the vision and structure for the WPC pilot as described in the application. Provide a general description of the WPC pilot, its structure, the target population(s) and how it will address the needs of the target population(s).

Include how the WPC pilot will reduce avoidable utilization of other system components (e.g. jails) and how it addresses any current system problem(s). Include the overarching vision of how the WPC pilot will: 1) build and strengthen existing efforts in the community and relationships, and improve collaboration among participating WPC pilot entities; 2) provide learnings for potential future local efforts beyond the term of this waiver; and 3) build sustainable infrastructure that can support communications about the populations across the delivery systems beyond the term of the pilot. Explain how the pilot infrastructure and interventions will be sustained in absence of federal and state funding following the end of the pilot. (Limited to 1000 words) (STC 110, 117.b.iii, STC 117.b.iv)

2.2 Communication Plan

Describe the communications process the WPC pilot will employ, including how communication among the lead entity and participating entities will occur; how integration will be promoted and silos minimized; how decisions will be made in consultation with the participating entities; and the schedule of regular meetings that will be convened. Describe the governance structure for the WPC pilot including who has decision-making authority, how the pilot will be organized, and how participating entities will

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be involved in decision-making. Identify a main point of contact to support and coordinate with participating entities. Describe the external communication plan that will be employed to communicate with providers, beneficiaries and stakeholders. (Limited to 500 words) (STC 117.b.v)

2.3 Target Population(s)

Identify the target population(s) that will be served by the WPC pilot, including an estimated total number of Medi-Cal beneficiaries to be served by the pilot as a whole. For pilots with more than one target population, include an estimate of the number of Medi-Cal beneficiaries to be served within each target population. Identify how the Lead Entity collaborated with other participating entities to identify each target population. If the WPC pilot plans to have individuals participate who are not Medi-Cal beneficiaries, please estimate the number of these participants for each target population. If the WPC pilot plans to have an enrollment cap for part of or the entire pilot, please provide information on the rationale for and level of the proposed cap for each subset of the target population(s) including the Medi-Cal and non-Medi-Cal population(s), as applicable. Describe the methodology used to identify the target population(s), including data analyses and a needs assessment of the target population(s). (Limited to 750 words per target population) (STC 117.b.vi, xxi, xxii)

Section 3: Services, Interventions, Care Coordination, and Data Sharing

The purpose of this section is to provide information on the services that will be provided under the WPC pilot, the interventions and strategies that will be employed, how care will be coordinated, and how data will be shared and utilized across the participating entities.

Services and Interventions Description

WPC pilots must define the interventions and other strategies they will use to provide integrated services to high users of multiple systems. WPC pilots shall include specific strategies to:

- a. Increase integration among county agencies, health plans, providers, and other entities within the participating county or counties that serve high-risk, high-utilizing beneficiaries and develop an infrastructure that will ensure local collaboration among the entities participating in the WPC pilots over the long term;
- b. Increase coordination and appropriate access to care for the most vulnerable Medi-Cal beneficiaries;
- c. Reduce inappropriate emergency and inpatient utilization;
- d. Improve data collection and sharing among local entities to support ongoing case management, monitoring, and strategic program improvements in a sustainable fashion;
- e. Achieve targeted quality and administrative improvement benchmarks;
- f. Increase access to or utilization of housing or other non-medical supportive services (optional); and
- g. Improve health outcomes for the WPC population. (STC 112)

WPC pilot payments will support: 1) infrastructure to integrate services among local entities that serve the target population; 2) services not otherwise covered or directly reimbursed by Medi-Cal to improve care for the target population, such as housing components; and 3) other strategies to improve integration, reduce unnecessary utilization of health care services, and improve health outcomes. (STC 113)

3.1 Services, Interventions, and Care Coordination

For each target population, describe the services that will be available to beneficiaries under the WPC pilot that are not otherwise covered or directly reimbursed by Medi-Cal for the target population in the geographic area where the pilot is being implemented. This includes medical, behavioral, social, and non-medical services. Explain why the services proposed are specifically well-suited to meet the needs of the target population. If a certain service will be limited to one, or some, target populations, please specify. Describe the network and providers that will deliver these services.

If housing-related services will be provided or a housing pool will be utilized, please describe the services and explain which services will be funded by pilot funds. Housing-related services funded by pilot funds must comply with the restrictions on federal financial participation for room and board in STC 114. Services funded by pilot funds may include housing-related activities services described in the June 26, 2015 CMS Informational Bulletin. (STC 117.b.vii)

For each target population, describe the specific interventions and other strategies that will be employed to integrate services for the target population. Provide information on prior experience or other projects or programs that the applicant can draw upon in implementing the WPC pilot and the existing programs and infrastructure can be leveraged to support the pilot. Explain how the interventions will be successful

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in engaging and connecting individuals to medical, behavioral health, and social supports, improving health outcomes for the target population, decreasing avoidable emergency department and inpatient utilization, and decreasing avoidable utilization of other systems (e.g., jails). If a certain intervention or other strategy will be limited to one, or some, target populations, please specify. Include how the Plan-Do-Study-Act (PSDA) process will be incorporated and utilized throughout the intervention and service model proposed.

For each target population, describe how care coordination will be implemented administratively, including what each participating entity will be responsible for, how they will link to other participating entities, as appropriate to provide wrap around care, and how the care coordination will be seamless to the beneficiary, taking into consideration other current care coordination efforts by pilot entities and other entities, and not duplicating those efforts. Explain how the participating entities will work together to create one system that provides wrap-around care coordination for beneficiaries. (Total response limited to 1500 words per target population) (STC 117.b.viii, ix, xi)

3.2 Data Sharing

For each target population, describe how data sharing will occur between the participating entities, including what data will be shared with which entity and how infrastructure and sharing will evolve over the life of the demonstration. To the extent any shared data contains Personal Health Information/Personal Information (PHI/PI), mental health or substance use disorder services information, the WPC pilot and its participating entities must comply with all applicable state and federal law. Provide information on the tools that will be utilized to support data sharing, the capabilities currently in place and the new development that will be needed to support data sharing under the pilot. Provide a timeline and implementation plan for developing the necessary infrastructure to support data sharing. Describe how the pilot will build sustainable infrastructure that can support communications about the population(s) across the delivery systems beyond the term of the pilot. Identify the data governance structure and approach. Indicate anticipated challenges and strategies the WPC pilot will employ to manage the challenges. (Limited to 750 words per target population) (STC 117.b.x)

Section 4: Performance Measures, Data Collection, Quality Improvement and Ongoing Monitoring

The purpose of this section is to provide information on the performance measures the WPC pilot will use to track progress; the plan for collecting, reporting and analyzing data; quality improvement; and the ongoing monitoring of the participating entities' performance.

Reporting Requirements Description

WPC pilot lead entities are required to submit mid-year and annual reports to DHCS. DHCS will issue a reporting template with instructions at a later date. The mid-year reports will be used to determine whether progress toward the WPC pilot requirements has been made. The purpose of the annual report is to demonstrate that the WPC pilot is conducted in compliance with the requirements set forth in the STCs and attachments, the approved application, and any agreement between DHCS and the lead entity and/or policy letters and guidance from DHCS. Attachment GG outlines the mid-year and annual reporting requirements. Metrics reported in Pilot Year 1 will be considered baseline data. (STC 121)

Performance Measures Description

WPC pilots will be required to report metrics in order to assess their success in achieving the goals and strategies specified in STCs 110 and 112. The reporting and metric requirements are outlined in Attachment MM. All WPC pilots must report metrics mid-year and annually unless otherwise specified. There are two types of metrics:

- (1) Universal metrics.
- (2) Variant metrics.

Universal metrics are a set of metrics required of all WPC pilots and must be reported for the duration of the demonstration.

Variant metrics are determined by each WPC pilot and must be developed based on the WPC pilot's unique target population(s), interventions, and strategies. In order to develop the variant metrics that must be provided below as part of the application submission, WPC pilots must follow a standardized process outlined in Attachment MM.

Each WPC pilot must report on a minimum of four variant metrics for each pilot year. WPC pilots implementing a housing component must report on a minimum of five variant metrics. The required variant metrics include:

- One administrative metric (in addition to the universal care coordination and data sharing metrics)
- One standard health outcome metric (e.g., Healthcare Effectiveness Data and Information Set) applicable to the pilot population.
- For pilots utilizing the PHQ-9, the Depression Remission at Twelve Months metric (NQF 0210) metric; all other pilots report one alternative health outcomes metric.
- For pilots with a severely mentally ill (SMI) target population, the Adult Major Depression Disorder (MDD): Suicide Risk Assessment (NQF 0104) metric; all other pilots report one alternative health outcomes metric.
- For WPC pilots implementing a housing component, a housing-specific metric.

WPC pilots may choose to include additional variant metrics. The metrics may include process and/or outcome measures and must utilize Plan-Do-Study-Act (PDSA) as set forth in Attachment MM. DHCS may request modifications or changes to proposed metrics included in the pilot application and/or additional California Medi-Cal 2020 Demonstration

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documentation. (STC 122, Attachment MM).

4.1 Performance Measures

Identify performance measures for each type of participating entity and the WPC pilot itself, including short-term process measures and ongoing outcome measures; these measures should be grouped by Demonstration Year and include an annual target benchmark. Provide the overarching vision of the performance measures and how they connect to each intervention and each target population. Describe your overall plan for tracking and documenting progress of the WPC pilot as a whole, as well as for each type of participating entity and each target population. (Limited to 750 words) (STC 117.b.xii)

4.1.a Universal Metrics

Please check the boxes below to acknowledge that all WPC pilots must track and report the following universal metrics. Please list the WPC pilot goal for each metric: (e.g., reduce emergency department visits by X percent per year). Details on the metrics are provided in Attachment MM. Lead entities are required to collect data from participating entities and report it timely to DHCS, when requested, to support the WPC pilot’s achievement of the universal and variant metrics. (STC 115.b.xii, STC 122, Attachment MM)

- Health Outcomes Measures**
- Administrative Measures**

4.1.b Variant Metrics

In the table below, please identify the variant metrics that your WPC pilot will report on for each pilot year (PY). Variant metrics must be determined using the process described in Attachment MM. Variant metrics may vary by PY, though some metrics must be consistent across all PYs. For pilots with more than one target population, include a variant metric table for each target population. Note – DHCS may require WPC pilots with similar measures to modify proposed variant metrics, as appropriate, to allow for additional standardization of variant metrics across pilots.

| Variant Metric | PY 1 | PY 2 | PY 3 | PY 4 | PY 5 |
|--|-------------|-------------|-------------|-------------|-------------|
| Administrative Metric | | | | | |
| Health Outcome Metric | | | | | |
| Depression Remission at Twelve Months or Alternative Metric (NQF 0210) | | | | | |

| Variant Metric | PY 1 | PY 2 | PY 3 | PY 4 | PY 5 |
|---|------|------|------|------|------|
| Adult Major Depression Disorder (MDD): Suicide Risk Assessment (NQF 0104) or Alternative Metric | | | | | |
| Housing-Specific Metric (if applicable) | | | | | |
| Other Metric (optional) | | | | | |
| Other Metric (optional) | | | | | |
| Other Metric (optional) | | | | | |

4.2 Data Analysis, Reporting and Quality Improvement

Describe the plan for ongoing data collection, reporting, and analysis of the WPC pilot’s interventions, strategies, participant health outcomes, and return on investment. Identify existing and new data sources and a timeline for developing any new capabilities that are needed to support the WPC pilot.

Explain the approach for quality improvement and change management that your organization plans to use. Explain how the WPC pilot will identify needed adjustments, a process for carrying out the change, a process for observing and learning from the implemented change(s) and the implications, and a process to determine necessary modifications to the change based on the study results and to implement them. (Limited to 1000 words) (STC 117.b.ix, xv)

4.3 Participant Entity Monitoring

Describe the lead entity’s plan to conduct ongoing monitoring of the WPC pilot participating entities and to make subsequent adjustments if issues are identified. This should include a process to provide technical assistance, impose corrective action, and terminate the WPC pilot if poor performance is identified and continues. (Limited to 500 words) (STC 117.b.xiv)

Section 5: Financing

The purpose of this section is to describe the WPC pilot financing structure, the funding flow to the lead entity and participating entities, and a total requested annual funding amount to operate the WPC pilot. A total of \$1.5 billion in federal funding is available for the five-year WPC pilot. A single WPC pilot may not receive more than 30 percent of the total statewide funding (\$300 million) available in a given year, unless additional funds are available after all initial awards are made and the WPC pilot receives approval through a subsequent request process.

Funding and Budget Description

WPC pilot payments are intended to support the WPC pilots for:

- 1) Infrastructure and non-Medicaid covered interventions that support increased integration among the lead entity and participating entities;
- 2) Increased coordination and appropriate access to care for the most vulnerable; and
- 3) Improved data collection and sharing among local entities to support ongoing case management, monitoring, and strategic program improvements.

Available funding in Pilot Year 1 is based on approval of the WPC pilot application and the submission of baseline data.

Budgets should not include costs for services directly reimbursable with Medi-Cal or other federal funding resources. Additionally, WPC investments in housing units or housing subsidies, including any payments for room and board, are not eligible for federal financial participation. See STC 114 and the [Frequently Asked Questions](#) for additional information on the housing pool.

5.1 Financing Structure

Describe the financing structure of the WPC pilot, including a description of how WPC pilot payments will be distributed and any financing or savings arrangements; the oversight and governance structure that will oversee the intake and payment of funds; the timeline for payments; the payment structure (i.e. bundled payments, fee-for-service, etc.); the payment process (i.e. claims payment vs. scheduled bundled payments); how payments will be tracked; and any system changes or new systems development needed to support payment. Specify how the applicant will ensure funds are sufficient to provide reimbursement for provided services. Describe how the financing and payment approaches will help participants to be better prepared for value based payment approaches in the future. (Limited to 1000 words) (STC 117.b.xvii)

5.2 Funding Diagram

Attach a funding diagram illustrating the flow of requested funds from DHCS to the lead entity and other participating entities. (Attachment) (STC 117.b.xviii)

5.3 Non-Federal Share

List the entity(ies) that will provide the non-federal share to the lead entity to be used for payments under the WPC pilot. (STC 117.b.xiii)

5.4 Non-Duplication of Payments and Allowable Use of Federal Financial Participation

Describe the relationship between WPC pilot funding and the provision of services broadly, how payments will comply with STC 113, and how federal financial participation will be received only for services provided to Medi-Cal beneficiaries (Limited to 500 words) (STC 111 & 114)

5.5 Funding Request

For Budget Year 1, indicate that the requested budget is for the submission of the application and the required baseline data. Baseline data collection is an applicable activity for Budget Year 1 only. For Budget Years 2-5, WPC Pilot applications must include discrete details regarding all components of the requested budget. Insert the annual requested funding amount for each individual item (deliverable) for which funding is proposed. These deliverables may include data collection, infrastructure, interventions, and outcomes. For example, include the specific activities that will be performed; interventions, supports and services that will be implemented; and/or the achievement of outcomes. Indicate the total requested annual dollar amount for each of these under each of Budget Years 2-5. Provide the total requested dollar amount for the five-year pilot.

If the pilot is requesting a per member per month (PMPM)/service bundle payment, include detail on how each PMPM service bundle amount (the monthly service bundle cost for each beneficiary who receives the service bundle) was determined by showing the value associated with each individual service or activity that comprises the service bundle. The WPC Pilot application must include a total maximum service bundle funding amount (limit) for each service bundle for each of Budget Years 2-5, which will be determined by the individual PMPM service bundle payment amount and the maximum number of PMPM service bundles provided (people served) in each budget year. The funding that DHCS will provide to the Pilot in each budget year for each service bundle will be calculated according to the number of Medi-Cal beneficiaries serviced by the service bundle for each month of the year.

Please see the budget example on the Department of Health Care Services (DHCS) website (<http://www.dhcs.ca.gov/services/Pages/WholePersonCarePilots.aspx>).

Budgets should not include costs (e.g., payments) for services reimbursable with Medi-Cal or other federal funding resources. (STC 117.b.xix)

Section 6: Attestations and Certification

6.1 Attestation

I certify that, as the representative of the WPC pilot lead entity, I agree to the following conditions:

- The WPC pilot lead entity will help develop and participate in regular learning collaboratives to share best practices among pilot entities, per STC 119.
- The intergovernmental transfer (IGT) funds will qualify for federal financial participation per 42 CFR 433, subpart B, and will not be derived from impermissible sources, such as recycled Medicaid payments, federal money excluded from use as a state match, impermissible taxes, and non-bona fide provider-related donations, per STC 126.a. Sources of non-federal funding shall not include provider taxes or donations impermissible under section 1903(w), impermissible intergovernmental transfers from providers, or federal funds received from federal programs other than Medicaid (unless expressly authorized by federal statute to be used for claiming purposes, and the federal Medicaid funding is credited to the other federal funding source). For this purpose, federal funds do not include PRIME payments, patient care revenue received as payment for services rendered under programs such as the Designated State Health Programs, Medicare, or Medicaid
- Within 30 days of the determination of the interim payment due based on the mid-year and annual report, DHCS will issue requests to the WPC pilot for the necessary IGT amounts. The WPC pilot shall make IGT of funds to DHCS in the amount specified within 7 days of receiving the state's request. If the IGTs are made within the requested timeframe, the payment will be paid within 14 days after the transfers are made.
- The WPC pilot lead entity will enter into an agreement with DHCS that specifies the requirements of the WPC pilot, including a data sharing agreement per STC 118. [See Exhibit A "HIPAA Business Associate Addendum (BAA)" of this Application. Many of the provisions in the DHCS boilerplate BAA apply only to BAA-covered information that is shared by DHCS to the pilot specifically for the purpose of Whole Person Care pilot operation and evaluation. DHCS does not anticipate that BAA-covered information will be shared with pilots for the purpose of Whole Person Care pilot operation or evaluation. DHCS anticipates limited, or no, BAA-covered information sharing from the pilot to DHCS. However, DHCS will include a BAA in the case that data need to be shared. The BAA will apply to the transfer of BAA-covered information should the need arise.]
- The WPC pilot will report and submit timely and complete data to DHCS in a format specified by the state. Incomplete and/or non-timely data submissions may lead to a financial penalty after multiple occurrences and technical assistance is provided by the state.
- The WPC pilot shall submit mid-year and annual reports in a manner specified by DHCS and according to the dates outlined in Attachment GG. The WPC pilot payments shall be contingent on whether progress toward the WPC pilot requirements approved in this application has been made.
- The WPC pilot will meet with evaluators to assess the WPC pilot.
- Federal funding received shall be returned if the WPC pilot, or a component of it as determined by the state, is not subsequently implemented.

- Payments for WPC pilots will be contingent on certain deliverables or achievements, and will not be distributed, or may be recouped, if pilots fail to demonstrate achievement or submission of deliverables (STC 126).
- The lead entity will respond to general inquiries from the state pertaining to the WPC pilot within one business day after acknowledging receipt, and provide requested information within five business days, unless an alternate timeline is approved or determined necessary by DHCS. DHCS will consider reasonable timelines that will be dependent on the type and severity of the information when making such requests.
- The lead entity understands that the state of California must abide by all requirements outlined in the STCs and Attachments GG, HH, and MM. The state may suspend or terminate a WPC pilot if corrective action has been imposed and persistent poor performance continues. Should a WPC pilot be terminated, the state shall provide notice to the pilot and request a close-out plan due to the state within 30 calendar days, unless significant harm to beneficiaries is occurring, in which case the state may request a close-out plan within 10 business days. All state requirements regarding pilot termination can be found in Attachment HH.

I hereby certify that all information provided in this application is true and accurate to the best of my knowledge, and that this application has been completed based on a good faith understanding of WPC pilot program participation requirements as specified in the Medi-Cal 2020 waiver STCs, Attachments GG, HH and MM, and the DHCS Frequently Asked Questions document.

Signature of WPC Lead Entity Representative

Date

Appendix: Application Selection Criteria

The Whole Person Care (WPC) pilot application evaluation is a competitive process that will result in the selection of qualified WPC pilots based on the quality and scope of their application. The application score will be factored into determining the funding amount for each WPC pilot. The Department of Health Care Services (DHCS) will conduct the evaluation process in two phases: (1) Quality and Scope of Application and (2) Funding Decision. WPC pilot applications that do not meet the basic requirements of the Special Terms and Conditions (STCs) and DHCS application guidance will be disqualified.²

Overview

1) Quality and Scope of Application. WPC pilot applications will be assigned a numerical score of up to 105 points based on the quality and scope of the application. Applications must achieve a minimum score of 77 points to be selected to participate in the WPC pilot. Applications that achieve the minimum score and also include priority program elements will receive bonus points that may increase their possibility of participation. Applications must receive a pass score on all pass/fail criteria to be eligible to participate.

2) Funding Decision. The funding amount for each WPC pilot will be determined based upon a combination of the funding request score and supporting financing information provided; comparisons to similarly-sized pilots based on specified county demographic and program design elements; and a final assessment of available funding relative to applications received.

Section 1: Quality and Scope of Application

A. Applications Will Be Assigned a Numerical Score

Scoring criteria will help DHCS assess whether applications meet the WPC pilot goals and requirements outlined in Medi-Cal 2020 demonstration's Special Terms and Conditions (STCs).

Each application will be assigned a numerical score based on a possible total of 105 points. Applicants must achieve a minimum score of 77 points to be selected to participate in the WPC pilot. Multiple DHCS reviewers will score applications and then assign a total average score.

Highest Possible Score by Application Section

Section 1: WPC Lead Entity and Participating Entity Information-**5 points**

Section 2: General Information and Target Population(s)-**25 points**

Section 3: Services, Interventions, Care Coordination, and Data Sharing-**35 points**

Section 4: Performance Measures, Data Collection, and Ongoing Monitoring-**30 points**

Section 5: Financing-**10 points**

Section 6: Attestations and Certification-**Pass/Fail**

Total Possible Points: 105

² DHCS's request to the federal Centers for Medicare and Medicaid Services (CMS) to amend the Medi-Cal 2020 demonstration to allow a federally recognized tribe or a tribal health program operated under a Public Law 93-638 contract with the federal Indian Health Services to be considered a "lead entity" will be submitted to CMS for approval. An application submitted by this type of lead entity will not be disqualified if the only basic requirement that it does not meet is that of being a lead entity.

B. Application Sections Will Be Scored Based on Specified Criteria

Each application section will be scored based on the criteria specified below:

Section 1: WPC Lead Entity and Participating Entity Information - 5 points

- 1.1 Lead Entity Information: Pass/Fail
 - Pass = Organization submitting the application meets lead entity requirements, and all required information is provided.
 - Fail = Lead entity does not meet lead entity requirements, and/or not all information is provided as required. The lead entity will be contacted and informed that they do not qualify as a lead entity.

- 1.2 Participating Entities: 5 points
 - Meets participating entity requirements as outlined in STC 115.
 - Information is complete.
 - Explanation of role in WPC pilot is clear.
 - Points may be reduced if exemption is needed due to non-participation as opposed to non-availability of a participating entity (even if approved).
 - Fail = WPC pilot does not meet the participating entity requirements and does not request an exemption (or exemption is not approved), or participating entities are not appropriate given the target population and strategies.

- 1.3 Letters of Participation from Participating Pilot Entities and Letters of and Support from Participating Providers and other Relevant Stakeholders: Pass/Fail
 - Pass = All letters provided.
 - Fail = Not all letters provided.

Section 2: General Information and Target Population - 25 points

- 2.1 Geographic Area and Target Population Needs: 10 points
 - Demonstrates community need for WPC pilot.
 - WPC pilot design is comprehensive, cohesive and well-designed to achieve goals.
 - Demonstrates how the WPC pilot will address community and target population needs.
 - Scope is ambitious but realistic/achievable.

- 2.2 Communication Plan: 5 points
 - Clear and comprehensive plan for collaboration, integration and communication between entities.
 - Mechanisms planned to minimize silos.
 - Clear plan to communicate state pilot requirements from the lead entity to participating entities.
 - Ability to provide learnings for potential future local efforts beyond the term of this demonstration.
 - Build sustainable infrastructure that can support communications about the populations across the delivery systems beyond the term of the pilot. Explain how the pilot infrastructure and interventions will be sustained in absence of federal and state funding following the end of the pilot.
 - Structure and process planned for making decisions.
 - Clear plan to convene regular meetings.

- Main point of contact identified to support and coordinate with participating entities.
- 2.3 Target Population(s): 10 points
 - Meets requirements outlined in STC 111.
 - Extent of scope and number of people in WPC target population(s) and target population cap(s), if applicable.
 - Target population(s) is/are appropriate given participating entities and strategies.
 - Quality of methodology used to define target population(s).
 - Plan for beneficiary identification and outreach.

Section 3: Services, Interventions, Care Coordination and Data Sharing - 35 points

- 3.1 Services, Interventions and Care Coordination: 25 points
 - Meets requirements as outlined in the STCs.
 - Appropriateness of services and interventions for target population(s).
 - Comprehensive approach of services, interventions, and strategies.
 - Likelihood that interventions will be achievable and successful in improving health outcomes for target population(s).
 - Alignment with other concurrent initiatives being implemented in the region (e.g., does the applicant articulate a vision of how pieces fit together).
 - Extent of infrastructure needed to implement intervention, demonstrating complete consideration of the infrastructure needs to support the pilot.
 - Tests new interventions and strategies for the target population.
 - Likelihood to improve housing stability (if applicable).
 - A clear and comprehensive plan for how a Plan-Do-Study-Act process will be incorporated to modify and learn from interventions during the Pilot.

Care Coordination:

- Meets care coordination requirements in the STCs.
- Includes a description of how care coordination will be implemented administratively, including what each participating entity will be responsible for, how they will link to other participating entities, as appropriate, to provide wrap around care.
- Leverages and connects existing community infrastructure.
- Builds new infrastructure between lead and participating entities.
- Likelihood of improving care coordination.
- Likelihood of increasing access to appropriate physical, behavioral health, and social services.
- 3.2 Data Sharing: 10 points
 - Creates sustainable infrastructure to support data sharing between entities and identifies existing resources for data sharing and existing gaps.
 - Increases care coordination across lead and participating entities.
 - Data sharing processes and expectations (or process to identify them) are clearly presented.
 - Reasonableness and quality of timeline and implementation plan to develop necessary infrastructure.
 - Quality of data governance structure and approach.

Section 4: Performance Measures, Data Collection, and Ongoing Monitoring - 30 points

- 4.1, 4.1a, 4.1b Performance Measures, Universal Metrics, Variant Metrics: 15 points
 - Identifies performance measures for each type of participating entity and the WPC pilot itself, including short-term process measures and ongoing outcome measures; grouped by Demonstration Year, including an annual target benchmark.
 - Demonstrates comprehensive plan for collecting, tracking, and documenting metrics.
 - Meets universal metric requirements outlined in Attachment MM.
 - Meets variant metric requirements outlined in Attachment MM.
 - Quality and appropriateness of variant metrics given target population(s), interventions and strategies.
 - Appropriate processes to utilize Plan-Do-Study-Act (PDSA) for all universal and variant metrics identified.

- 4.2 Data Analysis and Reporting: 10 points
 - Clear and high-quality plan for ongoing data collection, reporting, and analysis of interventions and strategies.
 - Clear plan for using analysis for sustainability planning.

- 4.3 Participant Entity Monitoring (5 points)
 - Quality of plan to conduct ongoing monitoring and make adjustments as needed.
 - Comprehensive plan for providing technical assistance, imposing corrective action, and terminating if poor performance is identified and continues.

Section 5: Financing - 10 points (7 point minimum required score)

- Reasonableness of the amount of the funding request in relation to proposed WPC pilot activities Detail of the payment amount requested for each deliverable for which funding is requested, including baseline data collection, infrastructure, interventions, and outcomes.
- Demonstrate a comprehensive approach to flow of funds, how reimbursement will take place and oversight and monitoring of payment.
- Reasonable methodology for establishing the budget request.
- Clear description or diagram explaining how the payment process will function.
- Alignment with/leverage of other funding sources.

Section 6: Attestations and Certification-Pass/Fail

- Pass = Applicant checks box and provides signature.
- Fail = Applicant does not check box and/or does not include a signature. Applicant may not participate in a WPC pilot unless Section 6 receives a score of "Pass."

C. Bonus Points Will be Awarded to Applications That Include Priority Elements

WPC pilot applications may qualify to receive bonus points if they include certain priority program elements in their WPC pilot. Applicants must achieve a minimum numerical score of 77 points (NOT including bonus points) in order to participate in the WPC pilot. These WPC pilots may then qualify for bonus points.

Priority Elements That Receive Bonus Points:

- **Plans:** More than one participating managed care plan in the geographic areas where the pilot operates (maximum of 5 points).

- **Community partners:** More than two participating community partners in the geographic areas where the pilot operates (maximum of 5 points).
- **Interventions:** Innovative interventions (maximum of 5 points)
 - Creative interventions, such as creative workforce strategies (e.g., effective use of community health workers; using community paramedics outside their customary emergency roles in ways that facilitate more appropriate use of emergency care resources; appropriately targeting digital health tools or other health information technology (HIT) solutions; addressing social determinants of health (e.g. food instability); including transportation strategies; using trauma-informed approaches to care; and engaging extensively with community partners.
 - Creative financing/use of innovative payment models that will better prepare them for value-based purchasing in the future.

Section 2: Funding Decision

A. Funding Allocation Will Be Determined Based on Three Factors

Funding will be determined based on the funding request and application financing responses, comparisons to similarly-sized pilots, and an assessment of available funds relative to applications received.

Funding Decision Criteria

1) Funding request and quality of financing application responses. The funding request and the financing application responses will be assessed and scored according to the Application Section 5 “Financing” scoring criteria listed above, including the annual budget amount requested for each individual item for which funding is requested, including baseline data collection, infrastructure, interventions, and outcomes. DHCS will determine the appropriateness of the funding request given the scope and ambitiousness of the pilot, how well the applicant demonstrates the soundness of their approach, the clarity of the governance structure, presence of oversight mechanisms and internal controls to ensure payment and accountability related to participating entities, the needs of the target population, the complexity of the interventions, and to ensure that payments are not duplicative of payments for existing services.

2) Comparisons to similarly-sized pilots. Funding requests from similarly-sized WPC applications will be compared based on pilot scope, design, and funding requested.

3) Assessment of Available Funding. DHCS will then assess the availability of funds relative to the applications received. If assigned funding amounts exceed the maximum available, either funding amounts for approved pilots will be reduced to meet the funding limitations or some pilots will not be approved.

Exhibit A
HIPAA Business Associate Addendum

I. Recitals

A. This Contract (Agreement) has been determined to constitute a business associate relationship under the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 ("the HITECH Act"), 42 U.S.C. section 17921 et seq., and their implementing privacy and security regulations at 45 CFR Parts 160 and 164 ("the HIPAA regulations").

B. The Department of Health Care Services ("DHCS") wishes to disclose to Business Associate certain information pursuant to the terms of this Agreement, some of which may constitute Protected Health Information ("PHI"), including protected health information in electronic media ("ePHI"), under federal law, and personal information ("PI") under state law.

C. As set forth in this Agreement, Contractor, here and after, is the Business Associate of DHCS acting on DHCS' behalf and provides services, arranges, performs or assists in the performance of functions or activities on behalf of DHCS and creates, receives, maintains, transmits, uses or discloses PHI and PI. DHCS and Business Associate are each a party to this Agreement and are collectively referred to as the "parties."

D. The purpose of this Addendum is to protect the privacy and security of the PHI and PI that may be created, received, maintained, transmitted, used or disclosed pursuant to this Agreement, and to comply with certain standards and requirements of HIPAA, the HITECH Act and the HIPAA regulations, including, but not limited to, the requirement that DHCS must enter into a contract containing specific requirements with Contractor prior to the disclosure of PHI to Contractor, as set forth in 45 CFR Parts 160 and 164 and the HITECH Act, and the Final Omnibus Rule as well as the Alcohol and Drug Abuse patient records confidentiality law 42 CFR Part 2, and any other applicable state or federal law or regulation. 42 CFR section 2.1(b)(2)(B) allows for the disclosure of such records to qualified personnel for the purpose of conducting management or financial audits, or program evaluation. 42 CFR Section 2.53(d) provides that patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by an appropriate court order.

E. The terms used in this Addendum, but not otherwise defined, shall have the same meanings as those terms have in the HIPAA regulations. Any reference to statutory or regulatory language shall be to such language as in effect or as amended.

II. Definitions

A. Breach shall have the meaning given to such term under HIPAA, the HITECH Act, the HIPAA regulations, and the Final Omnibus Rule.

- B. Business Associate shall have the meaning given to such term under HIPAA, the HITECH Act, the HIPAA regulations, and the final Omnibus Rule.
- C. Covered Entity shall have the meaning given to such term under HIPAA, the HITECH Act, the HIPAA regulations, and Final Omnibus Rule.
- D. Electronic Health Record shall have the meaning given to such term in the HITECH Act, including, but not limited to, 42 U.S.C Section 17921 and implementing regulations.
- E. Electronic Protected Health Information (ePHI) means individually identifiable health information transmitted by electronic media or maintained in electronic media, including but not limited to electronic media as set forth under 45 CFR section 160.103.
- F. Individually Identifiable Health Information means health information, including demographic information collected from an individual, that is created or received by a health care provider, health plan, employer or health care clearinghouse, and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, that identifies the individual or where there is a reasonable basis to believe the information can be used to identify the individual, as set forth under 45 CFR section 160.103.
- G. Privacy Rule shall mean the HIPAA Regulation that is found at 45 CFR Parts 160 and 164.
- H. Personal Information shall have the meaning given to such term in California Civil Code section 1798.29.
- I. Protected Health Information means individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or is transmitted or maintained in any other form or medium, as set forth under 45 CFR section 160.103.
- J. Required by law, as set forth under 45 CFR section 164.103, means a mandate contained in law that compels an entity to make a use or disclosure of PHI that is enforceable in a court of law. This includes, but is not limited to, court orders and court-ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information, and a civil or an authorized investigative demand. It also includes Medicare conditions of participation with respect to health care providers participating in the program, and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
- K. Secretary means the Secretary of the U.S. Department of Health and Human Services ("HHS") or the Secretary's designee.
- L. Security Incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI or PI, or confidential data that is essential to the ongoing operation of the Business Associate's organization and intended for internal use; or interference with system operations in an information system.

M. Security Rule shall mean the HIPAA regulation that is found at 45 CFR Parts 160 and 164.

N. Unsecured PHI shall have the meaning given to such term under the HITECH Act, 42 U.S.C. section 17932(h), any guidance issued pursuant to such Act, and the HIPAA regulations.

III. Terms of Agreement

A. Permitted Uses and Disclosures of PHI by Business Associate

Permitted Uses and Disclosures. Except as otherwise indicated in this Addendum, Business Associate may use or disclose PHI only to perform functions, activities or services specified in this Agreement, for, or on behalf of DHCS, provided that such use or disclosure would not violate the HIPAA regulations, if done by DHCS. Any such use or disclosure must, to the extent practicable, be limited to the limited data set, as defined in 45 CFR section 164.514(e)(2), or, if needed, to the minimum necessary to accomplish the intended purpose of such use or disclosure, in compliance with the HITECH Act and any guidance issued pursuant to such Act, the HIPAA regulations, the Final Omnibus Rule and 42 CFR Part 2.

1. Specific Use and Disclosure Provisions. Except as otherwise indicated in this Addendum, Business Associate may:

a. Use and disclose for management and administration. Use and disclose PHI for the proper management and administration of the Business Associate provided that such disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware that the confidentiality of the information has been breached.

b. Provision of Data Aggregation Services. Use PHI to provide data aggregation services to DHCS. Data aggregation means the combining of PHI created or received by the Business Associate on behalf of DHCS with PHI received by the Business Associate in its capacity as the Business Associate of another covered entity, to permit data analyses that relate to the health care operations of DHCS.

B. Prohibited Uses and Disclosures

1. Business Associate shall not disclose PHI about an individual to a health plan for payment or health care operations purposes if the PHI pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full and the individual requests such restriction, in accordance with 42 U.S.C. section 17935(a) and 45 CFR section 164.522(a).

2. Business Associate shall not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of DHCS and as permitted by 42 U.S.C. section 17935(d)(2).

C. Responsibilities of Business Associate

Business Associate agrees:

1. Nondisclosure. Not to use or disclose Protected Health Information (PHI) other than as permitted or required by this Agreement or as required by law.
2. Safeguards. To implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI, including electronic PHI, that it creates, receives, maintains, uses or transmits on behalf of DHCS, in compliance with 45 CFR sections 164.308, 164.310 and 164.312, and to prevent use or disclosure of PHI other than as provided for by this Agreement. Business Associate shall implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications and other requirements of 45 CFR section 164, subpart C, in compliance with 45 CFR section 164.316. Business Associate shall develop and maintain a written information privacy and security program that includes administrative, technical and physical safeguards appropriate to the size and complexity of the Business Associate's operations and the nature and scope of its activities, and which incorporates the requirements of section 3, Security, below. Business Associate will provide DHCS with its current and updated policies.
3. Security. To take any and all steps necessary to ensure the continuous security of all computerized data systems containing PHI and/or PI, and to protect paper documents containing PHI and/or PI. These steps shall include, at a minimum:
 - a. Complying with all of the data system security precautions listed in Attachment A, the Business Associate Data Security Requirements;
 - b. Achieving and maintaining compliance with the HIPAA Security Rule (45 CFR Parts 160 and 164), as necessary in conducting operations on behalf of DHCS under this Agreement;
 - c. Providing a level and scope of security that is at least comparable to the level and scope of security established by the Office of Management and Budget in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems, which sets forth guidelines for automated information systems in Federal agencies; and
 - d. In case of a conflict between any of the security standards contained in any of these enumerated sources of security standards, the most stringent shall apply. The most stringent means that safeguard which provides the highest level of protection to PHI from unauthorized disclosure. Further, Business Associate must comply with changes to these standards that occur after the effective date of this Agreement.

Business Associate shall designate a Security Officer to oversee its data security program who shall be responsible for carrying out the requirements of this section and for communicating on security matters with DHCS.

D. Mitigation of Harmful Effects. To mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate or its subcontractors in violation of the requirements of this Addendum.

E. Business Associate's Agents and Subcontractors.

1. To enter into written agreements with any agents, including subcontractors and vendors, to whom Business Associate provides PHI or PI received from or created or received by Business Associate on behalf of DHCS, that impose the same restrictions and conditions on such agents, subcontractors and vendors that apply to Business Associate with respect to such PHI and PI under this Addendum, and that comply with all applicable provisions of HIPAA, the HITECH Act the HIPAA regulations, and the Final Omnibus Rule, including the requirement that any agents, subcontractors or vendors implement reasonable and appropriate administrative, physical, and technical safeguards to protect such PHI and PI. Business associates are directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of protected health information that are not authorized by its contract or required by law. A business associate also is directly liable and subject to civil penalties for failing to safeguard electronic protected health information in accordance with the HIPAA Security Rule. A "business associate" also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate. Business Associate shall incorporate, when applicable, the relevant provisions of this Addendum into each subcontract or subaward to such agents, subcontractors and vendors, including the requirement that any security incidents or breaches of unsecured PHI or PI be reported to Business Associate.

2. In accordance with 45 CFR section 164.504(e)(1)(ii), upon Business Associate's knowledge of a material breach or violation by its subcontractor of the agreement between Business Associate and the subcontractor, Business Associate shall:

- a. Provide an opportunity for the subcontractor to cure the breach or end the violation and terminate the agreement if the subcontractor does not cure the breach or end the violation within the time specified by DHCS; or
- b. Immediately terminate the agreement if the subcontractor has breached a material term of the agreement and cure is not possible.

F. Availability of Information to DHCS and Individuals. To provide access and information:

1. To provide access as DHCS may require, and in the time and manner designated by DHCS (upon reasonable notice and during Business Associate's normal business hours) to PHI in a Designated Record Set, to DHCS (or, as directed by DHCS), to an Individual, in accordance with 45 CFR section 164.524. Designated Record Set means the group of records maintained for DHCS that includes medical, dental and billing records about individuals; enrollment, payment, claims adjudication, and case or medical management systems maintained for DHCS health plans; or those records used to make decisions about individuals on behalf of DHCS. Business Associate shall use the forms and processes developed by DHCS for this purpose and shall respond to requests for access to records transmitted by DHCS within fifteen (15) calendar days of receipt of the request by producing the records or verifying that there are none.

2. If Business Associate maintains an Electronic Health Record with PHI, and an individual requests a copy of such information in an electronic format, Business Associate shall provide such information in an electronic format to enable DHCS to fulfill its obligations under the HITECH Act, including but not limited to, 42 U.S.C. section 17935(e).

3. If Business Associate receives data from DHCS that was provided to DHCS by the Social Security Administration, upon request by DHCS, Business Associate shall provide DHCS with a list of all employees, contractors and agents who have access to the Social Security data, including employees, contractors and agents of its subcontractors and agents.

G. Amendment of PHI. To make any amendment(s) to PHI that DHCS directs or agrees to pursuant to 45 CFR section 164.526, in the time and manner designated by DHCS.

H. Internal Practices. To make Business Associate's internal practices, books and records relating to the use and disclosure of PHI received from DHCS, or created or received by Business Associate on behalf of DHCS, available to DHCS or to the Secretary of the U.S. Department of Health and Human Services in a time and manner designated by DHCS or by the Secretary, for purposes of determining DHCS' compliance with the HIPAA regulations. If any information needed for this purpose is in the exclusive possession of any other entity or person and the other entity or person fails or refuses to furnish the information to Business Associate, Business Associate shall so certify to DHCS and shall set forth the efforts it made to obtain the information.

I. Documentation of Disclosures. To document and make available to DHCS or (at the direction of DHCS) to an Individual such disclosures of PHI, and information related to such disclosures, necessary to respond to a proper request by the subject Individual for an accounting of disclosures of PHI, in accordance with the HITECH Act and its implementing regulations, including but not limited to 45 CFR section 164.528 and 42 U.S.C. section 17935(c). If Business Associate maintains electronic health records for DHCS as of January 1, 2009, Business Associate must provide an accounting of disclosures, including those disclosures for treatment, payment or health care operations, effective with disclosures on or after January 1, 2014. If Business Associate acquires electronic health records for DHCS after January 1, 2009, Business Associate must provide an accounting of disclosures, including those disclosures for treatment, payment or health care operations, effective with disclosures on or after the date the electronic health record is acquired, or on or after January 1, 2011, whichever date is later. The electronic accounting of disclosures shall be for disclosures during the three years prior to the request for an accounting.

J. Breaches and Security Incidents. During the term of this Agreement, Business Associate agrees to implement reasonable systems for the discovery and prompt reporting of any breach or security incident, and to take the following steps:

1. Notice to DHCS. (1) To notify DHCS immediately upon the discovery of a suspected security incident that involves data provided to DHCS by the Social Security Administration. This notification will be by telephone call plus email or fax upon the discovery of the breach. (2) To notify DHCS within 24 hours by email or fax of the discovery of unsecured PHI or PI in electronic

media or in any other media if the PHI or PI was, or is reasonably believed to have been, accessed or acquired by an unauthorized person, any suspected security incident, intrusion or unauthorized access, use or disclosure of PHI or PI in violation of this Agreement and this Addendum, or potential loss of confidential data affecting this Agreement. A breach shall be treated as discovered by Business Associate as of the first day on which the breach is known, or by exercising reasonable diligence would have been known, to any person (other than the person committing the breach) who is an employee, officer or other agent of Business Associate.

Notice shall be provided to the DHCS Program Contract Manager, the DHCS Privacy Officer and the DHCS Information Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves data provided to DHCS by the Social Security Administration, notice shall be provided by calling the DHCS EITS Service Desk. Notice shall be made using the "DHCS Privacy Incident Report" form, including all information known at the time. Business Associate shall use the most current version of this form, which is posted on the DHCS Privacy Office website (www.dhcs.ca.gov, then select "Privacy" in the left column and then "Business Use" near the middle of the page) or use this link:
<http://www.dhcs.ca.gov/formsandpubs/laws/priv/Pages/DHCSBusinessAssociatesOnly.aspx>

Upon discovery of a breach or suspected security incident, intrusion or unauthorized access, use or disclosure of PHI or PI, Business Associate shall take:

- a. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment; and
 - b. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.
2. Investigation and Investigation Report. To immediately investigate such security incident, breach, or unauthorized access, use or disclosure of PHI or PI. If the initial report did not include all of the requested information marked with an asterisk, then within 72 hours of the discovery, Business Associate shall submit an updated "DHCS Privacy Incident Report" containing the information marked with an asterisk and all other applicable information listed on the form, to the extent known at that time, to the DHCS Program Contract Manager, the DHCS Privacy Officer, and the DHCS Information Security Officer:
3. Complete Report. To provide a complete report of the investigation to the DHCS Program Contract Manager, the DHCS Privacy Officer, and the DHCS Information Security Officer within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. If all of the required information was not included in either the initial report, or the Investigation Report, then a separate Complete Report must be submitted. The report shall be submitted on the "DHCS Privacy Incident Report" form and shall include an assessment of all known factors relevant to a determination of whether a breach occurred under applicable provisions of HIPAA, the HITECH Act, the HIPAA regulations and/or state law. The report shall also include a full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure. If DHCS requests information in addition to that listed on the "DHCS Privacy Incident Report" form, Business Associate shall make reasonable efforts to provide DHCS with such information. If necessary, a Supplemental Report may be used to submit revised or additional information after the completed report is submitted, by

submitting the revised or additional information on an updated “DHCS Privacy Incident Report” form. DHCS will review and approve or disapprove the determination of whether a breach occurred, is reportable to the appropriate entities, if individual notifications are required, and the corrective action plan.

4. Notification of Individuals. If the cause of a breach of PHI or PI is attributable to Business Associate or its subcontractors, agents or vendors, Business Associate shall notify individuals of the breach or unauthorized use or disclosure when notification is required under state or federal law and shall pay any costs of such notifications, as well as any costs associated with the breach. The notifications shall comply with the requirements set forth in 42 U.S.C. section 17932 and its implementing regulations, including, but not limited to, the requirement that the notifications be made without unreasonable delay and in no event later than 60 calendar days. The DHCS Program Contract Manager, the DHCS Privacy Officer, and the DHCS Information Security Officer shall approve the time, manner and content of any such notifications and their review and approval must be obtained before the notifications are made.

5. Responsibility for Reporting of Breaches. If the cause of a breach of PHI or PI is attributable to Business Associate or its agents, subcontractors or vendors, Business Associate is responsible for all required reporting of the breach as specified in 42 U.S.C. section 17932 and its implementing regulations, including notification to media outlets and to the Secretary. If a breach of unsecured PHI involves more than 500 residents of the State of California or its jurisdiction, Business Associate shall notify the Secretary of the breach immediately upon discovery of the breach. If Business Associate has reason to believe that duplicate reporting of the same breach or incident may occur because its subcontractors, agents or vendors may report the breach or incident to DHCS in addition to Business Associate, Business Associate shall notify DHCS, and DHCS and Business Associate may take appropriate action to prevent duplicate reporting. The breach reporting requirements of this paragraph are in addition to the reporting requirements set forth in subsection 1, above.

5. DHCS Contact Information. To direct communications to the above referenced DHCS staff, the Contractor shall initiate contact as indicated herein. DHCS reserves the right to make changes to the contact information below by giving written notice to the Contractor. Said changes shall not require an amendment to this Addendum or the Agreement to which it is incorporated.

| DHCS Program Contract Manager | DHCS Privacy Officer | DHCS Information Security Officer |
|--|--|--|
| See the Scope of Work exhibit for Program Contract Manager information | Privacy Officer c/o: Office of HIPAA Compliance Department of Health Care Services P.O. Box 997413, MS 4722 Sacramento, CA 95899-7413 Email: privacyofficer@dhcs.ca.gov Telephone: (916) 445-4646 Fax: (916) 440-7680 | Information Security Officer DHCS Information Security Office P.O. Box 997413, MS 6400 Sacramento, CA 95899-7413 Email: iso@dhcs.ca.gov Fax: (916) 440-5537 Telephone: EITS Service Desk (916) 440-7000 or (800) 579-0874 |

K. Termination of Agreement. In accordance with Section 13404(b) of the HITECH Act and to the extent required by the HIPAA regulations, if Business Associate knows of a material breach or violation by DHCS of this Addendum, it shall take the following steps:

1. Provide an opportunity for DHCS to cure the breach or end the violation and terminate the Agreement if DHCS does not cure the breach or end the violation within the time specified by Business Associate; or
2. Immediately terminate the Agreement if DHCS has breached a material term of the Addendum and cure is not possible.

L. Due Diligence. Business Associate shall exercise due diligence and shall take reasonable steps to ensure that it remains in compliance with this Addendum and is in compliance with applicable provisions of HIPAA, the HITECH Act and the HIPAA regulations, and that its agents, subcontractors and vendors are in compliance with their obligations as required by this Addendum.

M. Sanctions and/or Penalties. Business Associate understands that a failure to comply with the provisions of HIPAA, the HITECH Act and the HIPAA regulations that are applicable to Business Associate may result in the imposition of sanctions and/or penalties on Business Associate under HIPAA, the HITECH Act and the HIPAA regulations.

IV. Obligations of DHCS

DHCS agrees to:

- A. Notice of Privacy Practices. Provide Business Associate with the Notice of Privacy Practices that DHCS produces in accordance with 45 CFR section 164.520, as well as any changes to such notice. Visit the DHCS Privacy Office to view the most current Notice of Privacy Practices at: <http://www.dhcs.ca.gov/formsandpubs/laws/priv/Pages/default.aspx> or the DHCS website at www.dhcs.ca.gov (select "Privacy in the left column and "Notice of Privacy Practices" on the right side of the page).
- B. Permission by Individuals for Use and Disclosure of PHI. Provide the Business Associate with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if such changes affect the Business Associate's permitted or required uses and disclosures.
- C. Notification of Restrictions. Notify the Business Associate of any restriction to the use or disclosure of PHI that DHCS has agreed to in accordance with 45 CFR section 164.522, to the extent that such restriction may affect the Business Associate's use or disclosure of PHI.
- D. Requests Conflicting with HIPAA Rules. Not request the Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA regulations if done by DHCS.

V. Audits, Inspection and Enforcement

- A. From time to time, DHCS may inspect the facilities, systems, books and records of Business Associate to monitor compliance with this Agreement and this Addendum. Business

Associate shall promptly remedy any violation of any provision of this Addendum and shall certify the same to the DHCS Privacy Officer in writing. The fact that DHCS inspects, or fails to inspect, or has the right to inspect, Business Associate's facilities, systems and procedures does not relieve Business Associate of its responsibility to comply with this Addendum, nor does DHCS':

1. Failure to detect or
2. Detection, but failure to notify Business Associate or require Business Associate's remediation of any unsatisfactory practices constitute acceptance of such practice or a waiver of DHCS' enforcement rights under this Agreement and this Addendum.

B. If Business Associate is the subject of an audit, compliance review, or complaint investigation by the Secretary or the Office of Civil Rights, U.S. Department of Health and Human Services, that is related to the performance of its obligations pursuant to this HIPAA Business Associate Addendum, Business Associate shall notify DHCS and provide DHCS with a copy of any PHI or PI that Business Associate provides to the Secretary or the Office of Civil Rights concurrently with providing such PHI or PI to the Secretary. Business Associate is responsible for any civil penalties assessed due to an audit or investigation of Business Associate, in accordance with 42 U.S.C. section 17934(c).

VI. Termination

A. Term. The Term of this Addendum shall commence as of the effective date of this Addendum and shall extend beyond the termination of the contract and shall terminate when all the PHI provided by DHCS to Business Associate, or created or received by Business Associate on behalf of DHCS, is destroyed or returned to DHCS, in accordance with 45 CFR 164.504(e)(2)(ii)(I).

B. Termination for Cause. In accordance with 45 CFR section 164.504(e)(1)(ii), upon DHCS' knowledge of a material breach or violation of this Addendum by Business Associate, DHCS shall:

1. Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by DHCS; or
2. Immediately terminate this Agreement if Business Associate has breached a material term of this Addendum and cure is not possible.

C. Judicial or Administrative Proceedings. Business Associate will notify DHCS if it is named as a defendant in a criminal proceeding for a violation of HIPAA. DHCS may terminate this Agreement if Business Associate is found guilty of a criminal violation of HIPAA. DHCS may terminate this Agreement if a finding or stipulation that the Business Associate has violated any standard or requirement of HIPAA, or other security or privacy laws is made in any administrative or civil proceeding in which the Business Associate is a party or has been joined.

D. Effect of Termination. Upon termination or expiration of this Agreement for any reason, Business Associate shall return or destroy all PHI received from DHCS (or created or received by Business Associate on behalf of DHCS) that Business Associate still maintains in any form, and

shall retain no copies of such PHI. If return or destruction is not feasible, Business Associate shall notify DHCS of the conditions that make the return or destruction infeasible, and DHCS and Business Associate shall determine the terms and conditions under which Business Associate may retain the PHI. Business Associate shall continue to extend the protections of this Addendum to such PHI, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

VII. Miscellaneous Provisions

A. **Disclaimer.** DHCS makes no warranty or representation that compliance by Business Associate with this Addendum, HIPAA or the HIPAA regulations will be adequate or satisfactory for Business Associate's own purposes or that any information in Business Associate's possession or control, or transmitted or received by Business Associate, is or will be secure from unauthorized use or disclosure. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.

B. **Amendment.** The parties acknowledge that federal and state laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Addendum may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations and other applicable laws relating to the security or privacy of PHI. Upon DHCS' request, Business Associate agrees to promptly enter into negotiations with DHCS concerning an amendment to this Addendum embodying written assurances consistent with the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations or other applicable laws. DHCS may terminate this Agreement upon thirty (30) days written notice in the event:

1. Business Associate does not promptly enter into negotiations to amend this Addendum when requested by DHCS pursuant to this Section; or
2. Business Associate does not enter into an amendment providing assurances regarding the safeguarding of PHI that DHCS in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and the HIPAA regulations.

C. **Assistance in Litigation or Administrative Proceedings.** Business Associate shall make itself and any subcontractors, employees or agents assisting Business Associate in the performance of its obligations under this Agreement, available to DHCS at no cost to DHCS to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against DHCS, its directors, officers or employees based upon claimed violation of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inactions or actions by the Business Associate, except where Business Associate or its subcontractor, employee or agent is a named adverse party.

D. **No Third-Party Beneficiaries.** Nothing express or implied in the terms and conditions of this Addendum is intended to confer, nor shall anything herein confer, upon any person other

than DHCS or Business Associate and their respective successors or assignees, any rights, remedies, obligations or liabilities whatsoever.

E. Interpretation. The terms and conditions in this Addendum shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA, the HITECH Act and the HIPAA regulations.

F. Regulatory References. A reference in the terms and conditions of this Addendum to a section in the HIPAA regulations means the section as in effect or as amended.

G. Survival. The respective rights and obligations of Business Associate under Section VI.D of this Addendum shall survive the termination or expiration of this Agreement.

H. No Waiver of Obligations. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

Attachment A
Business Associate Data Security Requirements

I. Personnel Controls

A. Employee Training. All workforce members who assist in the performance of functions or activities on behalf of DHCS, or access or disclose DHCS PHI or PI must complete information privacy and security training, at least annually, at Business Associate's expense. Each workforce member who receives information privacy and security training must sign a certification, indicating the member's name and the date on which the training was completed. These certifications must be retained for a period of six (6) years following contract termination.

B. Employee Discipline. Appropriate sanctions must be applied against workforce members who fail to comply with privacy policies and procedures or any provisions of these requirements, including termination of employment where appropriate.

C. Confidentiality Statement. All persons that will be working with DHCS PHI or PI must sign a confidentiality statement that includes, at a minimum, General Use, Security and Privacy Safeguards, Unacceptable Use, and Enforcement Policies. The statement must be signed by the workforce member prior to access to DHCS PHI or PI. The statement must be renewed annually. The Contractor shall retain each person's written confidentiality statement for DHCS inspection for a period of six (6) years following contract termination.

D. Background Check. Before a member of the workforce may access DHCS PHI or PI, a thorough background check of that worker must be conducted, with evaluation of the results to assure that there is no indication that the worker may present a risk to the security or integrity of confidential data or a risk for theft or misuse of confidential data. The Contractor shall retain each workforce member's background check documentation for a period of three (3) years following contract termination.

II. Technical Security Controls

A. Workstation/Laptop encryption. All workstations and laptops that process and/or store DHCS PHI or PI must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as Advanced Encryption Standard (AES). The encryption solution must be full disk unless approved by the DHCS Information Security Office.

B. Server Security. Servers containing unencrypted DHCS PHI or PI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.

C. Minimum Necessary. Only the minimum necessary amount of DHCS PHI or PI required to perform necessary business functions may be copied, downloaded, or exported.

D. Removable media devices. All electronic files that contain DHCS PHI or PI data must be encrypted when stored on any removable media or portable device (i.e. USB thumb drives,

floppies, CD/DVD, smartphones, backup tapes etc.). Encryption must be a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES.

E. Antivirus software. All workstations, laptops and other systems that process and/or store DHCS PHI or PI must install and actively use comprehensive anti-virus software solution with automatic updates scheduled at least daily.

F. Patch Management. All workstations, laptops and other systems that process and/or store DHCS PHI or PI must have critical security patches applied, with system reboot if necessary. There must be a documented patch management process which determines installation timeframe based on risk assessment and vendor recommendations. At a maximum, all applicable patches must be installed within 30 days of vendor release.

G. User IDs and Password Controls. All users must be issued a unique user name for accessing DHCS PHI or PI. Username must be promptly disabled, deleted, or the password changed upon the transfer or termination of an employee with knowledge of the password, at maximum within 24 hours. Passwords are not to be shared. Passwords must be at least eight characters and must be a non-dictionary word. Passwords must not be stored in readable format on the computer. Passwords must be changed every 90 days, preferably every 60 days. Passwords must be changed if revealed or compromised. Passwords must be composed of characters from at least three of the following four groups from the standard keyboard:

- Upper case letters (A-Z)
- Lower case letters (a-z)
- Arabic numerals (0-9)
- Non-alphanumeric characters (punctuation symbols)

H. Data Destruction. When no longer needed, all DHCS PHI or PI must be cleared, purged, or destroyed consistent with NIST Special Publication 800-88, Guidelines for Media Sanitization such that the PHI or PI cannot be retrieved.

I. System Timeout. The system providing access to DHCS PHI or PI must provide an automatic timeout, requiring re-authentication of the user session after no more than 20 minutes of inactivity.

J. Warning Banners. All systems providing access to DHCS PHI or PI must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only by authorized users. User must be directed to log off the system if they do not agree with these requirements.

K. System Logging. The system must maintain an automated audit trail which can identify the user or system process which initiates a request for DHCS PHI or PI, or which alters DHCS PHI or PI. The audit trail must be date and time stamped, must log both successful and failed accesses, must be read only, and must be restricted to authorized users. If DHCS PHI or PI is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least 3 years after occurrence.

L. Access Controls. The system providing access to DHCS PHI or PI must use role based access controls for all user authentications, enforcing the principle of least privilege.

M. Transmission encryption. All data transmissions of DHCS PHI or PI outside the secure internal network must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES. Encryption can be end to end at the network level, or the data files containing PHI can be encrypted. This requirement pertains to any type of PHI or PI in motion such as website access, file transfer, and E-Mail.

N. Intrusion Detection. All systems involved in accessing, holding, transporting, and protecting DHCS PHI or PI that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

III. Audit Controls

A. System Security Review. All systems processing and/or storing DHCS PHI or PI must have at least an annual system risk assessment/security review which provides assurance that administrative, physical, and technical controls are functioning effectively and providing adequate levels of protection. Reviews should include vulnerability scanning tools.

B. Log Reviews. All systems processing and/or storing DHCS PHI or PI must have a routine procedure in place to review system logs for unauthorized access.

C. Change Control. All systems processing and/or storing DHCS PHI or PI must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

IV. Business Continuity / Disaster Recovery Controls

A. Emergency Mode Operation Plan. Contractor must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic DHCS PHI or PI in the event of an emergency. Emergency means any circumstance or situation that causes normal computer operations to become unavailable for use in performing the work required under this Agreement for more than 24 hours.

B. Data Backup Plan. Contractor must have established documented procedures to backup DHCS PHI to maintain retrievable exact copies of DHCS PHI or PI. The plan must include a regular schedule for making backups, storing backups offsite, an inventory of backup media, and an estimate of the amount of time needed to restore DHCS PHI or PI should it be lost. At a minimum, the schedule must be a weekly full backup and monthly offsite storage of DHCS data.

V. Paper Document Controls

A. Supervision of Data. DHCS PHI or PI in paper form shall not be left unattended at any time, unless it is locked in a file cabinet, file room, desk or office. Unattended means that information is not being observed by an employee authorized to access the information. DHCS

PHI or PI in paper form shall not be left unattended at any time in vehicles or planes and shall not be checked in baggage on commercial airplanes.

B. Escorting Visitors. Visitors to areas where DHCS PHI or PI is contained shall be escorted and DHCS PHI or PI shall be kept out of sight while visitors are in the area.

C. Confidential Destruction. DHCS PHI or PI must be disposed of through confidential means, such as cross cut shredding and pulverizing.

D. Removal of Data. DHCS PHI or PI must not be removed from the premises of the Contractor except with express written permission of DHCS.

E. Faxing. Faxes containing DHCS PHI or PI shall not be left unattended and fax machines shall be in secure areas. Faxes shall contain a confidentiality statement notifying persons receiving faxes in error to destroy them. Fax numbers shall be verified with the intended recipient before sending the fax.

F. Mailing. Mailings of DHCS PHI or PI shall be sealed and secured from damage or inappropriate viewing of PHI or PI to the extent possible. Mailings which include 500 or more individually identifiable records of DHCS PHI or PI in a single package shall be sent using a tracked mailing method which includes verification of delivery and receipt, unless the prior written permission of DHCS to use another method is obtained.