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Date: August 17, 2018

Policy Letter 18-01
Supersedes PACE Policy Letter 17-03

To: Program for All-Inclusive Care for the Elderly (PACE) Organizations

Subject: PACE Application Process

Purpose

The purpose of this Policy Letter is to inform Program of All-Inclusive Care for the Elderly (PACE) Organizations (POs) and potential applicant organizations of the updated Department of Health Care Services (DHCS) application review process and timeline for new PO applications and PACE Expansion applications.

Background

In 2016, the California Legislature passed the PACE Modernization Act Trailer Bill (Sections 31-36 of SB 833, Chapter 30, Statutes of 2016) including updates to the payment and regulatory structure of PACE. The updated California PACE statutes, in part, removed the cap on the number of POs that could operate in the state, and allowed for-profit entities to become POs. As a result, DHCS has seen renewed interest in PACE and an increase in new/expansion applications submitted to DHCS for review. Therefore, DHCS is issuing revised guidance to clarify the Department's expectations with respect to the competitive nature of the review process.

The Centers for Medicare & Medicaid Services (CMS) releases annual updates to its PACE Application Guidance to address its electronic PACE application submission timelines, requirements, and review process. Applicants should review this guidance and be aware of CMS requirements for accessing HPMS. The downloadable PDF of the application and additional information can be found at:

<https://www.cms.gov/Medicare/Health-Plans/PACE/Overview.html>

State Application Review Process

All new and expansion PACE applications must go through an initial review process by DHCS in order to move forward with submission to CMS via HPMS. The initial submission components are detailed in this letter, which aims to provide DHCS with key organizational background and financial viability documentation. This information is

necessary for the State to complete/sign the State Assurance pages and authorize the submission of the full application to DHCS and CMS via HPMS.

Upon submission of the full application to CMS, the State will align its review of the remaining application with the CMS initial 45/90-day clock cycle, dependent on type of application, to create a concurrent review process. The initial CMS 45/90-day clock review begins upon receipt of the completed full application in HPMS, which must include the signed State Assurance pages.

DHCS will review the application according to state and federal laws and regulations. Prior to entering into a contract for the provision of Medi-Cal managed health care services, DHCS may consider any factor it determines to be necessary for consideration (Welfare & Institutions Code §§ 14095 and 14592(b)). This includes considering any information relevant to the issue of whether the application could result in unnecessary duplication of services or impair the financial or service viability of an existing program (42 USCA § 1395eee(e)(2)(B)).

Initial State Review

All new and expansion applications received by DHCS will follow the below initial state review timeframes for application submission:

Action	Due Date	Documents for Submission	Reviewer	Review Timeframe
Notification of Intent to DHCS	30 days prior to Initial Application Submission to DHCS	<ul style="list-style-type: none"> • Letter of Intent • Letter for Support from COHS (if applicable) 	DHCS	N/A
Initial Application Submission to DHCS	60 days prior to CMS application submission deadline	<ul style="list-style-type: none"> • Market Feasibility Study • Letters of Support • Application sections (see Attachment 1) 	DHCS	60 Calendar Days
Full Application Submission in HPMS	Align with CMS PACE Application Submission Deadline	<ul style="list-style-type: none"> • Remaining application sections • State Assurance Page 	DHCS/CMS	Align with CMS 45/90 day review clock

Concurrent Federal and State Review

The CMS review process of the PACE Application will include a series of attestations and uploads based on the type of application received, (Initial Application or Service Area Expansion).

Upon completion of the initial CMS 45/90-day clock review of the full application, CMS and/or DHCS may issue a Request for Additional Information (RAI) to the applicant. In the event a RAI is issued, the application is taken off the review clock during this period while the applicant responds to either the CMS and/or DHCS RAI. DHCS will align its remaining review and RAI (if necessary) with CMS timelines and ensure that any necessary changes are communicated to CMS. It is also during this period that DHCS conducts the Readiness Review (RR) onsite survey of the applicant PACE Center, as required. All initial applications and any Service Area Expansion (SAE) application that includes the addition of a new PACE center requires a RR of the new center. All deficiencies that may be identified during the DHCS Readiness Review onsite survey of the applicant PACE Center must be addressed through a corrective action plan submitted and accepted by DHCS.

Once CMS and/or DHCS have accepted the applicant's RAI response and the Readiness Review onsite survey has been completed by DHCS and the applicant and accepted by CMS, CMS will reinitiate the final 45/90-day clock review cycle. Conclusion of this cycle results in CMS notification to the applicant of final approval or denial.

PACE Growth and Expansion

All PACE growth and expansion falls into one of the below categories:

New PACE Organization – New entity applying to establish a PO

- Entity must identify specific zip codes to be served in one or more counties
- Entity must be able to serve all requested zip codes from PACE Center (subject to 60-minute one way travel time adult day health center (ADHC) requirement)
- Rate development required for each county requested

Existing PO Expansion (Existing County) – PO adding additional zip codes within existing county service area, opening a new PACE Center within existing county service area, or both

- Entity must be able to serve all requested zip codes from PACE Center(s) (subject to 60-minute one way travel time ADHC requirement)
- POs can add zip codes and use Alternative Care Settings (ACS) and Community-based physician waiver as an interim step before building new PACE Center
- Consider rate development/adjustment to account for expansion within the county and account for potential variance and/or changes in utilization
- Zip code only expansions subject to shorter CMS review period

Existing PO Expansion (New County) – PO adding zip codes in a new county of operation

- Usually requires a new PACE Center unless the zip codes requested fall within the required radius to be served by existing PACE Center and interdisciplinary team (IDT)
- Requires new rate development

Program Start Date

To align with state budget and rate development processes, all new PO applications and expansion applications requiring new rate development will only be able to begin operations on either January 1 or July 1 of a given year following receipt of final approval from CMS and DHCS. Prospective POs and expansion applicants requiring new rate development should take the available start dates into consideration when preparing to submit an application. Any delays in the application submission or review process may result in the program start getting pushed back to the next available program start date of either January 1 or July 1.

Initial Application Submission Components

Letter of Intent

All applicants must submit a Letter of Intent (LOI) to DHCS indicating their plans to submit a PACE application. The LOI should identify the applicant; the proposed service area, including a listing of proposed zip codes and a service area map; and the proposed site location for the applicant's PACE center. New applicants proposing to serve an area with an existing or pending PACE plan must identify the overlapping zip codes in their LOI. If an applicant has any questions about whether there is an existing or pending PO operating in its proposed service area it can refer to the DHCS PACE website for a listing of all zip codes by county that POs currently operate in at: <http://www.dhcs.ca.gov/individuals/Pages/PACEPlans.aspx>. Pending applications for new or expansion POs will also be posted to the DHCS website.

CMS application submission deadlines can be found under the application training guide here: <https://www.cms.gov/Medicare/Health-Plans/PACE/Overview.html>. The LOI to DHCS must be submitted at least 90 days prior to the proposed CMS submission date and the initial application must be submitted at least 60 days prior to the proposed CMS submission date.

Letters of Support

All PACE applicants must submit letters of support from local entities in the area that the applicant proposes to serve. These may include but are not limited to County Board of Supervisors, County Health and Human Services (HHS) Director, local hospitals, Medi-

Cal managed care plans, Independent Physician Associations (IPAs), Commission on Aging, Area Agencies on Aging (AAA), local Multipurpose Senior Services Program (MSSP) Waiver sites, etc. Letters of support should be attached to the LOI. The minimum requirements for letters of support in County Organized Health System counties is provided below.

Market Feasibility Study

All PACE applicants must submit a market analysis of the area that they propose to serve. The feasibility study should include the following:

- Estimate of the number of PACE-eligible individuals
- Description of the methodology/assumptions used to determine potential membership
- Identify all competitive factors impacting the market, such as:
 - Existing POs
 - Managed care plans (MCPs)
 - Demonstration County MCPs (Cal MediConnect and Managed Long-Term Services and Supports (LTSS))
 - Medi-Cal Waiver Programs
 - In-Home Supportive Services (IHSS)
- Identify projected market capture/saturation rates
- Demonstrate that there is an unmet need for PACE in the proposed service area
 - Please note that when multiple applications are received for the same county/zip code service area the order of submission and number of pre-existing plans may have an impact on the decision to approve / deny an application.

State Application Narrative

The following PACE application sections must be submitted to DHCS for initial review (see Attachment 1):

New PACE Application	Service Area Expansion (Existing and New County)
<ul style="list-style-type: none"> • 3.1 – Service Area • 3.2 – Legal Entity and Organization Structure • 3.3 – Governing Body • 3.4 – Fiscal Soundness 	<ul style="list-style-type: none"> • 3.1 – Service Area • 3.4 – Fiscal Soundness • 3.5 – Marketing • 3.13 – Contracted Services • 3.23 – Transportation Services

In addition to the attestations and documents required in the PACE application, DHCS requires detailed narrative in each of these sections to better understand the organizational background and financial standing of the applicant.

Additional Considerations and Limitations

Overlapping service area

New applicants proposing to enter an area already served by an existing PO must identify the overlapping zip codes in their LOI. DHCS will immediately notify any existing and/or pending POs of the new applicant's intent, and the existing and/or pending PO(s) will have an opportunity to submit their own market analysis in response. The counter-analysis must be submitted to DHCS by the initial application submission date. Overlapping service areas are determined at the zip code level. Therefore, if a PO is only servicing a portion of a county and a new or expansion application is requesting a zip code not in the POs service area, by zip code, then the new or expansion application would not trigger notification to the existing/pending PO for an overlapping service area competing market analysis.

DHCS will conduct its own analysis using Medi-Cal data to verify the market feasibility studies that applicants/POs submit. DHCS will evaluate actual numbers of Medi-Cal beneficiaries by age and aid code and will use historical trends of clinical eligibility and market capture to compare against market analyses submitted by applicants/existing POs.

DHCS, in consultation with other State Administering Agencies, has developed a review tool to assist in considering prospective PO applications and the overlapping service area they propose to enter. The review tool is included as Attachment II (Service Area Overlap Review Criteria) to this letter. DHCS will take all factors into consideration and ultimately decide whether to move forward with signing the State Assurance page.

Restrictions on Delegation

DHCS is using this PACE Policy Letter to provide explicit clarification to its policy on the use of delegation in the PACE model. DHCS prohibits existing and applicant POs from delegating a separate entity to operate existing and/or additional (expansion) PACE Centers and IDTs. POs are responsible for coordinating and delivering the medical and long term care of frail and vulnerable elderly Californians so that they can remain living safely in their community rather than receiving institutional care. Because of the complexity of this responsibility, the Department has serious concerns with arrangements to delegate the administration of a PACE Center or PACE IDT to third parties. DHCS intends to amend its PACE contracts to include this prohibition. The validity of the DHCS concerns regarding delegation in the PACE model are reflected in the Responses of CMS to Comments presented in the Federal Register, Volume 71, No. 236, pages 71247 to 71263, and 71270 to 71272, regarding Title 42, Code of Federal Regulations, parts 460.60, 460.70, and 460.71.

There is one existing delegated delivery model within PACE in California. The On Lok delegation contract with the Institute of Aging was originally established on August 1, 1996. This model was identified as a contractual arrangement in place on or before July 1, 2000, and was confirmed as “grandfathered” in by CMS in a January 15, 2002, letter. Grandfathering was necessary as the arrangement was not explicitly allowed under the PACE permanent provider regulations at that time.

While DHCS explicitly prohibits full delegation of the fundamental program elements of operation of the PACE Center and IDT, POs have the ability to subcontract for any service(s), as determined necessary by the IDT, to ensure that all services necessary to maintain a participant in their home/community are accessible by the PO. POs may enter into subcontracting agreements using the PACE Subcontract Boilerplate template provided by DHCS. Any amendments to the boilerplate template require the Department’s prior written approval.

Please note that DHCS’ prohibition on the use of delegation in PACE does not impact POs option to utilize alternative care settings (ACS). An ACS is any physical location in the POs approved service area other than the participant’s home, an inpatient facility, or PACE Center. A PACE participant receives some (but not all) PACE Center services at an ACS on a fixed basis during usual and customary PACE center hours of operation. An ACS cannot replace a PACE Center and all PACE participants receiving services at an ACS must be assigned to a PACE Center and IDT.

POs in County Organized Health System Counties

Counties that provide Medi-Cal services through a County Organized Health System (COHS) are the sole source for Medi-Cal services in that county. Specifically, Welfare & Institutions code §14087.5 et seq. provides that counties that elect to organize as COHS hold the exclusive right to contract for Medi-Cal services in those counties. DHCS will only consider the operation of a third party PO in a COHS county if the applicant includes a COHS’ letter of support that includes the following:

- The COHS’s support for the establishment of the independent PO in the county, and;
- The COHS request that DHCS submit an amendment to the 1115 Waiver to allow the independent operation of a specified PO in the county.

The COHS letter of support should be included with the LOI submitted by the applicant organization signifying its intent to expand into a COHS county or to start a new PO in a COHS county. DHCS will ultimately decide whether to move forward with a PACE applicant in a COHS and recommend an 1115 Waiver amendment. Any recommendation from DHCS will be subject to CMS review and approval. In the instance that independent operation of a third party PO is approved, the third party PO must contract directly with the State (DHCS) and CMS as the PACE entity in the three-way program agreement. It is not acceptable for the COHS to contract with DHCS and CMS as the PACE entity in the three-way program agreement and delegate operation of the PO to a separate entity.

This policy reflects the process that was utilized to approve the operation of Redwood Coast PACE in Humboldt County. Redwood Coast PACE was approved to operate independently from the COHS because its PACE application was submitted and accepted prior to the launch of the rural Medi-Cal managed care expansion. The COHS (Partnership Health Plan) endorsed the Redwood Coast PACE application and the exception was made possible by an amendment to California's existing 1115(a)(1) Bridge to Reform Demonstration Waiver.

Licensing

PACE Centers must maintain both a Primary Care Clinic License and an ADHC License. POs must also choose to either maintain a Home Health Agency (HHA) License or contract with a licensed HHA for home health services. Assembly bills 847 (Chapter 315 of 2005) and 577 (Chapter 456 of 2009) established the authority for CDPH/DHCS to authorize exemptions to a PO from licensing and regulatory requirements applicable to clinics, adult day health care services, and home health agencies. If requesting exemption from licensure, a PO must maintain at least one of the PACE Center required licenses (Clinic or ADHC) for each PACE Center. Applicants should consult with the California Department of Public Health (CDPH) to verify licensing requirements. CMS will not accept State Readiness Review until all required licenses are secured. Licensure applications can be found at: <https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/ApplyForLicensure.aspx> .

Replacement PACE Centers

Existing POs may move locations or consolidate PACE Center sites by constructing a replacement PACE Center. This scenario is distinct from the construction of a new PACE Center, which requires the submission of a service area expansion application. Replacement Centers require the following transition planning items:

- Administrative Notifications: Notify CMS and DHCS at least 120 days prior to projected transition date.
- Transition Plan: PO's must submit a detailed transition plan that outlines the occupancy timeline, replacement center capacity, contingency planning, transportation plan, notification to participants, and details of any changes in staffing, policies and procedures, etc.

POs seeking to replace its PACE Center(s) should refer to CMS guidance released on October 21, 2016 that provides further detail on the requirements for transition. Replacement Centers are not subject to the January 1 or July 1 start dates.

If you have any questions regarding the requirements of this Policy Letter, please contact your Integrated Systems of Care contract manager.

Sincerely,

ORIGINAL SIGNED BY

Sarah Eberhardt-Rios, Division Chief
Integrated System of Care Division

Enclosures

Attachment 1
Attachment 2

Attachment I - PACE Application Required Attestations and Uploads

Attestation Topic	Section #	Initial	SAE	Upload Required (Initial)	Upload Required (SAE)
Service Area	3.1	X	X	X	X
Legal Entity and Organizational	3.2	X	X	X	X
Governing Body	3.3	X	X	X	X
Fiscal Soundness	3.4	X	X	X	X
Marketing	3.5	X	X	X	X
Explanation of Rights	3.6	X	X	X	X
Grievance	3.7	X	X	X	X
Appeals	3.8	X	X	X	X
Enrollment	3.9	X	X	X	X
Disenrollment	3.10	X	X	X	X
Personnel Compliance	3.11	X	X		
Program Integrity	3.12	X	X		
Contracted Services	3.13	X	X		
Required Services	3.14	X	X		
Service Delivery	3.15	X	X		
Infection Control	3.16	X	X		
Interdisciplinary Team	3.17	X	X		
Participant Assessment	3.18	X	X		
Plan of Care	3.19	X	X		
Restraints	3.20	X	X		
Physical Environment	3.21	X	X		
Emergency and Disaster	3.22	X	X		
Transportation Services	3.23	X	X		
Dietary Services	3.24	X	X		
Termination	3.25	X	X	X	X
Maintenance of Records &	3.26	X	X		
Medical Records	3.27	X	X		
Quality Assessment Performance Improvement	3.28	X	X	X	X
State Attestations	3.29	X	X	X	X
Waivers	3.30	X	X	X (as applicable)	
Application Attestations	3.31	X	X	X	X
State Readiness Review	3.32	X	X (as applicable)	X	X (as applicable)

Attachment II: Service Area Overlap Review Criteria

This tool identifies criteria that DHCS will take into consideration when evaluating applications requesting overlap of existing PACE service areas. DHCS is not limited to the use of only this criteria and will take under consideration additional factors as it determines appropriate to fully assess the application. DHCS will take all factors into consideration and ultimately decide whether to move forward with signing the State Assurance page.

Category	Subcategory	Criteria
Service Area Overlap with Existing PACE Operator	Service Area Overlap	Overlap includes less than 25% of potential participants in existing service area
		Overlap includes between 25% and 50% of potential participants in existing service area
		Overlap includes between 50% and 75% of potential participants in existing service area
		Overlap includes over 75% of potential participants in existing service area
	Facility Overlap	Proposed service area includes existing PACE facility or alternative care setting
		Proposed service area does not include existing PACE facility or alternative care setting
Level of Success & Investment of Existing PACE Operators/ Applicants	Market Penetration of Existing Operators in Proposed Service Area	Market penetration under 10%
		Market penetration between 10% and 30%
		Market penetration over 30%
	Recent Investments by Existing PACE Operator(s) and Recent Applicant(s) in Proposed Service Area	Facility investment over \$5M in the past year
		Facility investment over \$5M between 1 and 2 years
		Facility investment over \$5M between 2 and 3 years
No facility investments over \$5M in last 3 years		
Local Support	Local Government Support	Formal vote of city council or comparable body in support of new applicant
		Letter of support from city council member or comparable official
		No written support from local government official
	Local Service Provider Involvement	Lead applicant is a services provider in proposed service area
		Supporting applicant is a services provider in proposed service area
		No part of applying entity is services provider in proposed service area