

DATE: July 12, 2023 Policy Letter 23-02

TO: Program of All Inclusive Care for the Elderly (PACE) Organizations

SUBJECT: APPROVAL PROCESS FOR OPERATING PRIMARY CARE CLINICS, ADULT DAY HEALTH CARE CENTERS, AND HOME HEALTH AGENCIES UNDER AB-1128

PURPOSE

This policy letter outlines the process for current and prospective PACE organizations (PO) to obtain approval from the Department of Health Care Services (DHCS) to operate a primary care clinic (PCC),¹ Adult Day Health Care (ADHC),² and/or a Home Health Agency (HHA)³ serving only PACE participants and applicants, as authorized by California Welfare & Institutions Code (WIC) 14592(c).⁴

Effective January 1, 2021, PCCs, ADHCs, and HHAs that exclusively serve PACE participants are exempt from the Health & Safety Code (HSC) requirements to obtain a license from the California Department of Public Health (CDPH), and must instead obtain approval to operate from DHCS, and shall operate under the regulation and oversight of DHCS pursuant to WIC section 14592(c).

To obtain approval to operate from DHCS, such PCCs, ADHCs, and HHAs must demonstrate compliance with the licensing requirements set forth in the HSC and implementing regulations, subject to any modifications specified by DHCS through policy letter to meet the needs of PACE participants or those individuals being assessed. Once DHCS issues its approval, DHCS will continue to regulate and oversee the operations of such PCCs, ADHCs, and HHAs in compliance with those same standards.

DHCS requires PCCs operated by POs not subject to CDPH licensing requirements (such as those operated by for-profit POs), to operate in compliance with the HSC licensing standards and implementing regulations, subject to any modifications specified by DHCS through policy letter.

BACKGROUND

Historically, POs subject to the jurisdiction of the HSC for the licensing of PCCs were required to maintain both a PCC and an ADHC license through CDPH. HSC section 100315 authorizes CDPH and DHCS to process exemptions from specific HSC

¹ Health & Safety Code (HSC) section 1200(b)(1).

² HSC section 1570.7(b).

³ HSC section 1727 (a).

⁴ Welfare and Institutions Code (WIC) section 14592(c).



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licensing statutes and regulations for PCCs, ADHC centers, and HHAs if those statutes and regulations are duplicative, conflicting, or inconsistent with PO requirements. However, if a PO requested an exemption from licensure entirely, the PO was still required to maintain either the PCC or ADHC license for each PACE center.

POLICY

If a currently operational PO serves only PACE participants⁵ in its PCC, ADHC, or HHA, then the PCC, ADHC, or HHA operated exclusively by the PO is exempt from licensure by CDPH and is overseen and regulated by DHCS under WIC section 14592(c).

If the PO currently serves or plans to serve populations in addition to PACE participants in PCCs, ADHCs, or HHAs it operates, the PO will not fall within the scope of WIC section 14592(c) and must obtain and/or maintain each legally required license through CDPH and is subject to oversight and regulation by CDPH under the HSC licensing statutes and regulations.

Any full exemption to ADHC or PCC licensure previously approved by CDPH and DHCS under HSC section 100315 has already been determined to meet the WIC section 14592(c) criteria, as settings exclusively serving PACE participants. These ADHC and PCC settings, are now subject to DHCS oversight and regulation under WIC section 14592(c).

Program Flexibilities

For POs that fall under the DHCS oversight and regulation according to WIC section 14592(c), DHCS will reevaluate any previously approved program flexibilities (also known as Program Flexes) to determine if they should be extended under the terms of WIC section 14592(d).

Such POs will need to identify to DHCS any currently approved program flexibilities for the licenses formerly held with CDPH. New program flexibility requests for PCCs, ADHCs and HHAs that are operating under the DHCS authority must be submitted directly to DHCS for review and approval.

DHCS only has statutory authority to approve regulation flexibilities to meet the needs of PACE participants or those individuals being assessed, per WIC section 14592 (d). DHCS will work with POs to identify applicable program wide flexibilities necessary to meet PACE participant needs and will document these flexibilities in a separate policy letter.

PO-operated PCCs, ADHCs, and HHAs that maintain CDPH licensure will continue to request specific licensure program flexibilities through the current process under HSC section 100315, by submitting required documentation through DHCS for CDPH review and approval.

⁵ Including individuals being assessed for enrollment in the PACE program as defined in WIC section 14592(c)(1)

Transfer Process for POs with an Existing CDPH License

The following process governs the transfer of POs with existing CDPH licensure to DHCS oversight and regulation under WIC section 14592(c):

- If a PO determines that its PCC, ADHC, and/or HHA licensed by CDPH is currently exclusively serving PACE participants and has no intention of serving non-PACE participants in the future, it must relinquish its CDPH license to CDPH.
- Prior to the license being relinquished, the PO must submit notification to DHCS of that determination to relinquish license(s) and after review and confirmation, DHCS will communicate to CDPH when the PO has met all requirements for approval to operate under WIC section 14592(c).
- Any outstanding fee due to CDPH must be paid prior to the relinquishing of a license.
- Any application submitted to CDPH for REPORT OF CHANGE/INITIAL/CHOW must be withdrawn prior to the relinquishing of a license.
- Upon receipt of the communication from DHCS, CDPH will instruct the PO to surrender its CDPH license. At that time, the PCC, ADHC, or HHA operated exclusively by the PO will become subject to DHCS oversight and regulation under WIC section 14592(c) and will then pay the appropriate Administrative Fee to DHCS as required under WIC section 14592(n).
- If at a later date the PO decides that it will begin serving people other than PACE participants through its PCC, ADHC, and/or HHA, it would fall within CDPH licensing jurisdiction. The PO must start the licensing process over and re-apply for a license from CDPH before serving non-PACE participants. To start the process, the PO must notify their ISCD contract manager of the decision to seek licensure through CDPH. The PO must then submit a new initial licensing application to CDPH and complete the entire license application process with CDPH before serving non-PACE participants. It is the responsibility of the ADHCs, HHAs, and PCCs or the POs that operate them to inform DHCS if it is exclusively serving PACE participants and therefore qualifies for an exemption from CDPH licensing requirements.
- For provider instructions, checklists, sample applications, application packets, and tutorial videos for guidance when completing application packets, visit the [CDPH Licensing and Certification Program website](#).

The language of WIC section 14592(c) does not provide for ADHCs, HHAs, and PCCs, or the POs that operate them, to operate under both CDPH licensure and DHCS oversight and regulation on the basis that they intend to serve non-PACE participants in the future.

DHCS will be the point of contact for POs if a transfer between DHCS or CDPH authority is at issue.

Restrictions to the Transfer Process

If any of the following have occurred with respect to a CDPH license, DHCS will not approve the PO PCC, ADHC, or HHA to operate under WIC section 14592(c) until the issue has been resolved with CDPH:

- If a license has been revoked;
- If a PO has an active or open investigation;
- If a PO has a significant Plan of Correction with CDPH that has not been resolved;
- If a PO has any unpaid fees or penalties with CDPH.

Application Process for New PACE Organizations and Service Area Expansion Applications with PCCs, ADHCs, and HHAs Serving Only PACE Participants

DHCS has established a process to verify that each PCC, ADHC, and HHA setting applying to DHCS for approval to operate under WIC section 14592(c) meets the applicable licensure standards, as defined by the ADHC licensure statutes and regulations,⁶ PCC licensure statutes and regulations,⁷ and HHA licensure statutes and regulations.⁸

Entities applying to DHCS for approval to operate a PCC, ADHC, and/or HHA serving only PACE participants must take the following steps:

- Include in the Letter of Intent (LOI) submitted to DHCS, in accordance with the process established in the current PACE Application Process PL, specification that it intends to operate a PCC, ADHC, or HHA that exclusively serves PACE participants.
- Include in the PACE application submitted to DHCS, the DHCS PACE application checklist (see attachment).
- Submit all applicable licensure checklists (see Attachments) and desk review materials required for the State Readiness Review (SRR) to DHCS 90 days in advance of the planned SRR date.

For a PACE Organization with multiple locations, the HHA license exemption will be granted at the PACE Organization level.

WIC section 14592(c) sets forth the initial application process spelled out in in the PACE Application Process PL and addresses PCC, HHA, and ADHC requirements that must be met under the DHCS oversight and regulation authority. As part of the application approval process, DHCS will conduct an onsite and desk review of the PCC, ADHC or

⁶ HSC division 2, chapter 1, section 1200; California Code of Regulations, title 22, division 5, chapter 10

⁷ HSC division 2, chapter 1, section 1200; California Code of Regulations, title 22, division 5, chapter 7

⁸ HSC division 2, chapter 1, section 1200; California Code of Regulations, title 22, division 5, chapter 6

HHA to verify compliance with applicable standards, that will occur concurrently with the SRR process.

DHCS will not sign off on a SRR until the PO has identified an acceptable corrective action plan for all findings identified in the SRR. The Centers for Medicare and Medicaid Services (CMS) will not accept a signed SRR as part of the request for additional information (RAI) response necessary to start the second 90-day review period, unless it includes verification of all licensures required by the state or confirmation of exemption from licensure.

Once the SRR process has been completed, DHCS will provide the PO with a “Certification of DHCS Approval to (Operate Primary Care Clinic/Adult Day Health Care Center/Home Health Agency) for PACE Participants Only” notice, that must be posted by the PO in the applicable PCC, ADHC, or HHA setting space.

Alternative Care Setting Process

POs requesting a concurrence letter from DHCS for a new Alternative Care Setting (ACS) that will be serving only PACE participants, specific to ADHC and PCC settings, shall fall under the DHCS authority for oversight and regulation under WIC section 14592(c). The ACS request should be submitted to DHCS 60 days prior to a CMS submission. POs should continue to follow the CMS ACS guidance memo dated December 5, 2014, that states that the concurrence letter from the state should be submitted to CMS 30 days prior to the ACS opening its doors. This ACS process will be similar to the SRR process and will include both a desk review and an on-site review by DHCS. The desk review and on-site review will pertain to the documents specifically related to the ACS.

Background Check and Finger Printing

ADHCs and HHAs subject to DHCS oversight and regulation under WIC section 14592(c) must satisfy the background check requirements set forth in WIC section 14592(f) and (g). During the request for additional information (RAI) period and before the second 90-day CMS window, DHCS will provide POs with the Request for Live Scan Service form (BCIA 8016). POs will complete the form and submit to a live scan operator including all applicable fees. DHCS will notify the PO once clearance from the Department of Justice (DOJ) has been received.

Medi-Cal Certification Process

The current Medi-Cal certification process through CDPH will not change. If a new PO determines they want to be certified, CDPH will process the certification paperwork.

For POs with a PCC, ADHC, and/or HHA that serves people not enrolled in a PO, going through the Medi-Cal certification process is still required in order to bill DHCS for non-

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PACE participants. When submitting the initial licensing application to CDPH, the PO will need to identify that they are also requesting to become Medi-Cal certified and submit the appropriate certification documents with the application packet.

DHCS Administrative Fees Schedule

In accordance with WIC section 14592(n), POs must pay an annual administrative fee to DHCS to operate the PCC, ADHC, and/or HHA under WIC section 14592(c). For details regarding the DHCS administrative fees schedule, refer to Policy Letter 22-03 AB1128 Fees Collection.

Complaints Process

All Complaints regarding PCCs, ADHCs, and HHAs operating under the DHCS regulatory and oversight authority established in WIC section 4592(c) regardless of complaint source, are to be submitted directly to DHCS at PACECompliance@dhcs.ca.gov. This includes, but is not limited to, complaints from participants, relatives, participants, an organization's staff, a health care facility's staff, etc.

If you have any questions regarding the requirements of this Policy Letter, please contact your DHCS-ISCD Contract Manager.

Sincerely,

ORIGINAL SIGNED BY

Cortney Maslyn
Division Chief
Integrated System of Care Division
Department of Health Care Services

Enclosures

Attachment I – PACE Application Checklist
Attachment II – ADHC Checklist
Attachment III – PCC Checklist
Attachment IV – HHA Checklist
Attachment V – Request for PACE Flex
Attachment VI – CMS ACS Guidance Memo dated December 5, 2014
Attachment VII – HPMS Memo PACE ACS June 30, 2016