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Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM

September 12, 2024

VIA ELECTRONIC MAIL

Attn: Joy Yegoyan, CEO
Synergy Dialysis LLC
16030 Ventura Blvd., Suite 110
Encino, CA 91436

RE: Response to Petition (P-24-03) Requesting Rulemaking for Congregate Health Facilities to offer Home Hemodialysis to Dialysis Patients

Dear Joy Yegoyan,

Thank you for contacting the California Department of Public Health (CDPH) on behalf of Synergy Dialysis LLC. Under Government Code section 11340.6, any interested person may petition CDPH requesting the adoption, amendment, or repeal of a regulation. On August 15, 2024, CDPH received Synergy Dialysis's (Petitioner) petition requesting rulemaking regarding home hemodialysis services for patients in congregate living health facilities. CDPH recognizes the importance and complexity of the issues Petitioner raises. As set forth below, CDPH is, however, denying Petitioner's request.

Summary of Petitioner's Request:

Petitioner requests that CDPH take rulemaking or other regulatory or quasi-regulatory action to allow home dialysis in congregate living health facilities (CLHFs). CDPH understands the petition to specifically request that CDPH perform at least one of the four following actions:

1. Amend the California Code of Regulations, title 22, to authorize congregate living health facilities (CLHFs) to offer home dialysis as an optional service;
2. Amend the California Code of Regulations title 22, section 70351, to authorize CLHFs to obtain a "special permit" to offer home dialysis services;
3. Extend AFL-20-66.1 to include CLHFs as providers of home dialysis; and/or
4. Create a pilot program or issue a special permit or special permission authorizing Synergy Dialysis to offer home hemodialysis services in CLHFs.

To support its request, Petitioner notes that transportation of high acuity CLHF residents for off-site hemodialysis three times per week results in poorer quality of care due to transportation hazards and disruptions, inferior clinical outcomes, and high costs.

Reasons CDPH is Denying the Petition:

1. CDPH denies Petitioner's request to amend the California Code of Regulations (CCR), title 22, to authorize Congregate Living Facilities to offer home dialysis.

CDPH does not have the authority to amend California Code of Regulations, title 22, section 72401, to authorize CLHFs to provide home dialysis as an optional service. Sections 72401 through 72457 broadly regulate optional services that skilled nursing facilities may provide. Under Health and Safety Code section 1267.13, subdivision (n), CLHFs generally must "conform to regulations contained in Chapter 3 [skilled nursing regulations]. But this statute also expressly excludes CLHFs from these regulations allowing skilled nursing facilities to offer optional services, including 72401 *et seq.*

Although CDPH has the authority to amend the California Code of Regulations, the Health and Safety Code can only be amended through the legislative process. And CDPH may not make regulatory amendments that conflict with statutes. Therefore, CDPH lacks the authority to make this regulatory amendment.

2. CDPH denies Petitioner's request to amend California Code of Regulations, title 22, division 5, chapter 1, article 5, sections 70351 or 70042 to authorize CLHFs to receive a "special permit" to offer home dialysis services.

CDPH does not have the authority to amend California Code of Regulations, title 22, sections 70351 or 70042, to authorize CLHFs to receive a "special permit" to offer home dialysis. Section 70042 lists those license categories subject to chapter 1 and does not include CLHFs. CLHFs are not subject to the regulations in title 22, division 5, chapter 1, "General Acute Care Hospitals." Rather, as noted above, CLHFs are subject to the regulations in title 22, division 5, chapter 3, "Skilled Nursing Facilities." (Health & Saf. Code, §§ 1267.13, subd. (n).) Amending chapter 1, specifically California Code of Regulations, title 22, section 70351 or 70042, to include CLHFs would conflict with Health and Safety Code section 1267.13, subdivision (n). As previously noted, CDPH may not amend a regulation if doing so would conflict with a statute. Therefore, CDPH lacks the authority to make this amendment.

3. CDPH denies Petitioner's request to extend AFL-20-66.1 to include CLHFs as providers of home dialysis.

CDPH does not have the authority to extend AFL 20-66.1 to allow home hemodialysis services in CLHFs. AFL 20-66.1 summarizes updated federal guidance allowing dialysis facilities meeting certain standards to provide dialysis services to skilled nursing residents in the skilled nursing facility "home" setting. AFL 20-66.1 explains, "SOM Chapter 2, section 2271 ... and Appendix PP, section 483.25(l) ... issue specific requirements for dialysis facilities and SNFs for the administration of dialysis care to

SNF residents.” This federal guidance does not include CLHFs. Therefore, CDPH lacks the authority to include CLHFs in this AFL.

4. CDPH denies Petitioner’s request for a regulatory pilot program, special permit, or special permission authorizing Synergy Dialysis to offer home dialysis services in CLHFs.

CDPH cannot lawfully address Synergy Dialysis’s request for special permission to provide home dialysis in CLHFs through the petition process. The petition process is for adopting, amending, or repealing regulations under the authority of law. There is no law permitting Synergy Dialysis to be afforded special permissions. Absent such a law, it would be impractical and inequitable for CDPH to specify Synergy Dialysis in regulations.

Department Contact

Under Government Code section 11340.7, subdivision (d), any interested person has the right to obtain a copy of the petition submitted to the agency. A copy of the petition and this letter will be posted on the CDPH Office of Regulations website at the following:

https://www.cdph.ca.gov/Programs/OLS/Pages/Petitions_for_Regulatory_Action.aspx

In addition, interested persons may request a copy by contacting the Office of Regulations by email: regulations@cdph.ca.gov, by phone: (916) 558-1710, or by mail: California Department of Public Health, 1415 L Street, Suite 500, Sacramento, CA 95814.

If you have any questions, please contact me at drew.brereton@cdph.ca.gov. Thank you.

Sincerely,



Drew Brereton
Deputy Director and Chief Counsel
Office of Legal Services

cc:

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