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August 09, 2024

Via Electronic Mail

Tomás Aragón, M.D., D.Ph..  
Director and Public Health Officer  
California Department of Public Health (CDPH)  
1615 Capitol Avenue, MS 0503  
Sacramento, CA 95899-7377

Re: CDPH Should allow Congregate Health Facilities to offer Home Hemodialysis to Dialysis Patients

Dear Dr. Aragón:

Synergy Dialysis hereby submits its official petition according to the criteria listed in Government Code Section 11340.6 to amend portions of Title 22 of the California Code of Regulations to include in the Congregate Living Facilities (CLHFs" to allow bedside Home Dialysis.

We understand that home dialysis has expanded under CMS guidelines, and this is uncharted territory for all of us. We have been experiencing responses from CDPH surveyors that have stated, "dialysis is absolutely not allowed in Congregates... it is dangerous!" and a CLHF received a threat of "having their license revoked" if they "continue to pursue Home dialysis to be added to their license."

However, Congregate patients should have the choice to dialyze AT "HOME"... their HOME, which is the CONGREGATE Facility.

We do not understand these responses to refuse this critical need as transporting these high acuity patients back and forth to a chronic facility three (3) times a week is extremely dangerous and costly. This is especially more confounding given the fact that CLFs have a higher acuity staff level and a higher ratio of medical staffing to patient than the chronic dialysis facilities. These facilities have the equipment and high-level training to manage any patient emergency during dialysis just as the skilled nursing facilities and the chronic facilities do. Therefore, it is nonsensical that these facilities are treated differently than similarly operating facilities under the law.

Under Title 22 (see below), there are options we would like to explore to make this much needed service certifiable and available to the patients at the Congregates, and we are willing to be a pilot to give valuable feedback in order to regulate this.

**Who are we?**

Synergy Dialysis LLC is a specialty provider of home-based treatments for dialysis patients that implements the core principles of raising the standards for clinical excellence while enhancing the quality of life of dialysis patients. Through innovation, collaboration, and expertise, we are committed to providing safe, high-quality care with excellent service and exceptional outcomes.

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Our goal is that patients be treated with respect and compassion, and to have accommodations that help to improve this life-changing ordeal. Every patient should have the option of HOME bedside dialysis, including those residing in the Congregate Living Health Facilities.

Synergy's mission ---We believe in doing the right thing, for the right reason, all the time. We understand that we have a unique opportunity to make a positive impact and help change the lives of people on dialysis. We recognize that patient care is about more than improving health, it is about restoring their quality of life – and everything we do is with that in mind.

Synergy is and will always continue to be an advocate for kidney care patients.

### **Why is our Petition important?**

The benefits of performing dialysis at the bedside for patients that are in a facility are exponential and critically needed. Patients are able to spend the time receiving valuable rehabilitation services at home in the CLHF instead of:

- The long wait times for transportation to pick up and drop off in addition to the dangerous fall risk
- Patient Injury & discomfort due to inclement weather
- Time spent in traffic to and from the chronic dialysis unit on a gurney (especially with excruciating decubitus ulcers)
- 3-4 hours away from “home” on dialysis three times a week when they could be rehabilitating
- Expensive transportation costs
- Patient may be too sick for transport
- Disruption to care (rehab, meds, meals, & socialization)
- Patients limited to three times/week therapy
- Potential breakdown in the coordination of care
- Missing meals during these times away from their home facility
- **Decreased** hospitalizations and readmissions (saving the state hundreds of thousands of dollars).
- Better clinical outcomes
- Patient's body recovery time of 1 hour vs 8 hours recovery time after a chronic dialysis session

Additionally, bedside dialysis saves the state about \$12,000+ per month (\$144,00 annually). Why wouldn't the department want to save this amount per patient if the facility requesting the program flexibility demonstrates its ability to meet statutory requirements? Not to mention the cost to the state that will also be eliminated as transportation costs are approximately \$500 each way. Furthermore, bedside dialysis would save the government a significant amount of healthcare costs. The national estimated cost of dialysis transportation is nearly \$3.6 billion. The cost per dialysis patient per year is estimated to be about \$93,000. These costs would become non-existent in future if bedside dialysis were included.

Given the numerous benefits to patient care and government costs we genuinely believe we have justification for this essential and lifesaving service.

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It is exceedingly difficult to express and create an understanding about this issue unless you see it firsthand. We would like to invite you and your team to meet at the Congregate to speak with the patients directly about the impact this change would have on their rehabilitation and recovery.

### **What is the current legal landscape?**

At present, Title 22 regulations prohibit California Congregate Living Facilities from offering home dialysis to its patients. Currently, they must depend on unreliable transportation companies along with the other risks stated above. As a result, Title 22 stands in the way of these patients having the same options as any other dialysis patient- to dialyze in the safe and private environment of their own HOME.

AFL 20.69.1, states, "The provision of home dialysis services in SNFs as an optional service that is allowed by state regulation," and the service may be added to the facility's license. However, under the **H&SC 1267.13 (n) and Title 22, CCR Section 72401**, Optional Services is not applicable to CLHFs. Therefore, CLHFs are not authorized to provide dialysis services as an optional service. (The CLHF will not be "providing dialysis services as an optional service." We, the certified Home Dialysis Program, will be providing these mandatory and essential services in accordance with law.)

"Congregate Living Health Facilities (CLHF) are required to act in accordance with CCR, Title 22, Skilled Nursing Regulations, except as specified in H&SC § 1267.13 (n). Delivery of dialysis services may be provided as an optional service in Skilled Nursing Facilities, pursuant to title 22 CCR section § 72401, and the service must be added to the facility's license. However, under H&SC 1267.13 (n), 22 CCR § 72401 is expressly not applicable to CLHFs.

Congregate living health facilities (CLHFs) are not authorized to provide or arrange home dialysis services in the facility. While CLHFs are required to conform to regulations governing SNFs, HSC section 1267.13(n) exempts conformance to specific regulations, including Title 22 CCR 72401; thus, CLHFs are not authorized to provide or administer optional services, including in-facility dialysis treatments provided by a home dialysis service.

AFL 20-66.1 provides updated guidelines for the provision of hemodialysis and peritoneal dialysis services in skilled nursing facilities (SNFs) as optional services authorized by Title 22 California Code of Regulations (CCR) section 72401. This AFL is not applicable to CLHFs because CLHFs are not authorized to provide or administer optional services.

CHLFs are unable to pursue a pathway for a special permit. As defined in HSC section 1251.5, a special permit is "a permit issued in addition to a license, authorizing a health facility to offer one or more of the special services specified in Section 1255 when the state department has determined that the health facility has met the standards for quality of care established by state department pursuant to Article 3 (commencing with Section 1275)".

Special permits are only applicable to general acute care hospitals offering one or more special services after CDPH determines that the facility has met the established standards of quality care, which include, but are not limited to the following services (HSC section 1255):

- Radiation therapy department
- Burn center
- Emergency center

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- Hemodialysis center (or unit)
- Psychiatric
- Intensive care newborn nursery
- Cardiac surgery
- Cardiac catheterization laboratory
- Renal transplant
- Other special services as the department may prescribe by regulation

### **What types of regulatory changes are sought now?**

We would like to point out the following codes and standards that are left open to interpretation and not specifically disallowing Home Dialysis in the CLHF:

Pursuant to California Health and Safety Code 1267.13, a Congregate “(c) Facilities shall be in a **homelike residential setting.**” CLHF standards are found in H&S Code, Section 1267.13.

In addition to these standards, CLHF’s are required to conform to CCR, Title 22, **Skilled Nursing Regulations**, except for those sections or portions of sections specified in H&S Code, Section 1267.13(n). (These requirements in subsection 1267.13(n) are so specific to skilled nursing facilities, CLHFs were exempted from compliance with these sections.)

The All-Facilities Letter AFL-20-66.1 -The updated Guidance for the Provision of Home Dialysis Services in a Skilled Nursing Facility- offers guidance from CMS regarding the provision of dialysis services to SNF residents through a collaborative arrangement between the SNF and a qualified dialysis facility.

If Congregates are required to conform to CCR, Title 22, Skilled Nursing Regulations, and home hemodialysis is allowed by CMS, doesn’t that imply that a Congregate may offer Home Dialysis services to their residents?

CDPH Should allow Congregate Health Facilities to offer Home Hemodialysis to dialysis patients

It is true that the sections for the permit are specifically for hospitals, not congregates or SNFS. However, given the ambiguous language of the codes which have been left open for interpretation and for later additions regarding progress

and innovation in these specific areas of medical care, we are wanting to form a footprint in that regard. Compliance with the code was exempted and reasons state that exemption does not mean prohibition. There are no hard lines or specific regulations or codes that prohibit these facilities from having the same functions or being in compliance with the same rules as facilities that are “allowed” to have these services.

### **What are we proposing?**

It is of particular importance that Congregate facilities are held to the same standards as the other facilities that the law allowing for these services applies to. Additionally, that if congregates are held to the same standards and have exponential benefits to the patients' health care and the government's expenditures then it is only reasonable and inevitable that congregates and dialysis patients in congregates should have the same rights and protections as other facilities and dialysis patients do under the law.

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Home Dialysis has expanded under CMS guidelines, and this is uncharted territory for all of us. However, we believe we do have justification for this much needed service.

Under Title 22 (see below), there are options we would like to explore to make this much needed service certifiable and available to the patients at the Congregates,

Title 22 of the California Code of Regulations should be amended as follows:

(Start the petition generally that you would like to change title 22 and specify/suggest what wording or changes need to be made.)

If Pursuant to California Health and Safety Code 1267.13, a Congregate “(c) Facilities shall be in a **homelike residential setting.**” CLHF standards are found in H&S Code, Section 1267.13., and CLHF’s are required to conform to CCR, Title 22, **Skilled Nursing Regulations**, except for those sections or portions of sections specified in H&S Code, Section 1267.13(n). CLHFs should be included and not exempted from compliance with these sections.

The All-Facilities Letter AFL-20-66.1 -The updated Guidance for the Provision of Home Dialysis Services in a Skilled Nursing Facility- offers guidance from CMS regarding the provision of dialysis services to SNF residents through a collaborative arrangement between the SNF and a qualified dialysis facility, and the provisions should be amended to include CLHFs since the CLHFs are required to conform to CCR, Title 22, **Skilled Nursing Regulations**.

If Congregates are required to conform to CCR, Title 22, Skilled Nursing Regulations, and home hemodialysis is allowed by CMS, doesn’t that imply that a Congregate may offer Home Dialysis services to their residents?

Congregates are required to conform to CCR, Title 22, Skilled Nursing Regulations, and home hemodialysis is allowed by CMS, therefore there is an implication that a Congregate may offer dialysis. Even though there is no precedent for this matter it still is parallel to facilities that are specifically allowed to have dialysis services. These codes and regulations could still be used to apply for permission for Congregates to begin offering these services if only the authorities on the matter would be willing to aid innovation and expansion within the ambiguous codes and rules already set. If not, then we would highly recommend amending the codes and regulations or creating new ones that specifically apply to these facilities if that is the main issue. CDPH should allow Congregate Health Facilities to offer Home Hemodialysis to dialysis patients.

We understand the time it takes to change laws and regulations so another proposal would be that in the intervening period, Synergy Dialysis LLC is willing to be the pilot Home Dialysis Program with (1) CLHF to give valuable feedback in order to regulate this. We will demonstrate improved clinical outcomes and that these dialysis patients will have an improved quality of life eliminating unnecessary hours of transportation to go to the chronic dialysis facility 3-4 times per week, in addition to all of the substantial reasons listed above. If we are given the special permit to be the pilot, there will data to add to evidence that these successful results demonstrate the legal need to amend Title 22 to include CHLF’s offering Home Dialysis.

CDPH has the authority to grant program flexibility (PF) from regulatory requirements if the facility requesting the program flexibility demonstrates its ability to meet statutory requirements. Requests for program flexibility must include justification for the program flexibility request and adequate supporting documentation that the proposed alternative does

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not compromise patient care. Dialysis would be considered a special service under Title 22 CCR 70351 which specifically states the Department CAN grant a special permit. (Article 5. Special Permit §70351. Special Permit Required (a) Any licensee desiring to establish or conduct, or who holds out, represents, or advertises by any means, the performance of a special service shall obtain a special permit from the Department)

We are confident that if our company were allowed to be the pilot for allowing the Congregate to operate under Title 22, that it would be a successful endeavor that will roll out throughout California, and then the rest of the country. This would change the landscape of dialysis treatment for years to come. With your support and backing, you would be on the right side of medical policy reform history.

Therefore, the undersigned respectfully request that CDPH use its authority to amend regulations pursuant to Chapter 22, issue a special permit to dialyze patients in the "Home" setting at (1) CLHF as stated above in Article 5, as we are able to demonstrate the ability to meet the statutory requirements and/or approve our proposal to amend the Title 22 regulations to include home hemodialysis to be offered at the Congregate Living Facilities.

Respectfully submitted,

Joy Yegoyan, CEO  
President of Synergy Dialysis LLC



cc: Maral Farsi, Deputy Director, CDPH Office of Legislative and Governmental Affairs,  
Paulette Mascarino, District Director Assemblymember Philip Chen, 59<sup>th</sup> District., Ali Navid, Chief of Staff  
Assemblyman Phillip Chen, 59<sup>th</sup> District, Dr. Nicholas Mehis, Dr. Vartan Papazian

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Reference/Resource

Center for Medicaid and State Operations/Survey & Certification Group

Title 22

§70061. Special Permit Special permit means the document issued by the Department which constitutes the authority to perform those supplemental services which are identified as special services in Section 70351

§70012.1. Certificate of Need Certificate of need means a document containing Department approval for a specified project.

§70048. New Special Service (a) New special service means any special service identified in Section 70351 of this Chapter which is either offered or is intended to be offered and which was not approved by the Department prior to September 9, 1976. Approval of the Department is inferred if one of the following conditions exist: (1) The special service in question has been evaluated by the Department subsequent to July 13, 1975 and prior to September 9, 1976 and was found to be in compliance with all regulations regarding the service. (2) The special service in question was being provided prior to July 13, 1975, has been provided continuously since that date, and has not been inspected and evaluated by the Department for the quality of the service provided. Departmental approval in this case can be inferred only until such time as the service is evaluated by the Department

Article 5.

Special Permit §70351. Special Permit Required (a) Any licensee desiring to establish or conduct, or who holds out, represents, or advertises by any means, the performance of a special service shall obtain a special permit from the Department.