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May 28, 2022

U.S. Department of Health and Human Services
Departmental Appeals Board
Via DAB E-file

Re: Request for an ***Expedited*** Appeal Hearing of Notice of Survey findings, continuation of imposed remedies and termination of Medicare Provider Agreements for Laguna Honda Hospital & Rehabilitation Ctr D/P SNF 555020 and Request for Consolidation with Docket No. C-22-327 and C-22-478; Laguna Honda Hospital & Rehabilitation Center D/P SNF; Provider Number: 555020.

To DHHS Departmental Appeals Board:

Laguna Honda Hospital and Rehabilitation Center D/P SNF (Laguna Honda) hereby requests an expedited hearing with the U.S. Department of Health and Human Services (DHHS), Departmental Appeals Board, to appeal the DHHS, Centers for Medicare and Medicaid Services (CMS) “Notice of Survey findings, continuation of imposed remedies and termination of Medicare Provider Agreements for Laguna Honda Hospital & Rehabilitation Ctr D/P SNF 555020” dated March 30, 2022 (the Notice of Termination). Laguna Honda also seeks to consolidate this appeal with Laguna Honda’s two prior pending appeals, Docket Numbers C-22-327 and C-22-478.

CMS initiated the six-month cycle resulting in the Notice of Termination based on the Statement of Deficiencies dated December 16, 2021, for the extended survey conducted by the State Survey Agency—the California Department of Public Health (CDPH)—that concluded on October 14, 2021. That Statement alleges that Laguna Honda violated deficiency tag F689 by failing to ensure that the patient environment remained as free of accident hazards as is possible and that each patient received adequate supervision and assistance devices to prevent accidents.

As described in more detail below, CDPH instituted and enforced a zero-tolerance policy that was contrary to law. CDPH applied that unlawful policy to Laguna Honda during the October 14, 2021 survey, as well as several subsequent revisit surveys, to improperly determine Laguna Honda to be not in substantial compliance with applicable Medicare Conditions of Participation. And, as described in Laguna Honda’s previously filed appeals, CMS and CDPH misapplied deficiency tag F689 to the facility and held Laguna Honda to the wrong standard.

If CDPH had not instituted its arbitrary and capricious policy or, in the alternative, if CDPH correctly applied deficiency tag F689, then Laguna Honda would have been in substantial compliance with the Medicare Conditions of Participation based on the survey that ended on January 21, 2022. Because CMS erred in not finding Laguna Honda to be in substantial compliance, CMS improperly issued notices on February 24, 2022 and March 30, 2022 that resulted in termination of Laguna Honda’s Medicare provider agreement on April 14, 2022.

Letter to U.S. Department of Health and Human Services
Departmental Appeals Board
Via DAB E-file
Page 2
May 28, 2022

FACTUAL BACKGROUND

I. CDPH's Zero-Tolerance Policy

A. Verbal Communications from CDPH

On several occasions, starting with the October 2021 survey, CDPH surveyors verbally commented to Laguna Honda staff that as long as they continued to find patients using illicit substances or in possession of prohibited contraband (including cigarette lighters) on the whole of Laguna Honda's campus, Laguna Honda would not "pass" a survey, meaning CDPH would not find Laguna Honda to be back in substantial compliance with the Medicare Conditions of Participation. CDPH surveyors also verbally informed Laguna Honda staff that Laguna Honda needed to proactively take actions to prohibit the use of illicit substances and contraband and eliminate substances and contraband from the facility.

For example, in response to the January 2022 revisit survey, Laguna Honda submitted a plan of correction, which CDPH eventually accepted, in which Laguna Honda committed to achieving a 95% or greater compliance rate with several measures related to mitigating contraband brought into the facility. One such measure was assessing residents returning to the facility from a day pass to leave the campus, *i.e.*, screening patients for any contraband upon return to the facility.

During the March 2022 revisit survey, on or about March 16, 2022, Laguna Honda staff communicated to a CDPH surveyor that the facility achieved a 98% compliance pass rate on the patient assessments for those patients returning from a day pass, which surpassed the CDPH-accepted benchmark set forth in Laguna Honda's plan of correction of achieving a 95% pass rate. The CDPH surveyor responded that Laguna Honda should have achieved 100% since the facility was on a termination track and commented that "everything" should be 100%. In other words, contrary to what it accepted in the plan of correction, and contrary to both the definition and commonly understood meaning of "substantial compliance", CDPH expected Laguna Honda to achieve 100% success in its efforts to prevent all residents returning from a day pass from bringing contraband into the facility. *See* 42 C.F.R. § 488.301 (defining "substantial compliance"). This is same standard—perfection, rather than substantial compliance—against which CDPH evaluated Laguna Honda's corrective actions and compliance.

B. Statements of Deficiencies

The various Statements of Deficiencies that Laguna Honda received from CDPH also illustrate CDPH's policy that Laguna Honda had to achieve 100% success in its efforts to eliminate all contraband and illicit substances. The Statement of Deficiencies for the revisit survey ending October 14, 2021 stated that "the facility failed to ensure safe environment for all residents when the facility did not implement policies and procedures for the following practices: a. Prohibiting use and possession of illicit drugs . . . b. Possession of contrabands (a banned or illegal item), trading illicit substances, and consuming marijuana and alcohol inside the facility. . . ." CDPH, Statement of Deficiencies, Form CMS-2567, dated December 16, 2021, (hereinafter the "December 2021 Statement of Deficiencies"), at 8–9.

The Statement of Deficiencies for the revisit survey ending January 21, 2022 alleged that "[t]hree of 10 sampled residents (Resident 2, Resident 14 and Resident 31) were found in possession of contraband during clinical search." CDPH, Statement of Deficiencies, Form CMS-2567, dated February 15, 2022, (hereinafter the "February 2022 Statement of Deficiencies"), at 7.

Letter to U.S. Department of Health and Human Services
Departmental Appeals Board
Via DAB E-file
Page 3
May 28, 2022

The Statement of Deficiencies for the revisit survey ending March 28, 2022 alleged that Laguna Honda had an “[i]neffective system to eliminate [the] source of contrabands inside the facility. Resident [sic] were found in possession of contraband on several occasions.” CDPH, Statement of Deficiencies, Form CMS-2567, dated March 30, 2022, (hereinafter the “March 2022 Statement of Deficiencies”), at 2.

CDPH surveyors also prioritized enforcing the zero-tolerance policy. For example, during the March 2022 revisit survey, CDPH surveyors immediately went to the Laguna Honda staff in the mail room and units with previously identified patients with substance abuse issues to interview them and find lighters and other ignitors that constituted contraband.

C. CMS Confirms CDPH’s Policy is Contrary to State Operations Manual

During several virtual meetings with leadership from CMS and CDPH between March 25 and April 13, 2022, Laguna Honda leadership asked CMS and CDPH staff to clarify their expectation for the next revisit survey regarding illicit substances and prohibited contraband. During these meetings, Karen Tritz, Director, Survey & Operations Group Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, clarified that during the next revisit—which was the final opportunity for Laguna Honda to correct its deficiencies before the April 14, 2022 termination date—CMS would expect Laguna Honda to meet the standard established in the State Operations Manual, specifically the guidance provided in Appendix PP, for deficiency tag F689. During these meetings, CMS confirmed that CDPH surveys should not apply a zero-tolerance policy.

Following those meetings, CDPH conducted a final revisit survey of the facility from April 10, 2022 to April 13, 2022. As a result of that survey, CDPH issued a Statement of Deficiencies dated April 26, 2022. In that Statement of Deficiencies, CDPH again found Laguna Honda out of substantial compliance with deficiency tag F689. CDPH based this deficiency on a pair of scissors found inside the rooms of three residents. CDPH, Statement of Deficiencies, Form CMS-2567, dated April 26, 2022, (hereinafter the “April 2022 Statement of Deficiencies”), at 21. CDPH no longer cited Laguna Honda for possession of illicit substances or contraband using the F 689 deficiency tag. *See id.*

II. CDPH’s October 2021 Survey and January 2022 Revisit Survey

CDPH ended its initial survey on October 14, 2021. More than two months later CDPH issued a Statement of Deficiencies related to that survey in which it determined that Laguna Honda was out of substantial compliance with deficiency tags F689 and F726. December 2021 Statement of Deficiencies at 8, 57.

After CDPH accepted Laguna Honda’s plan of correction in response to the December 2021 Statement of Deficiencies, CDPH conducted a revisit survey on January 21, 2022. The Statement of Deficiencies issued as a result of that survey, in February 2022, again found Laguna Honda to be out of substantial compliance with deficiency tag F689. But, CDPH determined that Laguna Honda was no longer out of substantial compliance with deficiency tag F726. *See generally* February 2022 Statement of Deficiencies.

Letter to U.S. Department of Health and Human Services
Departmental Appeals Board
Via DAB E-file
Page 4
May 28, 2022

LAGUNA HONDA'S RESPONSE

I. CMS Erroneously Terminated Laguna Honda's Provider Agreement Because CDPH Applied a Zero-Tolerance Policy to the Facility

A. CDPH Applied a Zero-Tolerance Policy

CDPH applied an unwritten zero-tolerance policy that was contrary to federal regulations and the CMS State Operations Manual. As discussed above, CDPH communicated to Laguna Honda staff that CDPH expected Laguna Honda to eliminate the use of all illicit substances in the facility and prohibit the possession and introduction of contraband into the facility, which latter category included items as common as scissors and cigarette lighters. CDPH took the position that unless Laguna Honda prevented all instances of substance use and contraband possession, then the facility would remain out of substantial compliance.

The Statements of Deficiencies further indicate that CDPH instituted a policy where Laguna Honda was required to “*eliminate* [the] source of contrabands inside the facility.” March 2022 Statement of Deficiencies, at 2 (emphasis added). And, CDPH cited Laguna Honda for mere possession of any illicit substance or contraband. *See* December 2021 Statement of Deficiencies, at 8–9; February 2022 Statement of Deficiencies, at 7.

Thus, CDPH maintained a zero-tolerance policy that it consistently applied to Laguna Honda starting with the October 2021 survey and reaffirmed in the January 2022 and March 2022 revisit surveys.

B. CDPH's Policy is Contrary to Federal Law

In its prior appeals, Laguna Honda has discussed at length why the use and possession of illicit substances and contraband do not constitute an avoidable accident under deficiency tag F689. As relevant here, CDPH's blanket, zero-tolerance policy is contrary to federal regulations for at least two reasons.

First, CMS informed both Laguna Honda and CDPH that CDPH's policy was contrary to the CMS State Operations Manual. The CMS State Operations Manual imposes a four-part test to determine whether an accident is an “avoidable accident” and thus subject to deficiency tag F689. Generally, that test requires Laguna Honda to (1) identify a hazard; (2) implement interventions systemwide that are consistent with each patient's needs, goals, care plan, and current professional standards of practice to reduce the risk of potential accidents; (3) monitor the effectiveness of the interventions; and (4) modify the interventions as necessary, in accordance with current professional standards of practice, and the patients' right to privacy, dignity, and self-determination. *See* CMS State Operations Manual, Appendix PP. Guidance to Surveyors for Long Term Care Facilities. (Rev. 173, 11-22-17), F689, at 302–03.

After instituting and enforcing the zero-tolerance policy over the initial and revisit surveys in October 2021, January 2022, and March 2022, Laguna Honda staff requested CMS clarify the zero-tolerance policy since the deficiency tag cited by CDPH—F689—requires a multi-part evaluation of the facts and circumstances of each patient to determine whether a facility is out of substantial compliance with that deficiency tag. CMS confirmed that Laguna Honda's interpretation of the CMS State Operations Manual was correct and that CDPH's zero-tolerance policy was thus contrary to the CMS State Operations Manual.

CDPH did not present evidence that Laguna Honda failed to adhere to each of the four elements of the definition of avoidable accident under the CMS State Operations Manual. Rather, CDPH maintained that any possession of illicit substances or contraband is a *per se*

Letter to U.S. Department of Health and Human Services
Departmental Appeals Board
Via DAB E-file
Page 5
May 28, 2022

violation of its policy, which is contrary to the multi-part assessment required under the CMS State Operations Manual.

Second, CDPH's zero-tolerance policy is contrary to the requirement in the CMS State Operations Manual that the facility is responsible for hazards over which it has control. The CMS State Operations Manual defines "hazards over which the facility has control" as those hazards in the resident environment where reasonable efforts by the facility could influence the risk for resulting injury or illness." CMS State Operations Manual, at 304.

CDPH's zero-tolerance policy allows for no reasonable measure by which Laguna Honda could reduce or mitigate the harm caused by the possession of illicit substances or contraband.

C. CDPH Applied its Unlawful, Zero-Tolerance Policy to Laguna Honda Resulting in an Improperly Issued Notice of Termination

As stated, CDPH determined Laguna Honda to be not in substantial compliance with deficiency tag F689 starting with the October 2021 survey. CDPH issued the same deficiency tag for the same findings in the January 2022 and March 2022 revisit surveys. In each instance, CDPH determined that Laguna Honda had to eliminate 100% of the illicit substances and contraband entering into the facility even though CDPH agreed that Laguna Honda could achieve a 95% compliance rate in its plans of correction.

CMS relied on those deficiencies when it issued a Notice of Survey Findings and Imposition of Remedies on February 24, 2022 in which CMS cited the most serious deficiency as the F689 deficiency tag with a scope and severity level of H. *See* CMS, Survey Findings and Imposition of Remedies, Feb. 24, 2022, at 1. That notice confirmed that CMS would terminate Laguna Honda's provider agreement on April 14, 2022 if Laguna Honda failed to achieve substantial compliance before that date. *Id.* at 4.

On March 30, 2022, CMS issued a further Notice of Termination that is the subject of this appeal. In that notice, CMS cited the March 28, 2022 survey where the most serious deficiency was deficiency tag F689 with a scope and severity level of K. *See* Notice of Termination, at 3. Thus, CDPH's zero-tolerance policy led to the two CMS-issued notices resulting in the termination of Laguna Honda's provider agreement.

D. Laguna Honda Returned to Substantial Compliance as of January 21, 2022 and the April 14, 2022 Termination Was Improper

CDPH determined Laguna Honda was not in substantial compliance starting on October 14, 2021. Title 42 C.F.R. section 488.412(a) provides that if a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, CMS may either terminate the provider agreement or allow continued participation for no longer than six months from the last day of the survey. Subsection (d) requires CMS to terminate a provider agreement if the facility is not in substantial compliance within 6 months of the last day of the survey.

CDPH determined that two deficiency tags applied to Laguna Honda as a result of the October 2021 survey—F689 and F726. December 2021 Statement of Deficiencies, at 8, 57. CMS did not immediately terminate Laguna Honda's provider agreement and thus started a six-month clock on the facility during which time Laguna Honda was required to come back into substantial compliance.

CDPH revisited the survey in January 2022 and determined that only deficiency tag F689 applied to Laguna Honda. CDPH no longer assessed deficiency tag F726. Thus, F689

Letter to U.S. Department of Health and Human Services
Departmental Appeals Board
Via DAB E-file
Page 6
May 28, 2022

deficiency tag was the only deficiency identified that placed Laguna Honda not in substantial compliance.

But, as demonstrated above and in Laguna Honda's prior appeals, CDPH's application of F689 was flawed. And, as discussed herein, CDPH maintained a policy contrary to law that resulted in Laguna Honda being adjudged as not in substantial compliance. Under either theory, CDPH should not have issued deficiency tag F689 in January 2022, which would have meant that Laguna Honda was back in substantial compliance at that time and the six-month cycle ended in January 2022.

While CDPH assessed new deficiencies in surveys subsequent to the January 21, 2022 survey, any new deficiency would have initiated a new six-month period pursuant to title 42 C.F.R. section 488.412. Thus, CMS erred in issuing the March 30, 2022 Notice of Termination and proceeding to terminate Laguna Honda's provider agreement at the end of the original six-month cycle. Laguna Honda respectfully requests a reversal of that termination.

II. CDPH's Zero-Tolerance Policy Has a Disparate Impact on Disabled Patients and Likely Precludes a Vulnerable Population from Receiving Necessary Care

Laguna Honda serves a low-income and extremely low-income patient population. Many of the patients have disabilities, including a combination of behavioral health issues, substance use and addiction disorders, and other complex conditions.

CDPH's unlawful zero-tolerance policy has a discriminatory and disparate impact on those individuals because it deems any possession or use of illicit substances or contraband to be a *per se* deficiency no matter the individual facts and circumstances of the patient. If the Laguna Honda patients who are in possession or using illicit substances are transferred to other facilities, it will not change the disabilities or personal choices of these patients. Rather, at best it will shift the issue to another facility. Given the lack of SNF beds for Medicare and Medicaid patients in the San Francisco Bay Area and California as well as the nature of addiction disorders, however, the more likely result is that it precludes these individuals who suffer from multiple, complicated disabilities from receiving the care they need both now and in the future. In short, the CDPH zero-tolerance policy has a disparate impact on individuals with disabilities—substance use and addiction disorders, in particular—and will result in denial of health care to low income individuals.

Laguna Honda has policies and procedures that it follows to ensure the safety of its patient population through substantial compliance with Medicare Conditions of Participation, while also protecting their individual rights. It is unlawful and discriminatory for CDPH to require more.

III. CDPH Impermissibly Treated Laguna Honda Differently than Similarly Situated Facilities

As stated above, in its Plan of Correction dated March 15, 2022, Laguna Honda proposed that achieving a 95% or greater compliance rate with several measures related to mitigating contraband brought into the facility. CDPH accepted this plan of correction. The 95% facility threshold for substantial compliance has been a standing practice for several years.

CDPH held Laguna Honda to a higher standard than any similarly situated skilled nursing facility because it required a 100% threshold to be in substantial compliance.

Letter to U.S. Department of Health and Human Services
Departmental Appeals Board
Via DAB E-file
Page 7
May 28, 2022

IV. CMS Violated Laguna Honda's Due Process Rights by Failing to Issue Timely Statements of Deficiencies

CDPH initial survey ended on October 14, 2021. CDPH issued the resulting Statement of Deficiencies on December 16, 2021 over two months after the survey ended. CMS and CDPH are required to issue statements of deficiencies 10 days after the end date of the survey. 42 C.F.R. § 488.110(j) (“In accordance with your Agency’s policy, present the Statement of Deficiencies, form CMS-2567, on site or after supervisory review, no later than 10 calendar days following the survey.”).

CDPH’s determination that Laguna Honda was not in substantial compliance with the Medicare Conditions of Participation started a six-month enforcement cycle. *See* 42 C.F.R. § 488.412(a), (d). Due to CDPH’s delay, for the first two months of that six-month cycle Laguna Honda did not have sufficient notice of the specific deficiencies and findings—nearly one-third of the total time Laguna Honda had to correct its deficiencies. By reducing Laguna Honda’s enforcement cycle by one-third, CDPH harmed Laguna Honda’s opportunity to cure the deficiencies before termination.

Next, CDPH conducted a final revisit survey on April 10 through April 13, 2022. CMS terminated Laguna Honda’s provider agreement on April 14, 2022 at 12:01 a.m. Yet, Laguna Honda did not receive its final Statement of Deficiencies until April 27, 2022. Thus, CMS terminated Laguna Honda’s provider agreement without sufficient notice of the deficiencies that Laguna Honda allegedly violated. Laguna Honda could not challenge those findings before it suffered the irreparable injury of losing its Medicare provider agreement.

EXPEDITED HEARING

CMS terminated Laguna Honda’s provider agreement as of April 14, 2022. This appeal challenges the notice of termination and seeks to reverse that termination because CMS based that six-month cycle on the flawed F689 deficiency tag finding. An expedited hearing is warranted because the continued termination of Laguna Honda’s provider agreement puts residents at risk of trauma since CMS and CDPH are requiring the facility to discharge and transfer patients to other facilities. Because a successful outcome to this appeal would mitigate the harm to those patients, Laguna Honda respectfully requests an expedited hearing.

Very truly yours,

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