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Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

In the Case of: LAGUNA HONDA HOSPITAL & REHABILITATION CENTER D/P SNF (CCN: 05-5020), Petitioner, vs. Centers for Medicare & Medicaid Services, Respondent.	Hon. Steven T. Kessel Docket No: C-22-555 **LAGUNA HONDA'S PREHEARING EXCHANGE** Date: September 19, 2022

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INTRODUCTION

Laguna Honda Hospital & Rehabilitation Center ("Laguna Honda") serves a low-income and extremely low-income population, and provides a critical safety net for San Francisco's most vulnerable residents. Because of its commitment to serve the underserved, Laguna Honda often provides a last resort for patients who have nowhere else to go, and serves a crucial need for San Francisco. Laguna Honda also provides a nationally-recognized program for people with Alzheimer's and other dementias, the only dedicated skilled nursing facility for HIV/AIDS in the San Francisco Bay Area, and an award-winning restorative care program. In 2020, Laguna Honda received the top honor from the California Association of Public Hospitals and Health Systems for its response to the COVID-19 pandemic.

Despite Laguna Honda's successes and importance to the community, the Centers for Medicare and Medicaid Services ("CMS") terminated the facility's Medicare provider agreement because the state survey agency, the California Department of Public Health ("CDPH"), erroneously assessed a violation of 42 C.F.R. Section 483.25(d) based on the mere presence of illicit drugs and contraband in the facility. Out of a total population of 710, CDPH cited only 32 residents with incidents of illicit drug or contraband issues. CDPH ignored Laguna Honda's harm reduction measures designed to reduce drug use and the harms resulting from that use. And CDPH did not credibly allege any substantial harm to residents; even the two residents who overdosed and were sent to the emergency room likely would have died had they not been at Laguna Honda where staff could, and did, intervene and provide life-saving medical treatment.

By citing the presence of illicit drugs and contraband, without more, CDPH applied a strict liability standard. That was error. The surveyors failed to assess whether Laguna Honda provided adequate supervision, mitigated hazards, and followed its policies. Thus, CDPH erred by issuing any deficiency under Section 483.25(d). CMS compounded that error by terminating Laguna Honda by operation of law at the end of the six-month enforcement cycle. Laguna Honda was in substantial compliance by November 14, 2021, which interrupted the enforcement cycle.

Laguna Honda requests the court overrule CMS's remedies and its decision to terminate Laguna Honda's Medicare provider agreement. Laguna Honda also requests that the court find that

CMS erred when denying payments for new admissions, and when assessing the civil monetary penalties associated with Section 483.25(d).

ARGUMENT

CMS purported to terminate Laguna Honda by operation of law and never *exercised* its discretionary authority to terminate at any point during the six-month cycle that began October 14, 2021. CMS warned the facility that if it failed to reach and maintain substantial compliance by April 14, 2022, "it would be required to terminate [Laguna Honda's] Medicare provider agreement." (P. Ex. 1, at 306.) But, Laguna Honda reached and maintained substantial compliance in November 2021 for two reasons. First, CMS and CDPH erroneously issued a deficiency under Section 483.25(d). Second, Laguna Honda returned to substantial compliance with those deficiencies it did not challenge by November 14, 2021. Because Laguna Honda was in substantial compliance in November 2021, interrupting CMS's mandatory termination and resetting the enforcement cycle, CMS erred in terminating Laguna Honda's Medicare provider agreement.

I. Use or Possession of Illicit Drugs and Contraband Are Not *Per Se* Accidents

CDPH erred by applying a strict liability standard to residents who used or possessed illicit drugs and contraband. Laguna Honda took facility-wide steps to reduce the introduction of illicit drugs and contraband into the facility. These included clinical safety searches and urine toxicology screens based upon reasonable suspicion, as well as assessments for residents returning from out on pass.[1] (P. Ex. 2, at 34, ¶ 6, 9.) But, even with these measures in place, Laguna Honda cannot reasonably eliminate all illicit drugs from entering the facility. Residents have privacy and dignity rights and can refuse consent to search their person or packages. (*Id.* ¶ 10.) The facility is not locked and "residents have the right to move about the facility freely and to leave the facility freely if out on pass or going to an appointment." (*Id.*; *see also* State Operations Manual, CMS Pub. 100-07, App. PP, at 286 (hereinafter "SOM") ("This includes respecting residents' right to privacy, dignity and self-determination . . . .").)

[1] Out on pass is when a resident has a physician order allowing the resident to temporarily leave the facility. (P. Ex. 2, at 52, ¶ 13.)

Although the facility cannot entirely eliminate contraband from entering the facility, neither Laguna Honda's policies nor federal law required it do so. Laguna Honda's policies require staff to follow a harm reduction model, which is defined in part as "reducing unsafe practices rather than abstaining from dangerous behavior." (P. Ex. 12, at 91.) Laguna Honda's harm reduction policy instructs staff to design clinical interventions for residents with substance use disorder, including conducting assessments, educating residents, and monitoring and following up with residents who demonstrate an inability or unwillingness to participate in treatment. (*Id.* at 74–75.) The policy recognizes "relapse, or a return to unsafe practices as part of the recovery process, not as a 'failure of treatment' or 'failure of resident.'" (*Id.* at 76.) Laguna Honda provides "open access to behavioral health services, medication assisted treatment, and support groups." (P. Ex. 2, at 34, ¶ 9.)

CMS's regulatory guidance supports Laguna Honda's harm reduction approach. "Facilities are given 'the flexibility to choose the methods' they use to provide supervision or assistive devices to prevent accidents, so long as the chosen methods 'constitute an adequate level of supervision' for a particular resident's needs." (*Hazel Hawkins Mem'l Hosp.*, DAB No. CR6025, at 16 (2022) (quoting *Windsor Health Care Ctr.*, DAB No. 1902, at 5 (2003)).) CDPH's surveyors did not afford Laguna Honda such flexibility in implementing its policies. A CDPH surveyor expressed to Laguna Honda's Chief Quality Officer a concern that the facility was only "reactive" to resident drug use. (P. Ex. 2, at 35–36, ¶ 14.) That surveyor asked "what does the facility need to do to eliminate the presence of illicit substances." (*Id.*)

CDPH's strict liability policy is inconsistent with CMS's own guidance, which supports Laguna Honda's use of a harm reduction approach. CMS has distributed an advanced copy of Appendix PP of the SOM instructing surveyors to evaluate whether a facility followed a harm reduction approach by assessing and identifying at-risk residents for overdose and substance use disorder (SUD), whether there are interventions in the resident's care plan, whether the facility implements those interventions, and whether the facility is prepared to address emergencies, including by administering opioid reversal agents such as naloxone. (P. Ex. 13, at 326.) The advanced copy notes that "[s]urveyors should be aware that the occurrence of an overdose does not automatically mean that noncompliance exists. As noted above, drug overdoses can be expected with individuals

with SUD and facilities are not expected to fully cure these residents of their underlying disease or SUD." (*Id.* at 327.) While these harm reduction guidelines were not in Appendix PP at the time of the October 2021 survey, they are illustrative of the multi-factor analysis that CDPH failed to perform.

The best evidence of CDPH's failure to assess whether Laguna Honda mitigated accident hazards comes from a series of meetings during and following the March 2022 revisit survey[2] between representatives from Laguna Honda, CDPH, and CMS during which Laguna Honda sought clarification of the correct interpretation of Section 483.25(d). CMS's representative confirmed that "the facility needs to follow its policies. The representative said that they don't expect to come and see nothing or that Laguna Honda completely eliminated illicit substances." (P. Ex. 2, at 37, ¶ 17.) Following this meeting, CDPH conducted a third revisit of the facility from April 11 to 13, 2022. Despite months of focus on illicit drugs and contraband, including the revisit surveys in January and March 2022, meetings with CDPH and CMS representatives, and the facility working with an external quality improvement organization to address these issues, CDPH assessed no deficiencies related to illicit drugs, contraband, or smoking. (*Id.*) Instead, CDPH alleged new deficiencies—unrelated to illicit drugs and contraband—the day before termination went into effect affording Laguna Honda no opportunity to cure. (P. Ex. 1, at 374–428.) "They never even looked at illicit substances." (P. Ex. 2, at 37, ¶ 17.)

II. CMS Fails to Establish a Prima Facie Violation of 42 C.F.R. § 483.25(d)

CMS cannot establish a prima facie violation of Section 483.25(d) for each of the subparts (a) through (e) in the December 16, 2021 Statement of Deficiencies ("SOD").[3]

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[2] Surveyors also cited deficiency tag F689 in the January 21, 2022 and March 28, 2022 revisit surveys for use and possession of illicit drugs and contraband and that purported deficiency was a basis for the immediate jeopardy declared March 22, 2022. (P. Ex. 1, at 86–89, 175, 189–218.)

[3] CDPH issued the SOD on December 16, 2021, more than two months after the exit survey and in violation of 42 C.F.R. § 488.110(j), which requires CDPH to present the SOD "no later than 10 calendar days following the survey." (*See also* SOM, Ch. 7, § 7319.1 ("The State sends the facility Form CMS-2567 . . . within 10 working days of the last day of survey.").) That delay prejudiced Laguna Honda's ability to return to substantial compliance since the facility did not know the precise allegations in the SOD until over two months of the six-month enforcement cycle elapsed.

A. Subpart A—Use and Possession of Illicit Drugs

CMS cannot establish a violation of Section 483.25(d) based on subpart (a) because the surveyors failed to consider whether Laguna Honda reduced the risk of accident hazards to the extent possible or whether staff provided appropriate supervision. As discussed below, the facility eliminated illicit drugs whenever staff discovered them, usually during a clinical search. (*See infra* Sections II.B, III.B.) Also discussed below, the medical records for each resident cited in subpart (a) of the December 16, 2021 SOD confirm that staff followed facility policies by documenting and implementing interventions for substance use and Laguna Honda's psychiatrists followed policies and best practice for harm reduction by treating and counseling residents for substance use disorder. (*See infra* Sections III.A, III.F.)

CDPH did not evaluate the extent to which Laguna Honda implemented its interventions or harm reduction policy. The findings for Resident 24 are illustrative. CDPH cited two urine toxicology screens, dated July 7, 2021 and July 22, 2021, and a psychiatrist note that likewise documented those positive tests. (P. Ex. 1, at 21.) There is no finding that staff failed to implement interventions and a close reading indicates that staff were implementing interventions and monitoring the resident. Resident 24's care team notified the psychiatrist and Resident 24 was seeing a psychiatrist in response to the substance use. (*Id.*) Other interventions for Resident 24 are discussed below, but by failing to evaluate whether the facility reduced the risk of accident hazards, CDPH incorrectly assessed deficiencies.

Not only did surveyors fail to evaluate risk reduction, they even cited successful instances where staff documented interventions to address substance use disorder. For Resident 7, the progress note dated February 6, 2020 noted that a physician counseled Resident 7 on potential drug interactions, but the resident declined optimizing the medication. (P. Ex. 1, at 22; *see* P. Ex. 2, at 5, ¶ 10 ("Providers are in a continual discussion with patients based on their outcome goals.").) Resident 7's care plan dated May 14, 2020 stated that staff listed interventions including a 15-point plan such as discussing Laguna Honda's harm reduction policy and restarting Suboxone to help with addiction cravings. (P. Ex. 1, at 23; *see* P. Ex. 2, at 5, ¶ 9 ("Medication for Opioid Use Disorders is a main modality for treating opioid use disorder and is much safer than street opioid drugs."). Far from

showing a deficiency, Resident 7's example demonstrates that Laguna Honda was properly employing the harm reduction model and each of the residents cited in subpart (a) had similar interventions documented in their medical records. (*See infra* Sections III.A and III.F.)

B. Subpart B—Possession of Contraband

CMS cannot establish a prima facie violation of Section 483.25(d) based on subpart (b) of the December 16, 2021 SOD because the findings establish that Laguna Honda *eliminated* contraband where contraband was found by conducting clinical searches and confiscating the contraband. Staff confiscated any contraband found during a clinical search (P. Ex. 2, at 23, ¶ 3; *id.* at 43, ¶¶ 5, 7; *id.* at 50, ¶¶ 5–6), which is exactly what Laguna Honda's clinical search protocol required them to do. (P. Ex. 12, at 49–50.)

The surveyors documented successful searches in the SOD: "We're doing it (clinical search) almost on [a] regular basis." (P. Ex. 1, at 27 (Resident 14).) And for Resident 19, surveyors noted that the "Resident voluntarily surrendered the lighter and joint." (P. Ex. 1, at 35.) Staff found paraphernalia for Resident 3 after the resident was discharged and gave the items to the Sheriff's deputy. (*Id.* at 27.) "Resident 5 initially refused the search 'however, one small bag of a rock white substance was surrendered to sheriff.'" (*Id.* at 30.)

Resident records confirm that the findings in subpart (b) are not outliers: Resident 14 (P. Ex. 3, at 664, 685, 697, 699, 701, 704, 725); Resident 4 (*id.* at 403, 407); Resident 2 (*id.* at 155, 176, 187–88, 250); Resident 27 (*id.* at 1268 ("I got the pipe for the resident's safety."), 1280); Resident 11 (*id.* at 577–78 ("Deputy Duong picked up the contraband around 12:15 pm for disposal.")); Resident 17 (*id.* at 842, 847, 860); Resident 15 (*id.* at 796 ("Confiscated illegal substance was disposed in the cactus sink by PM CN witnessed by this writer and 2 standby pharmacist[s]."); Resident 16 (*id.* at 802 ("NM confiscated marijuana and escorted resident back to unit."), 804); Resident 23 (*id.* at 1116); Resident 21 (*id.* at 1074); Resident 25 (*id.* at 1237); Resident 32 (*id.* at 1515); Resident 12 (*id.* at 598, 605); Resident 18 (*id.* at 974, 981 ("[Nursing] director placed it in pharmacy drug box.")); Resident 33 (*id.* at 1552); Resident 10 (*id.* at 529, 541); Resident 24 (*id.* at 1186).

Not only do the findings demonstrate that the facility eliminated hazards to the extent possible, they also demonstrate that CDPH failed to assess whether the facility took steps to mitigate risks and

failed to assess whether Laguna Honda followed all of its policies.

C. Subpart C—Possession of Ignitable Items

CMS fails to establish a prima facie violation in subpart (c) of the SOD because surveyors cited instances where staff conducted clinical searches, found lighters and other ignitable items, and confiscated that contraband. The fact that staff found and confiscated lighters and other ignitable items demonstrates that they eliminated the hazards to the extent practicable. (*See Comm. Care Ctr. of Baker*, DAB No. CR1999, at 12 (2009) ("The success of Petitioner's surveillance is demonstrated by the fact that staff continued to find and seize contraband smoking materials, matches, and lighters . . . .").) For example, surveyors cited Resident 20's nursing note dated July 30, 2021, which stated that a unit-wide clinical search was conducted and four lighters were found. (P. Ex. 1, at 43.) Surveyors also selectively quoted Resident 20's care plan for an incident where staff observed Resident 20 lighting his own cigarette, staff "instructed [him] to surrender the lighter. He got upset . . ." (*Id*.) The full quote from the note is revealing: "He got upset, cursed, yelled and *he gave up the lighter* to the writer." (Ex. 3, at 1050 (emphasis added).)

Resident records also demonstrate that staff confiscated contraband: Resident 27 (P. Ex. 3, at 1268); Resident 17 (P. Ex. 1, at 42 ("LN 1 found two lighters . . . .");); Resident 18 (*id.* at 43 ("Clinical search conducted . . Lighters found . . . .")); Resident 26 (*id.* at 43); Resident 24 (*id.* at 45); Resident 19 (*id.* ("Resident voluntarily surrendered lighter and joint."); Resident 34 (P. Ex. 3, at 1586). For Resident 14, the surveyors did not even cite an instance of possession of a lighter, only that staff conducted a smoking assessment of Resident 14's past history of accidents, which shows that staff was complying with facility policies. (P. Ex. 1, at 44.) For Resident 25, the surveyors did not cite any lighter or ignitable item, only that staff found and confiscated "JOINTS" on the bathroom floor. (*Id.*)

CMS also fails to establish that Laguna Honda did not follow its policies and procedures with regard to possession of lighters and other ignitable items or that staff failed to provide appropriate supervision. Although the surveyors cited the "Safety Adult-Smoker" portions of the care plans for nine of the 11 residents as prohibiting those residents from carrying smoking materials, they did not include any allegations suggesting that staff failed to take steps to mitigate the accident hazards that could not be eliminated. Surveyors simply ignored the mitigation analysis (*see infra* Sections III.C,

III.F) and applied strict liability findings in the SOD.

D. Subpart D—Lighter Storage

CMS cannot establish a prima facie violation based on storage of lighters and other ignitable items because those items were not in the resident environment. The SOM defines "hazards" as elements of the resident environment that have the potential to cause injury or illness. (SOM, App. PP, at 285.) "Environment" is defined as any environment or area that is frequented by or accessible to residents. (*Id.*) "Whether or not a particular environment in which a resident is located is 'resident environment' within the meaning of 42 C.F.R. § 483.25(h) depends on the facts." (*Good Shepherd Home for the Aged, Inc.*, DAB No. CR4785, at 16 (2017).)

Here, the SOD demonstrates that Laguna Honda followed its COVID-19 lighter storage policy[4] to store lighters within resident units in areas not accessible to residents and thus not part of the resident environment. For example, the SOD alleges, "RN 15 stated that lighters are kept in the nursing station" and "RN 6 stated that lighters are kept in the treatment/medication room for safekeeping." (P. Ex. 1, at 45–46.) The medication room is locked and only staff have access to those rooms. (P. Ex. 2, at 39, ¶ 26; *id.* at 49, ¶ 4.) Although CDPH cited one instance where lighters were in an open basket, that basket was "in a conference room behind the nursing station" (P. Ex. 1, at 46), which is not accessible to residents unless they are escorted by staff. (P. Ex. 2, at 49, ¶ 4; *id.* at 38–39, ¶ 23.) While CDPH noted some instances where cabinets were unlocked "staff are present to redirect residents away" from the nursing station and, as the Chief Quality Officer testified, she was "not aware of any incident where a resident obtained a lighter from the unit." (P. Ex. 2, at 39, ¶ 23.)

Even if a lighter was accessible, CDPH did not assess resident vulnerability to the hazard. Appendix PP states that "to be considered hazardous, an element of the resident environment must be accessible to a vulnerable resident" and some "situations may be hazardous only for certain

[4] From March 24, 2020 to December 15, 2021, Laguna Honda was under a protective quarantine in response to the COVID-19 pandemic. (P. Ex. 14, at 1–12.) During that time, the facility closed the primary designated smoking area and residents were allowed to smoke in their units, either on the balcony or patio. (*Id.* at 18; *see* P. Ex. 2, at 42, ¶ 4; *id.* at 49, ¶ 4.) Because residents remained in their units to smoke, Laguna Honda "had a policy where staff kept some lighters on the unit" (P. Ex. 2, at 38, ¶ 22; *id.* at 42, ¶ 4; *id.* at 49, ¶ 4), which was later codified in a standard work. (P. Ex. 14, at 30.)

individuals (*e.g.*, accessible smoking materials)." (SOM, App. PP, at 291.) By failing to examine resident vulnerability to a purportedly accessible lighter, CDPH erred in citing a deficiency in subpart (d) of the SOD.

E. Subpart E—Tracking and Disposition of Confiscated Contraband

CMS also fails to establish a prima facie violation in subpart (e) of the SOD because the findings demonstrate that staff successfully confiscated contraband and thus eliminated hazards from the resident environment. Once confiscated, contraband no longer constitutes a "hazard" because it is no longer in the resident environment and thus no longer has the potential to cause injury or illness. The surveyors allege that confiscated contraband "had the potential for diversion, misuse, or uncontrolled redistribution" to the resident environment and thus once again have the potential to cause injury. (P. Ex. 1, at 72.) But, that allegation is not supported by any finding that confiscated contraband was actually, or had the reasonable potential to be, reintroduced to the resident environment. (P. Ex. 2, at 38, ¶ 21; *id.* at 50, ¶ 8; *id.* at 45, ¶ 12; *id.* at 57, ¶ 10.)

The surveyors cited an interview with NM 1 on October 14, 2021 where NM 1 showed surveyors plastic bags with lighters labeled with the names of Residents 35, 36, and 37. (P. Ex. 1, at 48.) Laguna Honda's clinical search protocol directs staff to bag, label and secure confiscated lighters for safekeeping. (P. Ex. 12, at 50.) Each nurse managers' office is locked and residents do not have access. (P. Ex. 2, at 23, ¶ 3; *id.* at 57, ¶ 11.) Thus, surveyors documented only that staff followed the facility policy, not noncompliance.

Even if Laguna Honda did not completely eliminate the potential hazard, CDPH failed to assess whether Laguna Honda took steps to mitigate any remaining hazard to the residents. Because the use of illicit drugs by itself is not a violation of Section 483.25(d), it follows that the purported failure to document disposal of contraband, without more, is not an accident for purposes of Section 483.25(d). As demonstrated below (*see infra* Sections III.A–III.C, III.F), Laguna Honda followed its harm reduction policies for each of the residents cited in subpart (e) of the SOD.

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III. Laguna Honda Was in Substantial Compliance with 42 C.F.R. § 483.25(d)

Even if CMS could establish its prima facie case, Laguna Honda was in substantial compliance with Section 483.25(d) because the facility complied with its policies and procedures,[5] implemented interventions, and supervised residents. (*See Logan Healthcare Leasing, LLC d/b/a Logan Care & Rehab.*, DAB No. 3036, at 14 (2021) ("A facility's obligations under section 483.25 also includes furnishing the care and services set forth in its own resident care policies."); *Heritage Plaza Nursing Ctr.*, DAB No. 2829, at 20 (2017) ("Once a facility adopts a policy that incorporates the measures that are appropriate to assure that residents receive adequate supervision and assistance devices to prevent accidents . . . the facility is held to follow through on them.").)

A. Laguna Honda Complied with its Policies Regarding Use of Illicit Drugs

Laguna Honda had policies and procedures in place that identified illicit drugs as a potential hazard and prescribed actions to eliminate the hazard to the extent possible. (P. Ex. 12, at 44–52 (Clinical Search Protocol).) While Laguna Honda's policy on "Illicit or Diverted Drugs and/or Paraphernalia Possession/Use by Residents or Visitors" prohibits the use of illicit drugs, it also follows a harm reduction model, which requires staff to recommend referrals for substance use treatment, identify intervention options in the resident's care plan, order urine toxicology screens and conduct clinical safety searches based on reasonable grounds, and implement progressive interventions. (*Id.* at 91–95; *id.* at 73–77 (Harm Reduction Policy).)

Laguna Honda followed its policies for all residents, including Residents 1 and 3, the self-reported nonfatal overdoses. Resident 1 was referred to Laguna Honda psychiatry on the day he was admitted and had multiple clinical encounters with Dr. Anand Iyer, a psychiatrist, before his overdose on July 22, 2021. (P. Ex. 2, at 6, ¶ 13; P. Ex. 3, at 1–15.) During the overdose incident, staff administered two doses of Narcan within 25 minutes of observing the resident slumped over. (P. Ex. 2, at 13–14, ¶ 10.) "Two physicians responded to Resident 1 and the 911 response was really good. There is nothing about this medical response that was out of the ordinary." (*Id.*) After readmission, Resident 1 has "shown a gradual improvement in mental status and cognition," had 26 documented

[5] CDPH did not allege that Laguna Honda's policies were deficient in any respect, only that "the facility did not implement policies and procedures." (P. Ex. 1, at 8.)

encounters with psychiatry since March 2021, and has not had a positive urine toxicology since returning to Laguna Honda. (P. Ex. 2, at 6, ¶ 15.)

Resident 3 was referred to Laguna Honda psychiatry on the same day she was admitted to the facility and assessed by Dr. Iyer a week later. (P. Ex. 2, at 7, ¶ 16.) She refused substance use services, but Dr. Iyer followed best practices like trauma-informed care, coming to the patient, and he continued to offer care, including on July 11 and 13, 2021. (*Id.* ¶¶ 16–17.) During the incident on July 17, Resident 3 had stable vital signs and good oxygen level, but was difficult to arouse. (*Id.* ¶ 18.) Staff conducted a prompt assessment of her altered mental status (*id.*) and suspected an overdose based on her past history of drug use. (*Id.* at 14, ¶ 11.) The attending physician sent her to the emergency department (ED) and her condition worsened en route to the ED. (*Id.*) "This was a timely intervention because when she was admitted to the ED, she had respiratory failure most likely from opiate use and she required intubation. She received Narcan in the ED." (*Id.* at 8, ¶ 18.)

Dr. Hathaway, the Chief Medical Officer, opined, "[t]his was a save by the on-call physician to send her to the ED. There is nothing in the resident's record that would say staff was not following standard care." (P. Ex. 2, at 14, ¶ 11.) Dr. Qian, the Head of Psychiatry, opined that "[i]f these two residents were not at Laguna Honda and the rescue resources were not readily accessible, they would have died. If no Laguna Honda staff had intervened, they would have died." (*Id.* at 9, ¶ 22.)

Surveyors also alleged changes of level of consciousness for Residents 4 and 27. (P. Ex. 1, at 8.) Staff found Resident 4 to be drowsy and the resident admitted to using edibles. (P. Ex. 2, at 14, ¶ 12.) Two physicians evaluated the resident and her vital signs were stable. (*Id.*) "Because the resident continued to be drowsy and admitted to ingesting edibles, she was at risk and the on-call physician transferred the patient to a higher level of care." (*Id.*) Resident 27 was found to be sleepy with low blood pressure, but his other vital signs were fine and he was verbally responsive. (*Id.* ¶ 13.) Resident 27 refused to be transferred and therefore staff monitored the resident. (*Id.*) In both cases the care rendered was medically appropriate. (*Id.* ¶¶ 12–13.)

Surveyors alleged falls for Residents 2 and 32 (P. Ex. 1, at 8), but the SOD contains no factual allegation of Resident 2's fall. (*See id.* at 17–19; *see infra* Section III.F for Resident 2 interventions.) Resident 32 fell twice on September 9, 2021 after receiving alcohol by mail (P. Ex. 3, at 1514), which

staff cannot search. (P. Ex. 2, at 45, ¶ 12.) Resident 32 had documented interventions in his care plan for falls and alcohol use disorder. (P. Ex. 3, at 1491, 1493.) Resident 32 was seen that evening by a physician and staff updated his care plan and monitored for 72 hours. (*Id.* at 1515, 1522, 1526, 1528.) A social worker contacted his family advising against future shipments of alcohol. (*Id.* at 1540.) His care plan was updated, and was seen by Dr. Behrman who referred him to substance treatment (STARS) on September 15, 2021, and noted that staff did a clinical search of his room. (*Id.* at 1541–42.) On September 24, 2021, Resident 32 was seen by a behavioral health therapist, but refused assistance from the therapist. (*Id.* at 1546.)

The surveyors alleged behavior changes for Residents 11, 18, 24, and 29. For Resident 11, surveyors cited a progress note dated January 6, 2021 that said the resident's "behavior would be classified as a[n] 'unhealthy practice' . . . has been referred to counseling." (P. Ex. 1, at 20.) In that note, Dr. Iyer stated that he planned on following up with the resident regarding medication, referring the resident to counseling, "continu[ing to] *follow harm reduction oriented interventions as per LHH PP24-25*." (P. Ex. 3, at 582 (emphasis added).)

For Resident 18, surveyors noted "bizarre behavior throughout the morning." (P. Ex. 1, at 20.) But this change in behavior triggered Resident 18's interventions, which included being seen by a physician, having a urine toxicology ordered, notifying the care team, conducting a clinical search (which resulted in confiscating four lighters), monitoring for adverse effects, and updating his care plan with additional interventions. (P. Ex. 3, at 901–02.)

Surveyors noted "short-term increased paranoia" for Resident 24. (P. Ex. 1, at 21.) On July 23, 2021, Resident 24 was seen by Dr. Thompson who noted two positive tox screens and stated that he would "ask psych/STARS to re-evaluate although the [patient] shows little interest in active management of psych or substance use problems." (P. Ex. 3, at 1135.) Even though the resident refused treatment, staff performed what interventions they could including conducting a clinical search, ordering a urine toxicology, and educating and monitoring the resident. (*Id.* at 1136, 1138–39, 1178.)

Resident 29 was noted to have an "increase in paranoid behavior" on July 27, 2021. (P. Ex. 1, at 21.) Staff had already included interventions in Resident 29's care plan, which was updated to note

that staff would monitor the resident. (P. Ex. 3, at 1429.) Resident 29's care team met on July 30, 2021 to discuss the incident and noted that they would refer Resident 29 to the psychiatry department for substance use and follow-up. (*Id.* at 1433.)

B. Laguna Honda Followed its Policies Regarding Possession of Contraband

Laguna Honda's clinical search protocol required staff to search a resident, their property, and their room based on reasonable suspicion, which could include smelling or seeing something, behavior changes, or reports from other staff. (P. Ex. 12, at 45; P. Ex. 2, at 24, ¶ 6; *id.* at 34, ¶ 6.) If staff found contraband, they confiscated it. (P. Ex. 2, at 50, ¶ 5–6; *id.* at 43, ¶ 5.) As discussed in Section II.B, CDPH's findings demonstrate that staff conducted clinical searches and confiscated contraband. This is not surprising because Laguna Honda provided CDPH with a table of unusual occurrences that included the successful clinical searches and urine toxicology screens (P. Ex. 15, at 1–5), which CDPH then used to select the unrepresentative[6] sample population cited in the SOD. (P. Ex. 2, at 38, ¶ 20; P. Ex. 1, at 31 (citing review of facility document "Clinical Searches with Items Found").)

Laguna Honda also followed its harm reduction policy (P. Ex. 12, at 73–77) by offering services, providing education to, meeting with, and monitoring the residents cited by surveyors in subpart (b). (*See infra* Section III.F.)

C. Laguna Honda Followed its Policies Governing Possession of Ignitable Items

Laguna Honda's Smoke and Tobacco Free Environment Policy states that "[s]moking and tobacco products are prohibited on the LHH campus, with the exception of smoking in the designated smoking areas as described below." (P. Ex. 12, at 106.) It also states that "[l]ighters, matches, electronic cigarettes (e-cigarettes), and other devices that ignite, light, or fuel a flame are not permitted and shall be collected from residents by staff for safekeeping." (*Id.*) Laguna Honda's smoking policy also acknowledges that some residents inevitably will violate the policy, in which case:

> Clinical care plan interventions shall be developed for those residents who have violated the smoke and tobacco free environment policy, and may include, [s]earch of a resident's belongs and room for, and safekeeping of, smoking or tobacco product materials [and] [m]eeting with [Resident Care Team] members to discuss the violation with resident and outline care plan to prevent further

[6] 42 C.F.R. § 488.110(d)(1) requires surveyors to "select residents for the sample in a random manner."

> smoking or tobacco product violations, which may include repeat searches, engagement in smoking cessation activities, referral to SATS and/or MD.

(*Id.* at 108; *see also id.* at 73 (Harm Reduction Policy).)

Here, the findings demonstrate that Laguna Honda followed its smoking and harm reduction policies.[7] Contrary to the assertion in the SOD, Resident 34's care plan does not state that the resident required one-on-one supervision to smoke. (P. Ex. 3, at 1561, 1578; *see also id.* at 1574.) And, Resident 34 was smoking on the patio outside the unit's great room, which was the designated smoking area during COVID-19. (P. Ex. 2, at 49, ¶ 4; *id.* at 42, ¶ 4; P. Ex 14, at 18.)

For Resident 2, staff responded to an incident on April 4, 2021 by declaring a Code Red and implemented interventions, including checking resident's whereabouts and activity to ensure compliance with the smoking policy, conducting clinical searches, and educating the resident. (P. Ex. 3, at 156; 169–70.) Staff also conducted clinical searches for lighters, monitored the resident for any signs of withdrawal or intoxication, offered services to address his SUD, and notifying the physician and nursing supervisor. (*Id.* at 155, 157.)

In addition to successfully confiscating Resident 20's lighters, staff revised his care plan to implement various interventions including educating the resident about the smoking policy. (P. Ex. 3, at 1004, 1050.) Staff also monitored the resident for any change in behavior or additional lighters. (*Id.* at 1022, 1030.) While Resident 14 had some incidents in 2020, staff implemented interventions following those incidents, and staff assessed Resident 14 to be a safe smoker on August 11, 2021. (*Id.* at 729.)

D. Laguna Honda Followed its Policies Governing Storage of Ignitable Items

Laguna Honda followed its COVID-19 storage lighter storage policy, which directed staff to store lighters at the nursing station because residents could not leave their units to smoke. (*See supra* note 4.) As Nurse Manager Namnama Angeles testified, during COVID-19:

> [S]taff would keep the lighters at the nurse station or in some units in the medication room for safety, which only licensed nurses can access by badge. Residents are not supposed to go beyond the nursing station and from my experience I have never seen nor ever heard of a resident going into the room behind the nursing station except if they have a care conference. There is

[7] The interventions and services provided to Residents 17, 18, 25, 26, and 27 for the incidents cited in subpart (c) are the same incidents cited in either subparts (a) or (b) and discussed in Sections III.A, III.B, and III.F.

> always a staff member at the nurse station and either a unit clerk or staff member overseeing the great room in front of the nurse station. We had a cabinet in the report room behind the nurse station where we kept the igniters. The filing cabinet was locked and only the charge nurse and nurse manager have the key.

(P. Ex. 2, at 49, ¶ 4.) The Chief Quality Officer testified, "Residents are not supposed to come over to where staff is located behind the nurse station and staff are present to redirect residents away and generally monitor residents. I am not aware of any incident where a resident obtained a lighter from the unit." (*Id.* at 38–39, ¶ 23.)

As discussed, CDPH also failed to assess whether any resident was vulnerable to the purported hazard. Laguna Honda followed its smoking and harm reduction policies for the residents noted in subpart (c) who may have been vulnerable to the hazard. (*See supra* Section III.C.)

E. Laguna Honda Safely Disposed of Confiscated Contraband

Laguna Honda's clinical search protocol required staff to document in the resident's medical record the disposition of items found and seized. (P. Ex. 12, at 49.) The protocol also required staff to dispose of cannabis using the smart sink in the supplemental drug room, alcohol by pouring it down the sink while witnessed by another staff member, cigarettes by holding or disposing based on the resident's care plan, lighters and other ignitable items secured by social services, dangerous objects (such as certain blades or illicit drugs other than cannabis) handed over to Sheriff's deputies, and pills and capsules to the pharmacy. (*See id.* at 49–51.)

For Residents 11, 15, 19, 2 and 18, documentation in the residents' records directly rebuts the surveyors' findings. Surveyors cited Resident 11's nursing note dated January 4, 2021, which said "[c]alled [sic] made to sheriff department . . . to come pick up the substance . . ." (P. Ex. 1, at 50.) That note goes on to state: "Deputy Duong picked up the contraband around 12:15 pm for disposal. He gave us a case number of 210006838." (P. Ex. 3, at 578.) Not only did staff track the disposition of the contraband, the nurse even recorded a case number. For Resident 15, there is a nursing note dated March 11, 2021 stating "[n]ickel size dry green leaves was taken [sic] to supplemental room: disposed at Cactus smart sink @ 1605 as witnessed by NM Namnama Angeles." (*Id.* at 797.) Surveyors cited Resident 19's nursing note dated May 15, 2021 because staff documented that the "lighter was labeled with his name and will keep [it] at the nursing station for him to use when he

lights his cigarette." (*Id.* at 992.) As discussed above, the facility's COVID-19 smoking policy allowed staff to store lighters on the unit for residents to use. (*See supra* Section II.D & note 4.)

For both Residents 2 and 18, staff transferred the contraband to the pharmacy, which meets the clinical search protocol: "[a]ny confiscated substances in pill or capsule form that cannot be identified, shall be transferred to the pharmacy for identification and proper disposal." (P. Ex. 12, at 51.) Resident 2 had unknown "white rocks substance" confiscated and staff noted that the Sheriff's deputy and the nursing supervisor "kept the substance for pharmacy to analyze in the morning." (P. Ex. 3, at 176.) For Resident 18's contraband "pharmacy was not able to ID the pill as the markings were not legible." (P. Ex. 1, at 54.)

F. Laguna Honda Implemented Interventions and Supervised Residents

For each resident, staff documented interventions in care plans, implemented interventions (*i.e.*, educating the resident, assessing residents returning to the facility, ordering urine toxicology, and conducting clinical searches), referred residents to behavioral health services, and monitored residents. (*See* (Resident 2 (P. Ex. 3, at 122–23, 136–37, 149–51, 178, 180–83, 185, 187, 212, 214, 239–52, 265–70); Resident 3 (*id.* at 275–86); Resident 4 (*id.* at 364–65, 372, 375, 403–11); Resident 5 (*id.* at 442–50); Resident 7 (*id.* at 456, 463–64, 472, 521–22, 525); Resident 10 (*id.* at 527–29, 535, 542, 544, 547); Resident 11 (*id.* at 557–59, 576–81, 584–86); Resident 12 (*id.* at 598–99, 603, 605, 607–10, 623–24); Resident 13 (*id.* at 641, 646, 648–51, 655–56); Resident 14 (*id.* at 685, 687, 696–75); Resident 15 (*id.* at 794, 797–98); Resident 16 (*id.* at 800–05, 814–15); Resident 17 (*id.* at 843–44, 848–51, 856, 868–69); Resident 18 (*id.* at 906–09, 939, 969, 982, 986); Resident 20 (*id.* at 1013, 1017, 1022, 1030); Resident 21 (*id.* at 1072, 1074–77, 1079, 1082–83); Resident 23 (*id.* at 1118); Resident 24 (*id.* at 1125–31, 1158–59, 1178, 1186–92); Resident 25 (*id.* at 1237–43); Resident 26 (*id.* at 1246–47, 1254, 1256–59); Resident 27 (*id.* at 1296, 1323); Resident 28 (*id.* at 1364, 1366–71, 1381, 1392, 1406); Resident 31 (*id.* at 1475–78, 1481, 1485–86).)

In sum, Laguna Honda followed its illicit substance, clinical search, smoking, and harm reduction policies for each resident cited by the surveyors in subparts (a) through (e) and, accordingly, the facility was in substantial compliance with Section 483.25(d).

IV. The January 21, 2022 Revisit Survey Demonstrates Laguna Honda's Compliance with Its Plan of Correction and Policies

The surveyors erred in issuing any deficiency based on the January 21, 2022 revisit survey. Instead, they applied the same flawed strict liability standard as they did during the October 14, 2021 survey. Rather than assessing whether Laguna Honda followed all of its policies, the surveyors cited three successful clinical searches and one documentation error as noncompliant.

A. Three Clinical Searches Demonstrate Compliance with the Plan of Correction

As agreed to by CDPH in the Plan of Correction, Laguna Honda implemented several changes before the January 21, 2022 revisit survey, including creating a facility-wide system for tracking the handling and disposition of confiscated contraband items for all residents, a transfer form for contraband items, and implementing a new Standard Work explaining how to conduct clinical searches. (P. Ex. 1, at 74; P. Ex. 4, at 195–202; P. Ex. 2, at 51, ¶ 10.)

During the January 21, 2022 revisit survey, surveyors determined that the facility failed to ensure a safe environment because Residents 2, 14, and 31 were found in possession of contraband during a clinical search. (P. Ex. 1, at 86–88.) Those findings in fact demonstrate Laguna Honda's substantial compliance. The Plan of Correction required clinical searches (*id.* at 74–75), Laguna Honda performed clinical searches. (P. Ex. 11, at 176, 179, 182–204.) Finding and confiscating contraband during a clinical search is precisely what Laguna Honda proposed, *and CDPH accepted*, in the Plan of Correction. (P. Ex. 1, at 74–75.) And, in any case, the surveyors failed to assess whether Laguna Honda mitigated any accident hazard by following its policies, including its harm reduction policy.

B. One Instance of Failure to Document Is Not an Avoidable Accident

CMS also alleges that on December 6, 2021, staff successfully confiscated two small bags with unknown powdered substance from Resident 31. (P. Ex. 1, at 88.) The bags were stored in medication storage and the nurse did not complete the contraband transfer form. (*Id.*)

That finding does not meet the standard for Section 483.25(d) for two reasons. First, the findings demonstrate that Laguna Honda successfully eliminated the hazard by (1) properly conducting a clinical search on Resident 31; and (2) storing the confiscated item in a locked

medication storage. (P. Ex. 1, at 88 (Staff "stored the confiscated items inside the Pavilion Mezzanine Medication Storage.").) Residents cannot access the medication storage area, which requires badge access. (P. Ex. 2, at 39, ¶ 26; *id.* at 49, ¶ 4.)

Second, the approved Plan of Correction does not require 100% compliance with the corrections, even though CDPH expected 100% compliance. (P. Ex. 2, at 39, ¶ 26.) Correction #9, cited by the surveyors, states "[c]ompliance with standard work shall be reviewed monthly and reported to PIPS and MEC . . . until three consecutive months of 95% compliance or greater has been achieved." (P. Ex. 1, at 76.) "Laguna Honda agreed to monitor several corrections for compliance over the long term, which is why the plan will say that the facility will monitor until the facility achieves three consecutive months of 95% compliance." (P. Ex. 2, at 39, ¶ 26.) Nor does the correction require immediate compliance because it required audits to continue *until* Laguna Honda meets three consecutive months of 95 percent. Similarly, correction #4 requiring a facility-wide system for tracking the handling and disposition of confiscated contraband contemplates audits until staff achieves three consecutive months of at least 95 percent. (P. Ex. 1, at 74.)

Even if the one instance of missed documentation constituted a deficiency, which Laguna Honda rejects, CDPH erred by not rating the deficiency as scope and severity of A because no resident could access the contraband. (*See Libertyville Manor Rehab. & Healthcare Ctr.*, DAB No. 2849, at 15 (2018) ("So when Petitioner asserted that its violation of section 483.10(b)(11) should have been cited at the A-level of seriousness, it was not merely challenging the *level of* noncompliance. Rather, it was also disputing the *existence* of noncompliance.") (emphasis in original).)

In sum, CDPH erred by issuing a deficiency for Section 483.25(d). Had CDPH not erred, Laguna Honda would have been cleared of the purported deficiencies from the October 14, 2021 survey, ending the six-month enforcement cycle.

V. Laguna Honda Returned to Substantial Compliance by November 14, 2021.

Laguna Honda returned to substantial compliance by November 14, 2021, or at the latest by November 22, 2021. As established above, the surveyors erroneously assessed, and CMS cannot allege, a violation of Section 483.25(d) in October 2021 and January 2022. During the October 14, 2021 survey, CDPH also alleged a violation of 42 C.F.R. § 483.35, and two complaint surveys were

completed October 15, 2021 and November 5, 2021, which the facility did not appeal. (P. Ex. 1, at 57, 316, 325.) But, neither CMS nor CDPH disputed that Laguna Honda demonstrated substantial compliance with Section 483.35 and the two complaint surveys. The latest date of compliance for those deficiencies was November 14, 2021 (or, at the latest by November 22, 2021), and Laguna Honda returned to substantial compliance on that date, ending the enforcement cycle that began October 14, 2021.

A. Laguna Honda Met its Plan of Correction for Section 483.35 by November 13, 2021

Laguna Honda proposed, and CDPH accepted, a Plan of Correction for Section 483.35 (deficiency tag F726) that first required the facility to provide Resident Care Team members an in-service learning module on clinical searches. (P. Ex. 1, at 79.) Next, to ensure competency, Laguna Honda proposed to test nursing staff until they achieved at least an 80% passing score. (*Id.*) The facility proposed an ongoing monitoring requirement until three consecutive months of 95% compliance or greater had been achieved. (*Id.*) Laguna Honda alleged a completion date of November 13, 2021 for both corrections. (*Id.*)

Here, the January 21, 2022 revisit survey certified compliance with Section 483.35, which was not cited on the SOD for the revisit survey. (*See* P. Ex. 1, at 80–89.) CDPH reviewed the education provided and informed staff that Laguna Honda came back into compliance. (P. Ex. 2, at 39, ¶ 25.) Because CDPH made no determination as to the date of compliance, "[c]ompliance is certified as of the latest correction date on the approved PoC." (SOM, Ch. 7, § 7317.2; *see Grace Living Ctr.*, DAB No. 2633, at 8 (2015) (finding "a trier of fact could reasonably conclude that the facility's PoC constituted an allegation that compliance had already been achieved on November 12 based on the measures taken by that date (such as in-service training, some audits, and a meeting of the QAC) and that ongoing monitoring through further audits and another QAC meeting were planned to ensure the correction would remain effective in the longer term, not to achieve substantial compliance in the first instance").)

In the alternative, Laguna Honda achieved substantial compliance by November 22, 2021 because it offered its in-service training via electronic learning module, which was sent via email to all

staff on November 22, 2021. (P. Ex. 2, at 19, ¶ 8.) The training department created the training by meeting with the Sheriff's office, who were the subject matter experts on how to conduct clinical safety searches. (*Id.* ¶ 7; P. Ex. 5, at 1–33.) Staff started taking the training in November 2021 and continued through December 2021. (P. Ex. 5, at 121–206.) The facility as a whole achieved an 80% compliance rate by December 20, 2021.[8] (*Id.* at 35–62.) Staff found the training informative and implemented it while conducting clinical searches. (P. Ex. 2, at 24, ¶ 8; *id.* at 51, ¶ 11; *id.* at 57–58, ¶¶ 12–13.)

The facility also provided additional training beyond that required by the Plan of Correction. With the assistance of the Sheriff's office, the training department created two on-demand training videos demonstrating how to search a resident's room and how to conduct a pat down. (P. Ex 2, at 19, ¶ 7.) The training department also offered a read and sign training on the clinical safety search standard work (*id.* ¶ 9), and each unit's nursing staff attested to reading the standard work. (P. Ex. 5, at 92–117.)

B. Laguna Honda Met its Plans of Correction for the October 15, 2021 and November 5, 2021 Surveys by November 14, 2021

For the survey completed October 15, 2021, Laguna Honda submitted its Plan of Correction on January 13, 2022, and alleged that the latest correction date was November 14, 2021. (P. Ex. 1, at 315, 322.) CDPH accepted the Plan on January 18, 2022 (*id.* at 316), and did not conduct an onsite revisit. (P. Ex. 2, at 39, ¶ 27.) Because CDPH did not conduct an onsite revisit and approved the Plan of Correction, CDPH accepted the latest correction date of November 14, 2021. (SOM, Ch. 7, § 7317.1.) And, Laguna Honda in fact met its Plan of Correction by that date. (*See generally* P. Ex. 7.)

For the survey completed November 5, 2021, Laguna Honda submitted its Plan of Correction on January 11, 2022, and alleged that the latest correction date was November 8, 2021. (P. Ex. 1, at 324, 331.) CDPH accepted the Plan on January 14, 2022 (*id.* at 325), and did not conduct an onsite revisit. (P. Ex. 2, at 39, ¶ 27.) Because CDPH did not conduct an onsite revisit and approved the Plan of Correction, CDPH accepted the latest correction date of November 8, 2021. (SOM, Ch. 7,

[8] The facility updated the ELM training in response to the January 21, 2022 revisit survey and issued it on February 7, 2022 and restarted the compliance rate tracking. (P. Ex. 5, at 207–331.)

§ 7317.1.) And, Laguna Honda actually met its Plan of Correction by that date. (*See generally* P. Ex. 8.)

C. Alternatively, Laguna Honda Met its Plan of Correction for 42 C.F.R. § 483.25(d) by November 13, 2021

Laguna Honda was in substantial compliance with 42 C.F.R. Section 483.25(d), but it also successfully implemented its Plan of Correction and can alternatively demonstrate substantial compliance based on that Plan. Laguna Honda alleged a latest completion date of November 13, 2021 for each of its corrections, except for corrections 10 through 14, which Laguna Honda proposed to monitor on an ongoing basis. (P. Ex. 1, at 73–78.) Laguna Honda implemented its Plan for each correction. (*See generally* Exhibit 4.) On the first revisit, "[c]ompliance is certified as of the latest correction date on the approved PoC" unless the surveyors determine otherwise. (SOM, Ch. 7, § 7317.2.) Other than the issues related to clinical searches and the new contraband transfer form, addressed in Section IV, CDPH assessed no findings with regard to any of Laguna Honda's other corrections. (P. Ex. 1, at 86–89.) Accordingly, Laguna Honda was in substantial compliance with Section 483.25(d) by November 13, 2021.

VI. Any Statement of Deficiencies Received After November 14, 2021 Would Have Triggered a New Enforcement Cycle

The Social Security Act ("Act") requires CMS to terminate the Medicare provider agreement of any facility that does not return to substantial compliance within six months of the date noncompliance began. (42 U.S.C. § 1395i-e(h)(2)(C) (Section 1819(h)(2)(C) of the Act).) CMS also has discretion to terminate a provider agreement before the running of the six-month statutory period. (*Id.* § 1395i-3(h)(2), (4) (Section 1819(h)(2), (4) of the Act).)

Here, CMS did not exercise its discretionary authority to terminate Laguna Honda's provider agreement before the running of the six-month statutory period. Rather, the March 30, 2022 Notice stated that "CMS previously notified you that if you failed to reach and maintain substantial compliance with the Medicare program's nursing home participation requirements at 42 C.F.R. Part 483 by April 14, 2022—six months from the first survey documenting your noncompliance—it would be required to terminate your Medicare provider agreement." (P. Ex. 1, at 306.) CMS notified Laguna

Honda that its provider agreement would terminate by operation of law six months after the end of the survey establishing noncompliance. (*Id.* ("[Y]our Medicare provider agreement will terminate in accordance with the statutory provisions at § 1819(h)(2)(C) of the Act.").)

Laguna Honda returned to substantial compliance with the Medicare conditions of participation on November 14, 2021. (*See supra* Section V.) Because CMS relied only on its mandatory termination authority pursuant to section 1819(h)(2)(C) of the Act, the facility's return to substantial compliance interrupted the six-month mandatory termination cycle and termination was not required. The SOM also provides "[a] noncompliance cycle begins with a . . . complaint . . . survey that finds noncompliance and ends when substantial compliance is achieved or the facility is terminated . . . ." (SOM, Ch. 7, § 7317.3.)

The facts here are similar to *Woodbine Healthcare and Rehabilitation Center*, DAB No. CR2140 (2010), where the state survey agency initially found the facility out of substantial compliance on February 20, 2009, conducted several revisit and complaint surveys during which the state alleged the facility never returned to substantial compliance, and CMS notified the facility it would be terminated on August 20, 2009, six months after the initial survey. (*Id.* at 1–2.) The facility conceded the deficiencies in surveys completed in February, March, and April 2009, but argued that it corrected all deficiencies cited in the April survey, returning to substantial compliance by May 27, 2009, which interrupted the six-month period that caused mandatory termination, even though additional deficiencies were found in July and August 2009. (*Id.* at 5–6.) The ALJ agreed that the petitioner produced unrebutted evidence that it met its plan of correction and returned to substantial compliance on May 27, 2009. (*Id.* at 31–32.)

The ALJ then found that "while the Secretary and her delegate, CMS, have authority to exercise discretion to terminate a facility's participation under other circumstances specified by section 1819(h)(2) and (4), the evidence shows that such discretion was not exercised at any time when there was a basis for imposing the remedy of termination." (*Id.* at 25.) Accordingly, the ALJ determined that "[t]he running of the six-month statutory period leading to termination triggered by the survey ended on February 20, 2009, therefore ended on May 27, 2009, with Petitioner's return to substantial compliance. Accordingly, the Act did not mandate termination of Petitioner's participation

on August 20, 2009, as CMS alleged." (*Id.* at 32; *see also In re Pinewood Care Center*, DAB CR 1621, at 39 (2007) (finding that, despite CMS's "discretionary authority to terminate," the "case does not involve a discretionary termination by CMS" and "[b]ecause Petitioner returned to substantial compliance not later than January 5, 2007 (the date Petitioner alleges it was in substantial compliance following the October survey), the regulation does not compel termination in this case").)

Woodbine's reasoning applies here. CMS did not exercise its discretionary termination authority at any point during the six-month enforcement cycle. Rather, CMS told Laguna Honda termination was required six months after the October 14, 2021 survey by operation of law. Because the facility returned to substantial compliance, it interrupted the mandatory six-month termination and CMS's termination of Laguna Honda's provider agreement was in error.

VII. CMS Erroneously Issued the DPNA and Civil Monetary Penalties Related to Section 483.25(d)

CMS erred for three reasons when on February 24, 2022 and March 30, 2022 it imposed civil money penalties ("CMP") based on Section 483.25(d). (P. Ex. 1, at 170, 309–10.) First, as set forth in Sections I and II above, CMS erroneously alleged a violation of Section 483.25(d). Second, as discussed in Section III, Laguna Honda consistently followed and enforced its illicit substance and contraband, smoking, lighter storage, and harm reduction policies. Third, even assuming that Laguna Honda was out of substantial compliance at some point, CMS failed to recognize that, as argued in Section V above, the facility returned to substantial compliance by November 14, 2021.

These errors undermine the basis for the CMP imposed in the February 24, 2022 and March 30, 2022 notices. CMP remedies may be issued "for the number of days that the facility is not in compliance, or for each instance that a facility is not in substantial compliance." (*Woodbine*, DAB No. CR2140, at 39 (citing 42 C.F.R. § 488.430(a)).) Thus, CMP are not available as remedy where, as here, a particular instance of alleged deficiency of Section 483.25(d) did not remove a facility from substantial compliance. Similarly, CMP may not be imposed for days in which a facility remains in substantial compliance, even if that substantial compliance was achieved during the time between two periods where the facility was not in substantial compliance. (*Id.* at 32 (finding the facility's "return to substantial compliance also ended the running of the DPNA and the per day CMP").)

To the extent CMPs may be imposed, they should be reduced under the 42 C.F.R. § 488.438(f) factors. CMS has not alleged any past noncompliance with regard to the deficiencies at issue during the enforcement cycle. As demonstrated in Sections I through III, Laguna Honda followed its harm reduction policy and timely intervened to save the only two instances of nonfatal drug overdose that the facility self-reported to CDPH. CMS has not alleged neglect, indifference, or disregard because, as discussed throughout, Laguna Honda staff actively implemented interventions, including the very clinical searches that the surveyors cited in the SOD. Finally, even though Laguna Honda still had residents with substance use disorder during the April 2022 revisit survey, the surveyors assessed no deficiencies related to that issue, in essence ratifying Laguna Honda's actions.

CMS also erred in issuing a denial of payment for new admissions ("DNPA") starting January 14, 2022 because Laguna Honda returned to substantial compliance by November 14, 2021. (*See supra* Section V.) CMS imposed a mandatory DPNA "3 months after the last day of the survey identifying the noncompliance." (42 C.F.R. § 488.417(b)(1).) By returning to substantial compliance, Laguna Honda reset the enforcement cycle, which would also reset the mandatory three-month DPNA.

CONCLUSION

For the foregoing reasons, Laguna Honda respectfully requests the court overrule CMS's termination of the facility's provider agreement, overrule the DPNA, and reduce the CMP.

Dated: September 19, 2022

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on this 19th day of September, 2022, I electronically filed the following documents:

LAGUNA HONDA'S PREHEARING EXCHANGE, PETITIONER WITNESS LIST, PETITIONER EXHIBIT LIST, DECLARATION OF CHARLES LAMB, and PETITIONER EXHIBITS 1 THROUGH 15

with the Department of Health and Human Services Departmental Appeals Board, Civil Remedies Division by using the DAB E-Filing System. Participants in this proceeding who are registered DAB E-Filing System users will be served by the DAB E-Filing System.

/s/ Henry L. Lifton
CITY AND COUNTY OF SAN FRANCISCO
Attorney for Laguna Honda Hospital and Rehabilitation Center