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

Re: Request for an ***Expedited*** Appeal Hearing of Survey Findings and Imposition of Remedies and Consolidation with Docket No. C-22-327 related to Incident Nos. CA744774, CA745390, CA747134, CA746900, CA675386, and CA747220; 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[1] 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) "Survey Findings and Imposition of Remedies" dated February 24, 2022. Laguna Honda also seeks to consolidate this appeal with Laguna Honda's pending appeal, Docket No. C-22-327. The CMS survey findings and remedies stem from the California Department of Public Health's (CDPH) Statement of Deficiencies dated December 16, 2021, for the extended survey that concluded on October 14, 2021, and the Statement of Deficiencies dated February 15, 2022 for the revisit survey that concluded on January 21, 2022. Those Statements allege 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. According to CDPH, Laguna Honda did not implement policies and procedures to prohibit use and possession of illicit substances, contraband, or lighters. Likewise, CDPH concluded that Laguna Honda failed to properly track and dispose of confiscated prohibited contraband. CDPH concluded that the scope and severity level of the alleged deficiency constitutes "substandard quality of care" as defined at 42 C.F.R. § 488.301.

As described in more detail below, Laguna Honda disagrees with CDPH's findings and legal conclusions. Because CDPH applied the wrong deficiency tag, mischaracterized the incidents as "avoidable accidents," and held Laguna Honda to the wrong standard, CDPH's findings and remedies must be reversed. CDPH's conclusions do not establish a pattern of actual harm that constitute substandard quality of care to justify the remedies issued by CMS, including the civil

[1] CMS terminated Laguna Honda's provider agreement as of April 14, 2022. This appeal seeks to reverse that termination because CMS based that six-month cycle on the flawed F689 deficiency tag finding. Because Laguna Honda seeks to reverse this extreme remedy, an expedited hearing is warranted.

money penalties (CMP), denial of payment for new admissions (DPNA), or the six-month cycle start date that resulted in Laguna Honda's termination on April 14, 2022.

DISPUTED DEFICIENCY

Both Statements of Deficiencies allege violations of the same deficiency tag, F689, and the associated regulation under 42 C.F.R. § 483.25(d) which states: "the facility must ensure that (1) The resident environment remains as free of accident hazards as is possible; and (2) Each resident receives adequate supervision and assistance devices to prevent accidents."

DEFICIENCY STANDARD

The standard under the cited regulation and deficiency tag F689 under the CMS State Operations Manual (SOM), Guidance to Surveyors for Long Term Care Facilities, requires facilities to,

> "ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents. This includes:
> - Identifying hazard(s) and risk(s);
> - Evaluating and analyzing hazard(s) and risk(s);
> - Implementing interventions to reduce hazard(s) and risk(s); and
> - Monitoring for effectiveness and modifying interventions when necessary."[2]

CDPH SURVEYOR FINDINGS

Based on the October 14, 2021 survey, CDPH found that Laguna Honda failed to ensure a safe environment under 42 C.F.R. § 483.25(d),

> "when the facility did not implement policies and procedures for the following practices:
>
> a. Prohibiting use and possession of illicit drugs; where 13 of 37 sampled residents tested positive for non-prescribed substances; use of which resulted in the following outcomes:
>
> i. Residents 1 and 3 experienced a life-threatening emergency and were hospitalized;
> ii. Residents 4 and 27 experienced a change of level of consciousness;
> iii. Residents 2 and 32 fell;
> iv. Residents 11, 18, 24, and 29 experienced behavior changes.
>
> b. Possession of contrabands, trading illicit substances, and consuming marijuana and alcohol inside the facility; where 23 of 37 sampled residents (Residents 14, 3, 4, 5, 2, 27, 11, 17, 13, 15, 16, 23, 20, 26, 21, 19, 25, 32, 12, 18, 33, 10, and 24) were found in possession of marijuana, syringes, pocket-knife, scissors, smoking paraphernalia, and bottles of alcohol, access to which posed a safety hazard that jeopardize the health and safety of residents, staff, and visitors.
>
> c. Monitoring and implementing care plan for 11 of 37 sampled residents who were identified as safe and unsafe smokers (Residents 2, 27, 17, 34, 18, 20, 26, 14, 25, 24, and

[2] CMS State Operations Manual, Appendix PP. Guidance to Surveyors for Long Term Care Facilities. (Rev. 173, 11-22-17) at p. 302.

> 19), for which unsafe possession of ignitable items had the potential to cause burn injuries and significant harm to residents, staff, and visitors.
>
> d. Storing lighters, combustibles in specific secure place according to policy to prevent misuse and control access.
>
> e. Tracking and disposition of confiscated contrabands for 16 of 37 sampled residents (Residents 17, 35, 36, 37, 13, 15, 23, 19, 11, 25, 12, 4, 10, 21, 34, and 2) had the potential for diversion, misuse or uncontrolled redistribution of confiscated contrabands and further harm to residents, staff, and visitors."[3]

CDPH found that "Laguna Honda's failure to implement policies and procedures for these practices placed residents in an unsafe living environment and negative health outcomes."[4]

Related to the January 21, 2022 revisit survey, CDPH found that,

> "the facility failed to ensure a safe environment where:
>
> 1. Three of 10 sampled residents (Resident 2, Resident 14 and Resident 31) were found in possession of contraband during clinical search.
> 2. The "two empty baggies with small amount of white residue" were stored inside the medication storage room after confiscation on 12/6/21 until 1/21/22 (total of 46 days).
> 3. The confiscated contraband was not disposed in accordance to the facility policy.
> 4. The staff did not complete the transfer of contraband form for items confiscated from Resident 31."[5]

CDPH found that Laguna Honda's "failure had the potential for diversion, misuse, or uncontrolled redistribution of confiscated contraband and further harm to residents, staff, and visitors."[6]

LAGUNA HONDA'S RESPONSE

CDPH's findings rest on a flawed contention: that an *intentional* act by a patient to use or possess illicit substances or prohibited contraband on its own establishes an *avoidable* and *unintentional* accident under the cited federal regulation and deficiency tag in the SOM. By applying this flawed reasoning to Laguna Honda, CDPH erred by finding Laguna Honda deficient under F689. CDPH's findings do not amount to avoidable accidents, a deficiency under F689, or a pattern of actual harm to constitute substandard quality of care. Additionally, Laguna Honda satisfied every element of the standard described in the SOM for the F689 deficiency tag.

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[3] CDPH, Statement of Deficiencies, Form CMS 2567, dated December 16, 2021, at p. 2.
[4] *Id*. at p. 4.
[5] CDPH, Statement of Deficiencies, Form CMS 2567, dated February 15, 2022, at p. 2.
[6] *Ibid.*

I. CDPH's Findings Are Not Accidents and Do Not Constitute "Avoidable Accidents" as Required to Form the Basis for a Deficiency Under F689

A. CDPH Mischaracterizes the Alleged Findings as Accidents

The SOM defines an accident as "any unexpected or unintentional incident, which results or may result in injury or illness to a resident."[7] The intent of F689 is to ensure that facilities provide "an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents."[8]

Yet the findings cited by CDPH are not accidents. They are events that reflect the intentional acts and challenges of a vulnerable patient population struggling with substance use disorders.

Although Laguna Honda treats substance use disorders very seriously, the facility cannot mandate substance use treatment. Laguna Honda can only offer treatment and related resources to those patients who wish to receive help with their addictions. Absent a court order, patients maintain the right to refuse treatment and to refuse to adhere to any aspect of their individual care plans.

Further, substance use disorder and addiction treatment does not guarantee abstinence from substances. The National Institute on Drug Abuse notes that addiction is a chronic illness that cannot be cured, with a relapse (return to use of substances) rate of 40 to 60 percent, even with treatment. And, "relapse doesn't mean treatment has failed." (https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/treatment-recovery). In addition, patients do not always seek abstinence as the goal of substance use disorder treatment. The prevailing standard of care acknowledges that patients will collaborate on their goals for substance use disorder treatment and the recommended harm reduction framework further acknowledges that some patients may not desire to stop using substances. (https://www.samhsa.gov/find-help/harm-reduction). Federal law and applicable regulations require that health care providers and patients collaborate on treatment goals, which may include implementing treatment goals that differ from the "ideal" outcome.[9]

Laguna Honda is committed to addressing the use and possession of drugs, alcohol, and related paraphernalia. However, Laguna Honda should not be held to the standard for "accidents," or be expected to eliminated all use of contraband. Relapse on substances (which by nature requires the possession and use of a substance) is not an accident, but rather part of the expected disease course of substance use disorder/addiction. Recurrent substance use in situations in which it is physically hazardous is not an accident, but rather one of the 11 diagnostic criteria/symptoms of a substance use disorder.[10]

B. F689 Is Not Intended to Apply to Possession of Illicit Substances

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[7] CMS State Operations Manual, Appendix PP. Guidance to Surveyors for Long Term Care Facilities. (Rev. 173, 11-22-17), F689 at p. 302
[8] *Ibid.*
[9] *See* CMS State Operations Manual Guidance to Surveyors for Long Term Care Facilities Appendix PP, deficiency tags F552 and F553, as well as 42 C.F.R. § 483.10.
[10] Diagnostic and Statistics Manual of Mental Health Disorders, Fifth Edition.

Deficiency tag F689 is not intended to apply to illicit substances and CDPH erred by applying that standard to the illicit substances and contraband at Laguna Honda.

The SOM defines the relevant terms as follows:

- "Environment refers to any environment or area in the facility that is frequented by or accessible to residents, including (but not limited to) the residents' rooms, bathrooms, hallways, dining areas, lobby, outdoor patios, therapy areas and activity areas."
- Hazards refers to elements of the resident environment that have the potential to cause injury or illness.
- "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.
- "Free of accident hazards as is possible" refers to being free of accident hazards over which the facility has control."[11]

The SOM does not contemplate illicit substances under this deficiency tag. Instead, the SOM imposes duties to properly store materials and chemicals that are typically found in a facility's normal course of business, such as cleaning supplies, plants or other natural materials that may cause injury or illness, for which the facility has control. Likewise, the SOM requires the safe storage of "drugs" and other "therapeutic agents," consistent with the requirement to properly store and handle legal prescription drugs and over the counter medications that a facility dispenses to its patients as part of their course of treatment.

Illicit substances and prohibited contraband are not under the control and supervision of the facility in its normal course of business and therefore are not subject to review under F689.

C. CDPH's Findings Do Not Amount to Avoidable Accidents and Therefore Do Not Constitute a Deficiency Under F689

CDPH's findings involve patients at Laguna Honda who have histories or current active illicit substance, marijuana, tobacco, or alcohol use and related substance-seeking behavior. Incidents related to the use or possession of these substances or related paraphernalia that is prohibited at Laguna Honda are not "avoidable accidents" within the meaning of the F689 deficiency tag. Likewise, the resulting harm, including the hospitalizations, falls, or changes in consciousness, cannot fairly be deemed to be avoidable accidents, but rather the unavoidable and unfortunate physical outcomes of intentional patient behavior that Laguna Honda had taken extraordinary steps to attempt to reduce prior to the two Statement of Deficiencies at issue here.

An avoidable accident is defined as "an accident that occurred because the facility failed to:

- "identify environmental hazards and/or assess individual resident risk of an accident, including the need for supervision and/or assistive devices; and/or

[11] CMS State Operations Manual, Appendix PP. Guidance to Surveyors for Long Term Care Facilities. (Rev. 173, 11-22-17), F689 at p. 304.

- evaluate/analyze the hazards and risks and eliminate them, if possible, or if not possible, identify and implement measures to reduce the hazards/risks as much as possible; and/or
- implement interventions, including adequate supervision and assistive devices, consistent with a resident's needs, goals, care plan and current professional standards of practice in order to eliminate the risk, if possible, and, if not, reduce the risk of an accident; and/or
- monitor the effectiveness of the interventions and modify the care plan as necessary, in accordance with current professional standards of practice."[12]

CDPH incorrectly concluded that the findings showed "avoidable accidents." Each of the following instances do not constitute an "avoidable accident" for the following reasons:

1. Resident 1: CDPH's only finding related to the hospitalization was that a urine toxicology screen indicated presence of fentanyl, amphetamine, marijuana, and benzodiazepine. CDPH does not assert or present evidence to show that Resident 1's hospitalization was an accident that occurred because Laguna Honda failed to eliminate avoidable risks of hazards, to provide adequate supervision, or otherwise to provide adequate care.
2. Resident 3: CDPH's only findings were that a urine toxicology screen indicated presence of amphetamines, methamphetamines, and fentanyl, and that the patient's care plan did not include intervention or planning to address history of illicit drug use. CDPH ignored, however, that the patient's chart included notations that the patient was referred to behavioral medicine for assessment related to their history of substance use. In addition, CDPH failed to acknowledge that this patient was receiving Medication Assisted Therapy (or Medications for Opioid Use Disorder), in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders.
3. Resident 4: CDPH's only findings related to the change of consciousness were that a urine toxicology screen indicated presence of marijuana and methamphetamines. CDPH points to nursing notes and interviews with staff about prior incidents where staff witnessed Resident 4 smoking marijuana, and where staff confiscated drugs or other contraband from Resident 4. CDPH overlooked, however, that the patient record notes and interviews with staff indicate that staff was implementing various interventions and modifying as needed, including assigning a coach, conducting regular clinical searches, confiscating drugs and other contraband, and disposing of the drugs and contraband or providing it to the Sheriff's Department for destruction.
4. Resident 27: CDPH's only findings related to the change of consciousness were that a urine toxicology screen indicated presence methamphetamines. CDPH points to nursing notes about prior incidents where staff confiscated Resident 27's drugs, smoking paraphernalia, or other contraband. The patient records notes indicate that staff was implementing various interventions, including conducting regular clinical searches, confiscating drugs and other contraband, and disposing of the drugs and contraband with the assistance of the Sheriff's Department.

[12] CMS State Operations Manual, Appendix PP. Guidance to Surveyors for Long Term Care Facilities. (Rev. 173, 11-22-17), F689 at pp. 302–03.

5. Resident 2: Laguna Honda cannot find any evidence that the resident actually fell. Accordingly, we believe CDPH made a factual mistake in the statement of deficiencies. Even if there was a fall, CDPH references nursing notes or interviews about prior incidents where Resident 2's drugs, smoking paraphernalia or other contraband were identified and confiscated. The patient records notes indicate that staff was implementing various interventions, including conducting regular clinical searches, identifying and confiscating drugs and other contraband, and disposing of the drugs and contraband with the assistance of the Sheriff's Department.
6. Resident 32: CDPH's only findings related to the fall were that Resident 32 possessed alcohol, that staff suspected alcohol use, and a urine toxicology screen indicated the presence of methadone. CDPH did not allege or point to evidence that Resident 32's fall was an accident that occurred because Laguna Honda failed to identify hazards, reduce the risk of hazards, provide adequate supervision, or otherwise provide adequate care.

Instead of presenting evidence that these incidents were avoidable accidents that the facility failed to identify, evaluate, reduce, monitor, or modify, CDPH simply asserts that the existence of these incidents necessarily shows that Laguna Honda has failed to prevent avoidable accidents. Listing six unrelated incidents that involve some form of substance use, alcohol use, or possession of drugs or other contraband over a one-year period among Laguna Honda's 700 residents does not establish that Laguna Honda failed to prevent avoidable accidents.

II. Laguna Honda Met Its Obligations Under the SOM and Federal Regulations

Laguna Honda has an obligation to create an environment that remains as free of accident hazards as possible and ensure that each resident receives adequate supervision and assistance devices to prevent accidents.

Laguna Honda has met this requirement, as described above for each patient, by (1) identifying the hazards (2) implementing 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) monitoring the effectiveness of the interventions, and (4) modifying the interventions as necessary, in accordance with current professional standards of practice, and the patients' right to privacy, dignity, and self-determination.

A. Laguna Honda Has Policies and Procedures in Place to Address the Alleged Deficiencies

Laguna Honda has implemented various policies and procedures to address all of the alleged deficiencies related to use and possession of illicit substance and possession of related paraphernalia and prohibited contraband, including all of the following (attached as Exhibit A):

1. LHHPP 20-04 Discharge Planning
    a. Attachment A: Residential Substance Use Treatment and Dual Diagnosis Treatment Placement for LHH Residents
    b. Attachment B: LHH Referral Protocol for Opiate Replacement Treatment
2. LHHPP 22-01 Abuse and Neglect Prevention, Identification, Investigation,

Protection, Reporting and Response
3. LHHPP 22-02 Resident Alcohol Consumption
4. LHHPP 22-03 Resident Rights
5. LHHPP 22-12 Clinical/Safety Search Protocol
6. LHHPP 23-01 Resident Care Plan (RCP), Resident Care Team (RCT) & Resident Care Conference (RCC)
7. LHHPP 24-12 Laguna Premier Club: A Neurobehavioral Day Program
8. LHHPP 24-25 Harm Reduction
9. LHHPP 25-12 Drug Diversion Reporting and Response
10. LHHPP 75-05 Illicit or Diverted Drugs and/or Paraphernalia Possession/Use Residents or Visitors
11. LHHPP 75-10 Appendix K: Enforcement of the Smoking Policy
12. LHHPP 75-12 Firearms, Dangerous Weapons and Contraband
13. LHHPP 76-02 Smoke and Tobacco Free Environment
14. MSPP D08-03 Access to LHH Psychiatry Services
15. MSPP D08-07 LHH Substance Treatment and Recovery Services
16. MSPP D08-09 Mental Health Services
17. MSPP D08-10 Behavioral Management Services by LHH Psychiatry

Laguna Honda staff successfully followed and implemented the established policies and procedures to identify and confiscate drugs and other contraband, to monitor the established interventions, and update care plans where substance use is identified. Evidence that Laguna Honda *confiscated contraband* and *offered or provided treatment* does not show that Laguna Honda failed its duties—it demonstrates exactly the opposite. CDPH's findings (based on Laguna Honda's reports) demonstrate that Laguna Honda already had interventions in place to address and reduce the amount of illicit substances and contraband in patients' possession.

B. CDPH's Expectations Related to its Findings Require More than Reasonable or Adequate Supervision

CDPH adopted a zero-tolerance policy, and simply assumed deficiencies based on the fact that Laguna Honda was not able to prevent 100% of contraband from entering the facility. CDPH's expectations of Laguna Honda are not supported by law or policy. By requiring Laguna Honda to essentially eliminate all illicit drug use and possession of contraband, CDPH contravenes the federal definition and requirement of "adequate supervision."

The SOM explains that "Supervision/Adequate Supervision" refers to a facility's obligation to provide adequate supervision to prevent accidents. Under this deficiency tag, "adequate supervision is determined by assessing the appropriate level and number of staff required, the competency and training of the staff, and the frequency that supervision is needed."[13]

Here, in the language of the Statements of Deficiencies and communications with CDPH staff related to these alleged deficiencies, CDPH suggests that Laguna Honda should have 24/7 oversight over patients that have a history of substance use or drug seeking behavior to eliminate use of illicit substances or related prohibited contraband completely. Laguna Honda's

[13] CMS State Operations Manual, Appendix PP. Guidance to Surveyors for Long Term Care Facilities. (Rev. 173, 11-22-17), F689 at p. 304.

established policies and procedures are to search patients and their belongings based on a history of illicit substance use and incidents or factual circumstances that establish a reasonable suspicion that a patient may have illicit substances or other prohibited contraband. That policy is reasonable considering the expectation that Laguna Honda establish a therapeutic environment and respect all patients' right to privacy, dignity, and self-determination.

C. Laguna Honda Cannot Reasonably Eliminate All Contraband from Its Facility

CDPH unreasonably expects Laguna Honda to eliminate all contraband from the facility. The cited regulation and deficiency tag F689 do not mandate, and CMS does not expect, Laguna Honda to achieve a zero-tolerance standard. As stated above, the SOM defines the term "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. Here, Laguna Honda has acted reasonably, in compliance with the applicable standard under deficiency tag F689.

Laguna Honda permits patients to leave and return to the facility (with some restrictions). Unfortunately, some patients use this right to intentionally consume illicit substances or obtain contraband, sometimes smuggling those illicit substances and contraband into the facility. Laguna Honda employs extraordinary efforts to search, identify, and confiscate substances and contraband from patients before they reach their units: efforts CDPH has acknowledged. Laguna Honda staff search patients and patients' rooms based on reasonable suspicion to identify and confiscate drugs and contraband that can impact the health and safety of patients, doing so in a manner consistent with the rights of a patient's privacy, dignity, and self-determination.

CDPH's findings document that staff have been successful in identifying and confiscating drugs and other paraphernalia, but they cannot completely eliminate incidents that are unavoidable among a population where 20 percent of residents (160 residents out of 700) have a history of substance use disorder. Even among the most successful substance use treatment programs, relapse among participants is still a significant reality that is built into the treatment programs. Thus, even with its best efforts, Laguna Honda does not have complete control over whether a patient will use illicit drugs or smuggle contraband.

III. CDPH Failed to Establish A Pattern of Actual Harm to Constitute Substandard Quality of Care

CDPH acknowledged that the findings listed in sections "b-d" of the December 16, 2021 Statement of Deficiencies, and all of the deficiencies under the February 15, 2022 Statement of Deficiencies only posed the "potential" for harm. As described in detail below, CDPH failed to establish that the findings under section "a" of the December 16, 2021 Statement of Deficiencies show a pattern of actual harm that would constitute "substandard quality of care," or justify level of money penalties CDPH imposed based on these findings.

A. CDPH Failed to Show Any Sort of "Pattern" of Actual Harm

Every alleged finding in subsection "a" of the December 16, 2021 Statement of Deficiencies involves factual circumstances that were considerably different from each other, and CDPH failed to establish any sort of pattern around the actual harm that would require the same type of corrective action. The applicable regulations do not define what constitutes a pattern, but the

term is commonly defined as "frequent or widespread incidence," or "a reliable sample of traits, acts, tendencies, or other observable characteristics of a person, group, or institution."[14]

The incidents that led to actual harm in subsection "a" mainly involved patient use of fentanyl or methamphetamines, but each incident was different in the way patients acquired those substances and evaded detection by Laguna Honda staff. Other than the similarity of the drugs that patients used, CDPH did not find that the alleged deficiencies resulted from a pattern of conduct by Laguna Honda staff, or any failure by staff to identify and evaluate the risks, implement measures to reduce the risk, and monitor/modify the measures implemented to reduce the risks.

Each incident was an isolated, unique incident that did not amount to a "pattern" of deficiencies to warrant a scope and severity level of H. Other than identifying the illicit drugs used by the patients under section "a" and listing the variety of physical outcomes on patients, ranging from a nonfatal overdose, to change in consciousness, and a fall, CDPH failed to establish the pattern of actual harm resulting from either a common avoidable accident or other action or inaction by Laguna Honda staff.

B. CDPH Failed to Establish that the Deficiency Constitutes Substandard Quality of Care

CDPH concluded that the alleged deficiencies for the October 14, 2021 survey constituted substandard quality of care because they constituted a pattern of deficiencies that resulted in actual harm that is not immediate jeopardy. Substandard quality of care is defined as "one or more deficiencies related to participation requirements," including title 42 C.F.R. section 483.25, "which constitute … a pattern of or widespread actual harm that is not immediate jeopardy..."[15] While section 483.24 could constitute substandard quality of care, the alleged deficiencies are not "accidents" or amount to "avoidable accidents" as defined by section 483.25 and deficiency tag F689. Additionally, as described in detail above, CDPH failed to establish that the alleged incidents constitute a pattern of actual harm, and when taken together the substandard quality of care finding cannot be sustained to be the basis for the Statements of Deficiencies.

IV. Laguna Honda Returned to Substantial Compliance as of January 21, 2022, and the January 14, 2022 DPNA and April 14, 2022 Termination Date Were Improper

When CMS or the state agency finds a facility to be out of substantial compliance with the Medicare Conditions of Participation or applicable federal regulations, CMS has the option of imposing various remedies. CMS may choose to terminate a facility's provider agreement or as an alternative impose other initial remedies, such as CMP and DPNA as CMS did in Laguna Honda's case—as long as the facility complies with certain requirements. These requirements include submitting a plan of correction that adequately addresses each of the identified findings, which must be approved by CDPH. The facility must also resume substantial compliance with all Medicare Conditions of Participation and applicable federal regulations by a certain date set by CMS or face termination of the facility's provider agreement, but such date must not exceed six months from the "cycle start date" or the last day of the survey where the substantial non-

[14] Pattern. 2022. In Merriam-Webster.com. Retrieved April 21, 2022, from https://www.merriam-webster.com/dictionary/pattern.
[15] 42 C.F.R. § 488.301. "Definitions," which includes the deficiencies under 42 C.F.R. § 483.25(d) "Accidents."

compliance was identified.[16] In addition, the cycle start date also initiates the mandatory three-month time frame that a facility is given to get back to substantial compliance before the mandatory DPNA begins.

In this instance, CMS required Laguna Honda to resume substantial compliance by April 14, 2022, based on the six-month cycle start date of October 14, 2021. The cycle started then because CDPH found two deficiencies—deficiency tag F689, the subject of this appeal, and deficiency tag F726, which involved inadequate training for clinical safety patient room searches. CDPH issued a deficiency at a scope and severity level of "F" for deficiency tag F726. Laguna Honda, however, resumed substantial compliance with this deficiency tag on January 21, 2022. And, because CDPH erred in finding Laguna Honda deficient under F689, CDPH erred in issuing the DPNA beginning on January 14, 2022 and terminating the Laguna Honda's provider agreement on April 14, 2022.

A. Laguna Honda Resumed Compliance with the Six-Month Cycle Start Date that Triggered Termination of Laguna Honda's CMS Provider Agreement on April 14, 2022

CDPH did not identify Laguna Honda to be deficient under deficiency tag F726 in its findings for the January 21, 2022 survey. Thus, Laguna Honda resumed substantial compliance for F726 as of January 21, 2022.

With respect to the four findings issued by CDPH during the January 21, 2022 survey, all were related to the use and possession of illicit substances and related paraphernalia and contraband under deficiency tag F689. As stated above, CDPH erred in finding Laguna Honda deficient under this deficiency tag.

Because CDPH erred in finding Laguna Honda deficient under F689 and because the F726 deficiency ended as of January 21, 2022, Laguna Honda came into compliance with the Conditions of Participation, ending the six-month cycle.

B. The Single, Isolated Incident in the January 2022 Survey Is Insufficient to Place Laguna Honda out of Substantial Compliance

The three remaining findings from the January 21, 2022 survey involved a single incident where an employee did not follow the established policy and protocols to appropriately dispose and log the confiscated contraband. The incident did not result in actual harm to the patient or anyone else. Laguna Honda rightfully treated the item, an empty zip lock bag with trace amounts of an unknown residue, as contraband because it was an unknown substance. CDPH could not and did not establish that the unknown substance was an illicit substance that had the potential to cause more than just minimal harm.

In addition, neither Laguna Honda nor CDPH established that the amount of residue in the bag would have been enough to cause more than just minimal harm if a patient, visitor, or another staff member could have misappropriated the confiscated item. After the bag was confiscated from the patient, it was placed in the medication room for the unit which requires badge access through two doors, which only a limited number of staff on that specific unit have. If this incident were to be considered an avoidable accident under deficiency tag F689, the facts surrounding this single incident would most appropriately result in a deficiency with scope and

[16] *See* 42 C.F.R. § 488.412.

severity level "A," because it was an isolated incident that resulted in no actual harm with the potential for minimal harm. A deficiency with this level of scope and severity would have placed Laguna Honda back in substantial compliance with all Medicare Conditions of Participation and all applicable federal regulations as of January 21, 2022.

CONCLUSION

For all of the reasons set forth herein, Laguna Honda respectfully requests that the DHHS, Departmental Appeals Board reverse CMS survey findings and imposition of remedies, including CMPs and DPNA between January 14, 2022 and February 2, 2022, related to CDPH's findings and rescind the deficiencies under F689 issued under Statements of Deficiencies dated December 16, 2021 and January 21, 2022, for Incident Nos. CA744774, CA745390, CA747134, CA746900, CA675386, and CA 747220; find that Laguna Honda was in substantial compliance with the federal regulations; find that these incidents do not amount to a pattern of actual harm to constitute substandard quality of care, and find that the April 14, 2022 provider agreement termination date was improperly issued.

Very truly yours,

DAVID CHIU
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