Redacted ALJ-Decision

IN THE MATTER OF SAGEPOINT	*	**BEFORE** [redacted]
NURSING AND REHABILITATION	*	**AN ADMINISTRATIVE LAW JUDGE**
CENTER	*	**OF THE MARYLAND OFFICE**
	*	**OF ADMINISTRATIVE HEARINGS**
	*	**OAH No.: MDH-OHCQ-44-20-15515**

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PROPOSED DECISION

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STATEMENT OF THE CASE

On May 8, 2020, the Office of Health Care Quality (OHCQ), a part of the Maryland Department of Health (MDH or Department) issued a Notice to Sagepoint Nursing and Rehabilitation Center (Respondent or Facility) that included a statement of deficiencies and imposed State civil and monetary penalties for two categories of deficiencies: serious and immediate threat to the health and safety of the nursing facility's residents. On June 2, 2020, the Department revised the Notice to add a federal citation at the request of the Centers for Medicare and Medicaid Services (CMS). Among other things, the Notice advised that the OHCQ was imposing on the Respondent a civil money penalty (CMP) of (a) $10,000.00 per day beginning March 30, 2020, and extending through May 6, 2020, for a total of $380,000.00 and (b) $1,000.00 per day beginning May 7, 2020 through the date on which the facility returns to substantial compliance. The total sum of the CMP imposed was $440,000.00. Md. Code Ann., Health-Gen.

§§ 19-359 to 19-1401 (2019 Replacement Volume & Supp. 2020) and Code of Maryland Regulations (COMAR) 10.07.02.70.

On May 22, 2020, the Appellant filed an appeal of the CMPs and requested an Informal Dispute Resolution which was held on June 3, 2020. On July 10, 2020, the Department affirmed the previously imposed State CMPs and attached the final statement of deficiency. On July 21, 2020, the MDH referred this matter to the Office of Administrative Hearings (OAH) for a hearing.

On September 21, 2020, I held a prehearing conference. At that conference, I granted the Respondent's Motion for Admission *Pro Hac Vice* asking that Joseph Bianculli, an attorney in good standing in Virginia and Washington D.C., and general counsel for the Facility, be permitted to represent it for the limited purposes of this hearing as co-counsel along with Thomas Whiteford, an attorney in good standing in Maryland. On September 25, 2020, I issued a Prehearing Conference Report and Scheduling Order noting that the parties agreed to schedule the hearing for December 8, 9, 10 and 11, 2020. On October 5, 2020, the Respondent filed a Motion to Amend Scheduling Order and on November 5, 2020, I issued an Amended Scheduling Order incorporating the Parties' Joint Statement of Issues.

On December 8, 9, 10 and 11, 2020, I conducted a hearing at the OAH office in Hunt Valley, Maryland. Assistant Attorney General Juliana Bell represented the OHCQ. Joseph Bianculli, Esq., represented the Respondent.

Procedure in this case is governed by the contested case provisions of the Administrative Procedure Act (APA), Md. Code Ann., State Gov't §§ 10-201 through 10-226 (2014 & Supp. 2020); COMAR 10.01.03; and the Rules of Procedure of the OAH, COMAR 28.02.01.[1]

ISSUES

FACTUAL ISSUES

1. What was the content of the guidance issued by the Center for Disease Control and Prevention (CDC) Infection Control regarding COVID-19 pertinent at all times to this case?

2. Did the Respondent identify and implement appropriate infection control protocols to prevent the introduction of COVID-19 to the Facility prior to the identification of its first COVID-19 positive resident on or about March 30, 2020?

3. Did the Respondent correctly implement applicable transmission-based infection control precautions and protocols after receiving notice of its first COVID-19 positive resident on or about March 30, 2020?

4. Did the Respondent develop and follow an effective working plan to manage resident cohorting according to COVID-19 status?

5. Did the Respondent actually implement an effective plan to cohort residents based on COVID-19 test status according to CDC and Department guidance, after receiving COVID-19 test results, beginning April 9, 2020?

6. Did the Respondent follow CDC and Department guidance regarding isolation of COVID-19 positive residents at all times pertinent to this case?

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[1] Pursuant to the Delegation Letter from MDH to OAH (Jan. 6, 2020); Health-Gen. § 19-2406(c)(3) (nursing homes timeframe); and COMAR 10.07.02.74C (comprehensive and extended care facilities timeframe), the OAH has been asked to issue a proposed decision that is due ten working days following the close of the record. In this case, I held the record open to review the recorded testimony of one witness, and the parties agreed to a briefing schedule, and to extend my time to render a proposed decision until after the receipt of the transcript and submission of briefs. That timeline was again extended when a delay arose regarding the transcript. As a result, the parties' briefs were due on March 15, 2021 with any reply briefs due by March 22, 2021, and my proposed decision was due ten working days later, on April 5, 2021.

7. Did the Respondent follow CDC and Department guidance regarding isolation of "under investigation" residents whose COVID-19 status was unknown, or whose test results were pending, at all times pertinent to this case?

8. Did the Respondent follow CDC and Department guidance regarding mask use by residents at all times pertinent to this case?

9. Did the Respondent follow CDC and Department guidance regarding cohorting staff, that is, assigning staff to work only on a COVID-19 positive or negative unit, at all times pertinent to this case?

10. Did the Respondent follow CDC and Department guidance regarding use of personal protective equipment (PPE) by staff, including both direct caregivers, and non-direct caregiving staff, at all times pertinent to this case?

11. Did the Respondent follow applicable CDC and Department guidance regarding using, donning, doffing, and disposal of PPE, including the location of such PPE and donning and doffing stations, at all times pertinent to this case?

12. Did the surveyor's observations support that the Facility staff violated CDC or Department guidance regarding use or disposal of PPE at any time during the survey?

13. Was reuse and sanitization of gloves permitted by CDC and Department guidance at any time pertinent to this case?

14. Did the Respondent follow applicable CDC and Department guidance regarding reuse and sanitization of gloves at all times pertinent to this case?

LEGAL ISSUES

1. What MDH COVID-19 guidance established legally binding requirements at all times pertinent to this case?

2. Which CDC Infection Control and COVID-19 guidance was the Facility legally required to follow at all times pertinent to this case?

3. Did the Respondent implement infection control protocols pursuant to applicable CDC and Department requirements and/or guidance at all times pertinent to this case?

4. Did the Respondent implement a system for ordering, tracking, and documenting COVID-19 tests and test results during April 2020 that met the requirements of COMAR 10.07.02.28 and 10.07.02.33?

5. Did the Respondent's failure to note a lab's delay in reporting Resident #[redacted] COVID-19 test result between April 6 and April 20, 2020 violate COMAR 10.07.02.28 and 10.07.02.33?

6. Did the Respondent's efforts to cohort residents according to COVID-19 test status after April 9, 2020 meet the requirements of COMAR 10.07.02.33A?

7. Were Resident numbers [redacted] appropriately isolated and "cohorted" at all times pertinent to the case?

8. Did a surveyor's observation of Resident #[redacted] and another resident being fed in a dining room on April 23, 2020, together with the surveyor's related interviews of staff, demonstrate an infection control violation of COMAR 10.07.02.33A?

9. Did supposed violations of CDC and Department PPE guidance as observed by a surveyor and cited in the Statement of Deficiencies actually violate any such guidance or infection control requirement?

10. Did the Department establish that the Facility violated COMAR 10.07.02.28?

11. Did the Department establish that the Facility violated COMAR 10.07.02.33?

12. Did noncompliance by the Facility pose a serious and immediate threat ("immediate jeopardy") to any resident?

13. Is the civil money penalty the Department imposed arbitrary and capricious?

SUMMARY OF THE EVIDENCE

The Exhibit list is attached as an Appendix.

Testimony

The following witnesses testified on behalf of the Department:

[redacted] nurse surveyor, OHCQ;

[redacted], nurse surveyor II, OHCQ;

[redacted] nurse surveyor, OHCQ; and

Patricia Tomsko Nay, M.D.,[2] Executive Director OHCQ, whom I accepted as an expert in medicine, geriatrics, and Maryland Nursing home regulations.

The Respondent presented the following witnesses:

David Grabowski, Ph.D., Professor of Health Care Policy, Harvard Medical School, whom I accepted as an expert in health care policy particularly as it relates to nursing homes;

Andrea Dwyer, nursing home administrator, Sagepoint Senior Living Services;

Bryan Wallace McEachern, M.D., pediatrician, whom I accepted as an expert in infection control; and

Morgan Katz, M.D.,[3] assistant professor, Johns Hopkins University Hospital, whom I accepted as an expert in infection control in long-term care facilities.

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[2] The sound quality of Dr. Nay's testimony was poor on the audio recording and therefore the transcript was incomplete. On agreement of the parties, the Department submitted an errata sheet along with their post-hearing brief and those clarifications to the transcript have been accepted and adopted as part of the record.

[3] Dr. Katz testified virtually prior to the hearing via deposition that was attended by counsel for both the Facility and the MDH. Her testimony – both direct examination and cross examination – was recorded and the recording and transcript of the testimony was accepted and included in the record.

FINDINGS OF FACT

I find the following facts by a preponderance of the evidence:

1. The Facility is a 170 bed not-for-profit nursing and rehabilitation center located in LaPlata, Maryland. The majority of the Facility's residents suffer from confusion caused by conditions such as dementia. Eighty percent of the residents qualify for end-of-life or palliative care. In March 2020, the Facility had approximately one hundred-twenty-seven residents.

2. On January 17, 2020, the CDC published its first advisory to health care providers regarding the COVID-19 outbreak in China. At that time, it was believed the virus was contained in China, and the CDC recommended that health care providers determine whether persons with symptoms of respiratory illness including fever, cough, and shortness of breath, recently had been in Wuhan China, or in close contact with someone diagnosed with COVID-19. After the virus spread to the United States, the CDC issued a second advisory on February 1, 2020 with the same advice.

3. On February 6, 2020, CMS issued its first guidance instructing states to remind all health care facilities, including nursing homes, to monitor CDC and CMS Guidance, reinforce typical infection control practices, including "standard," "contact," "droplet," and "airborne" precautions described in the CDC's 2007 "Guideline for Isolation Precautions in Healthcare Settings" (2007 CDC Guidance).[4]

4. On March 3, 2020, OHCQ completed an annual licensure survey for the Facility (licensure survey). During that survey, OHCQ conducted a review of all of the Facility's administrative systems, including its infection control and laboratory processes. As a result of the review, OHCQ cited a handful of minor deficiencies, none of which related to infection control, laboratory services, or administration.

[4] COMAR 10.07.02.02 specifically incorporates the 2007 CDC Guidance as a Maryland regulatory requirement.

5. On March 5, 2020, the first case of COVID-19 was confirmed in Maryland and Governor Hogan declared a state of emergency.

6. On March 6, 2020, the Facility implemented reduced visiting hours, increased visitor screening, limitation of resident trips outside of the facility, and reinforcement of basic infection control techniques. The Facility implemented symptom screening of all staff twice per shift, including temperature checks. The Facility's three infection control nurses posted informational posters regarding cough and sneeze etiquette and began reinforcing trainings on PPE use and "don/doff" (putting on and taking off PPE) sequencing. Throughout March 2020, those nurses conducted ongoing CDC infection control training sessions and audits with the staff.

7. On March 9, 2020, the Facility limited access to all nursing units to residents and staff of those units; required patients who had to go off-site for dialysis treatment to wear masks; canceled routine outside physician appointments; put all long term admissions on hold; closed its large dining room; ended large group activities; limited in-person care planning meetings; enhanced deep cleaning of therapy equipment between users; required all deliveries, including resident laundry, to be picked up and dropped off at the door; put a hold on the student rotations from local nursing education programs; and started taking and documenting all residents' temperatures and vital signs on each nursing shift (or every eight hours).

8. On March 10, 2020, the MDH issued its first recommendations regarding COVID-19 to health care facilities serving older adults. (Resp. Ex. 12). That document recommended screening residents, staff, and visitors for respiratory symptoms, to monitor CDC website for updates, and to follow CMS guidance regarding admission or readmission of COVID-19 positive residents. The MDH also encouraged facilities to monitor MDH's web site

and social media accounts "as these recommendations may be updated from time to time." In terms of regulatory compliance, the document provided:

> MDH acknowledges that implementation of these regulations may cause regulated Senior Care Facilities to be in non-compliance with certain State regulatory requirements, including without limitation, regulations relating to visitation, resident activities, and staffing ratios. **MDH will not take enforcement action under State law or regulation against any regulated Senior Care Facility for regulatory non-compliance that arises solely from the good faith implementation of these recommendations during the period in which the Governor has proclaimed a state of emergency related to COVID-19.** (Emphasis in original).

9. On March 13, 2020, the MDH drafted a letter to health care providers supplementing its former guidance on COVID-19. Specifically, the letter provided that asymptomatic and mildly symptomatic persons do not need to be tested; that the MDH is performing COVID-19 testing for…persons "who reside in a nursing home or long-term care facility AND who has (sic) either fever or signs/symptoms of a lower respiratory illness AND who tested negative for influenza on initial workup and no alternative diagnosis." (Emphasis in original). The guidance also acknowledged the shortage of N95 respirators and advised that surgical masks were sufficient for individuals collecting specimens for COVID-19 testing.

10. On March 13, 2020, the Facility prohibited employees from working at other health care facilities or services.

11. On March 17, 2020, the CDC issued its first guidance for conserving, reusing, and improvising substitutes for masks and gowns. The Facility experienced a gown shortage and volunteers sewed several hundred gowns for them. Eventually, the Facility relied on the Maryland Emergency Management Agency for gowns, masks and other supplies. (MDH Ex. 14, 15).

12. On March 19, 2020, in a PowerPoint presentation prepared by MDH epidemiologists who held weekly phone conferences with nursing facilities to discuss the latest

COVID-19 guidance, the MDH stated that nursing homes should continue to admit COVID-19 positive residents, that staff with "low level" exposure to COVID-19 should continue working as long as they remained asymptomatic and wear a cloth face covering, and that prior approval was required for any COVID-19 testing. (Resp. Ex. 18).

13. On March 20, 2020, the MDH published a Frequently Asked Questions memorandum regarding COVID-19. (Resp. Ex. 17). In that document, the MDH advised against wearing a face mask unless you were infected with COVID-19 *and* showing symptoms or were a health care worker caring for someone with COVID-19 in a close setting.

14. On March 23, 2020, the MDH issued further COVID-19 guidance specific to long-term care and assisted living facilities. That guidance advised facilities to initiate measures to optimize their current supply of PPE. Specifically, the guidance stated, "[i]f PPE supply allows, consider having health care personnel wear all recommended PPE (gown, gloves, eye protection, facemask) for the care of all residents, regardless of presence of symptoms." The MDH also advised nursing homes to continue to admit and re-admit residents with confirmed COVID-19 diagnosis or symptoms. The guidance advised that once a facility had a confirmed case of COVID-19, the response priorities were as follows:

- Quick identification and isolation of residents and exclusion of health care personnel with signs and symptoms
- Strict active monitoring of all residents and facility staff members
- Compliance with strict visitor restrictions
- Correct donning and doffing of PPE
- Reinforcement of hand hygiene practices and respiratory etiquette for staff and residents
- Enhanced environmental cleaning of frequently touched surfaces three times per day
- Frequent, transparent communication with public health

15. On March 23, 2020, CMS publicized its plan to utilize state survey agencies to conduct a new Targeted Infection Control Survey (CMS TIC Survey) to assess compliance with existing infection control requirements amid the pandemic. CMS disseminated the CMS TIC

Survey to facilitate healthcare facilities in educating them on the latest practices and expectations related to COVID-19. CMS made clear that this checklist would be utilized during Targeted Infection Control surveys.

16. On March 27, 2020, the Facility adopted its first COVID-19 specific Infection Control Policy and Procedure to reflect new CDC and CMS guidance regarding COVID-19 and the unique challenges posed by COVID-19 such as supply chain disruption and PPE shortages. The new policy incorporated all of the practices the Facility had put into place since March 6, 2020, as detailed above. It also provided that all residents with known or suspected COVID-19 would be isolated in single occupancy rooms with the door closed; cohort staff as possible; limit resident movement in the building; and consult with local and State officials for assistance. The Policy provided for following CDC and other guidance regarding conservation and substitutions of PPE.

17. On March 26, 2020, the MDH issued another guidance advising against testing of asymptomatic nursing home residents, and providing that asymptomatic residents in nursing facilities would get "third priority" for testing after symptomatic hospital patients, healthcare professionals and emergency personnel. (Resp. Ex. 27).

18. On March 27, 2020, the CDC published guidance in its Morbidity and Mortality Weekly Report modifying its earlier guidance that COVID-19 precautions at nursing facilities should be similar to those commonly implemented for influenza, and described in the 2007 CDC guidance, because it had been discovered, through studying the COVID-19 outbreak at a nursing home in King County, Washington, that COVID-19 transmission could occur from asymptomatic and pre-symptomatic people. That guidance also addressed modifications

suggested due to the related supply chain disruptions and shortages of PPE. Specifically, that report stated:

> Once [COVID-19] is introduced in a long-term care skilled nursing facility, rapid transmission can occur....[S]ymptom screening could initially fail to identify approximately one half of [nursing home] residents with [COVID-19] infection. Unrecognized asymptomatic and pre-symptomatic infections might contribute to transmission in these settings. During the current COVID-19 pandemic, [nursing homes] and all long-term care facilities should take proactive steps to prevent introduction of [COVID-19], including restricting visitors except in compassionate care situations, restricting nonessential personnel from entering the building, asking staff members to monitor themselves for fever and other symptoms, screening all staff members at the beginning of their shift for fever and other symptoms, and supporting staff member sick leave, including for those with mild symptoms. Once a facility has a case of COVID-19, broad strategies should be implemented to prevent transmission, including restriction of resident-to-resident interactions, universal use of facemasks for all health care personnel while in the facility, and if possible, use of CDC-recommended PPE for the care of all residents (i.e., gown, gloves, eye protection, N95 respirator, or, if not available, a face mask). In settings where PPE supplies are limited, strategies for extended PPE use and limited reuse should be employed. As testing availability improves, consideration might be given to test-based strategies for identifying residents with [COVID-19] infection for the purposes of cohorting, either in designated units within a facility or in a separate facility designated for residents with COVID-19. During the COVID-19 pandemic, collaborative efforts are crucial to protecting the most vulnerable populations.

MDH Ex. 28, pg. 4.

19. Charles County, Maryland, where the Facility is located, had ten confirmed cases of COVID-19 on March 26, 2020; sixty-nine cases on April 1, 2020; one-hundred-sixty-four cases on April 9, 2020; and six-hundred-ninety-eight cases on May 7, 2020.

20. On March 30, 2020, the Facility learned that one of its residents tested positive for COVID-19 while hospitalized for reasons related to a terminal condition. That patient returned to the Facility on April 6, 2020, was isolated, and died on April 7, 2020. The Department does not allege any noncompliance relating to that case.

21. On March 30, 2020, the Facility implemented universal source control transmission-based precautions throughout the entire center. The Facility treated every resident

as potentially infected; required all staff to wear masks; and required full PPE for staff providing direct, hands-on care to any resident.

22. On April 1, 2020, by memorandum, the OHCQ specifically required nursing homes to continue to admit and re-admit individuals who had tested positive for COVID-19. (Resp. Ex. 30). On April 5, 2020, the Secretary of MDH issued an Order specifically requiring nursing homes to readmit COVID-19 positive residents from hospitals, (Resp. Ex. 34) and the MDH continued to advise nursing homes to admit COVID-19 positive residents. (Resp. Ex. 20). That April 5, 2020 guidance also included directives requiring nursing homes to cohort known COVID-19 positive residents, and the staff caring for them, "to the best of their abilities." In its weekly call with providers, the MDH illustrated various alternatives to cohorting based on the varying capabilities of the many Maryland facilities. (Resp. Ex. 21).

23. On April 2, 2020, the Facility presented a plan to the Charles County Health Department to obtain COVID-19 tests for all of its residents. The County could not accommodate all of the lab requirements for these tests. The Facility arranged with a private company, [redacted] to do the balance of the tests. The Facility did not regularly use [redacted], but the Facility's regular lab, [redacted], could not accommodate the volume of tests required.

24. On April 6, 2020, the Facility tested one hundred thirty-five residents and over the course of several days, beginning on April 9, 2020, more than seventy tests came back positive. Approximately sixty percent of those patients who tested positive remained asymptomatic.

25. Prior to these COVID-19 tests, [redacted] would call or fax lab test results to the Facility. The nurse who received the results would review them and relay the results to the ordering physician who would then provide any necessary orders. For the COVID-19 tests, [redacted] provided the Facility with access to a web portal that the

Facility's Director of Nursing or her designee would check and match against "line listings" of tests that the Center prepared on a MDH-generated form designed for systematically tracking metrics for infection control purposes.

26. Beginning on April 9, 2020, the Facility began to cohort all of its residents based on symptoms, test results, and exposure. The Facility has four wings, called units. The Facility earmarked the 100 and 200 units for Covid-19 positive residents and admissions. By April 11, 2020, the Facility had moved most residents who were symptomatic and/or had tested positive onto the [redacted] and [redacted] units. Each resident room contained at least one trash receptacle and units [redacted] and [redacted] also had centrally located trash receptacles. The Facility also limited movement of non-essential staff between the units.

27. The Facility also separated residents who were asymptomatic and tested negative for COVID-19 but had resided in areas of the Facility with a high number of positive cases. Residents #[redacted] were isolated for this reason. During all relevant times, they were each kept on COVID-19 negative units, in single occupancy rooms, were bedbound, and could not get out of bed or leave their rooms without assistance.

28. On April 6, 2020, along with all of the other residents, the Facility tested Resident [redacted] for COVID-19 and [redacted] test result, returned on April 10, 2020, was negative. On April 17, 2020, Resident #[redacted] presented with a low-grade fever and reduced oxygen saturation level and was re-tested for COVID-19. That test, received by the Facility on April 20, 2020, was positive. Resident #[redacted] remained in her single occupancy room with a private bathroom. Resident #[redacted] was not required to wear a mask while in her room, where she was bedbound. The bed in Resident #1's room was more than six feet from the door. Resident #[redacted]'s medical record provided that at times, her door was to be kept open to allow for observation for safety.

29. On April 6, 2020, along with all of the other residents, the Facility tested Resident #[redacted] for COVID-19 and [redacted] test result was negative. On April 20, 2020, Resident #[redacted] was re-tested for COVID-19. That test, received by the Facility late on April 21, 2020, was positive. Resident #2 remained in [redacted] single occupancy room with a private bathroom for the remainder of that day and was moved onto the COVID-19 positive unit on the morning of April 22, 2020.

30. On April 6, 2020, along with all of the other residents, the Facility tested Resident #[redacted] for COVID-19. [redacted] did not upload Resident #[redacted]'s test results to the web portal and the Facility did not notice the omission. On April 20, 2020, after Resident #[redacted]'s family inquired about [redacted] test results, the Facility retrieved the result and learned that Resident #[redacted] had tested positive when [redacted] was tested on April 6, 2020. At all relevant times, Resident #[redacted] was asymptomatic, resided in a single occupancy room with a private bathroom, was bedbound, had limited interaction with staff, and no close interaction with other residents. Resident #[redacted]'s bed was more than six feet from the door. On April 23, 2020, a geriatric nursing assistant fed Resident #[redacted] in a small common area within [redacted] Unit, while another nursing assistant fed another bed-bound Resident more than six feet away. It was common for Resident #[redacted] to be fed in that small common area because the staff had better success feeding [redacted] outside of [redacted] room.

31. On April 9, 2020, the MDH issued guidance on the use of gowns for COVID-19 prevention at Maryland nursing homes. (Resp. Ex. 37). In part, that guidance stated the following:

> - …staff in close contact with nursing home residents should use appropriate PPE … based on the procedures being performed and the availability of specific forms of PPE;
> - Gowns per se do not necessarily need to be an element of the PPE worn in all interactions with residents;
> - The use of gowns is primarily to prevent infectious droplets from being spread from resident to resident via healthcare providers by direct contact and this risk may not be present for all interactions with residents;

- Gowns are most important when a healthcare workers (sic) is in close direct contact with a resident (via such activities as dressing, bathing/showering, transferring, providing hygiene, changing linens, changing briefs or assisting with toileting, device care or use, and wound care);
- Walking into a room or handing out food or meds is different and does not require use of a gown. Additionally, [healthcare workers] who work in areas of the facility where they do not come into contact with residents, e.g. in the kitchen or exclusively administratively, do not need to wear gowns and gloves;
- Gowns should be prioritized for residents with other infections requiring contact precautions, e.g. infectious diarrhea, C. difficile;
- Nursing homes making a good faith effort at following the gown prioritization guidance above are considered in compliance with section 2. B. of the Secretary's Order and Directive Regarding Nursing Home Matters

32. On April 11, 2020, Dr. [redacted], the Charles County Health Officer, visited the Facility, reviewed its infection control interventions, and expressed no concerns.

33. On April 13, 2020, the CDC published guidance specific to COVID-19 and healthcare settings such as nursing homes. (Resp. Ex. 46). That guidance was titled as "Summary of Changes to the Guidance" and stated that it was an update based on "currently available information about COVID-19...." The guidance addressed asymptomatic and pre-symptomatic transmission, implementation of source control, and strategies for optimizing the supply of PPE and other equipment. It also advised that the virus is mostly spread via respiratory droplets produced when an infected person speaks, coughs or sneezes and the droplets are inhaled by those in close proximity to the infected person when the droplets are produced.

34. During Spring 2020, the generally recommended isolation period for an individual with diagnosed or suspected COVID-19 infection was ten to fourteen days after the later of either a positive test or the end of symptoms.

35. Beginning on April 13, 2020, the Facility Administrator, Andrea Dwyer, held daily telephone status consultations with Dr. [redacted] the MDH State Epidemiologist.

Based on information from Dr. [redacted], and because universal retesting was not yet possible, the Facility treated roommates of residents who had tested positive, and residents who lived in close proximity to others with positive test results, as suspect, and isolated them in private rooms.

36. On April 14, 2020, the Facility assigned Registered Nurses to make daily calls to every resident family each weekday to provide personal clinical updates.

37. On April 17, 2020, [redacted], an MDH epidemiologist, also visited the Facility to review its response to the outbreak. In her report, Ms. [redacted] wrote:

> Leadership was incredibly knowledgeable and intricately acquainted with data from the outbreak. They had begun preparing for a potential outbreak long before their first case and had taken advanced steps to prevent and prepare for an outbreak before mandates were released from public health. It is unfortunate that despite all of their preparedness, they have been so incredibly impacted by this virus. Our on-site visit provided evidence that infection control at this time is optimal at the facility and leadership is strongly invested in maintaining strong outbreak control measures and continuing to support their staff and residents.

(Resp. Ex. 38).

38. On April 29, 2020, the Secretary of the MDH issued another Directive requiring nursing facilities to admit COVID-19 positive residents. On May 7, 2020, the MDH amended the Directive to provide that nursing home residents remained a low priority for COVID-19 testing.

39. On April 30, 2020, the CDC published "Strategies for Optimizing the Supply of Disposable Medical Gloves," including when "there is limited supply," or when "glove supplies are stressed." (MDH Ex. 24). The document refers to crisis strategies to deal with supply chain disruptions, including sanitizing gloves with alcohol-based sanitizer in some instances.

40. Maryland created COVID-19 strike teams to support nursing homes through the COVID-19 pandemic and one of these teams visited the Facility on April 20, 2020. During that visit, a physician on the team advised Facility staff that cleaning disposable gloves with

alcohol-based hand sanitizer was a best practice for optimizing the use of disposable gloves when doing tasks other than direct patient care.

41. OHCQ conducted a "Focused COVID 19 Infection Control Survey" at the Facility from 6:40 p.m. on April 21, 2020 through May 6, 2020. This was the first CMS-directed survey of its kind in Maryland. During the survey, surveyors were on site at the Facility for a few hours on April 21, 23, and May 1, 2020.

42. On April 21, 2020, Facility staff hung an isolation precaution sign on Resident #[redacted]'s door. At some point on that same day, Resident #[redacted]'s door was left open, and Resident #[redacted] did not wear a mask while in [redacted] room. There was a trash can inside Resident #[redacted]'s room, and the bed was more than six feet from the door.

43. On April 21, 2020, there was an isolation precaution sign on Resident #[redacted]'s door, but at some point, the door was left open and the Resident #[redacted] did not wear a mask while in [redacted] room. There was a trash can inside Resident #[redacted]'s room, and the bed was more than six feet from the door.

44. On April 21, 2020, a licensed practical nurse (LPN) on a unit which was designated for COVID-19 positive residents, was wearing full PPE gear including gloves when [redacted] touched a resident's door and then a laptop at the nurses station without changing or sanitizing her hands or gloves.

45. On April 21, 2020, on the [redacted] unit, which was designated for COVID-19 positive residents, the Administrator, Andrea Dwyer, and the Director of Nursing, Michelle Buscher, walked through the hallway wearing masks and gloves, but not gowns.

46. On April 23, 2020, a floor tech, which is similar to a janitor, walked into the [redacted] unit which was designated for COVID-19 positive patients, without PPE. When [redacted] entered the

unit, he pulled his mask over [redacted] face and put on a gown and gloves but did not first wash or sanitize [redacted] hands. At the time, the floor tech was preparing to mop the floors.

47. On April 23, 2020, a registered nurse administered medication to a patient in [redacted] or [redacted] room, exited the room, returned the medication container to her cart and removed [redacted] gloves. [redacted] then pulled out a new pair of gloves, put them on and then sanitized the exterior of the gloves with alcohol-based hand sanitizer.

48. On April 23, 3020, a social worker picked up a food tray from a resident's room, exited the room and placed the food tray on a cart. [redacted] then sanitized the gloves [redacted] was wearing with alcohol-based hand sanitizer and entered another resident room.

49. Each resident room in the Facility has at least one trash can, although the trash can is not always directly next to the door. The units also each have trash cans at the centrally located nursing stations. Staff can take off and discard PPE at any of these trash cans.

50. On April 23, 2020, a nursing assistant who was on a COVID-19 positive unit, removed [redacted] gown in the hallway, rolled the exterior of the gown to the inside and carried it thirty-fifty feet to the nursing station to throw it away.

51. On May 6, 2020, by letter, the Department advised the Facility that "conditions at [the facility] posed immediate and serious jeopardy to the health and safety of your residents," and that "based upon the deficiencies cited at [the Facility]," the Department was imposing a CMP in the amount of $10,000.00 a day, effective March 30, 2020.

52. On May 8, 2020, by letter, the Department advised that, as of May 6, 2020, the Facility had abated the immediate jeopardy; that OHCQ was imposing a CMP of $10,000.00 per day from March 30, 2020 through May 6, 2020 for "both immediate jeopardies" defined as alleged violations of two federal regulations similar to the State "laboratory services" and "infection control" regulations; and that OHCQ was imposing a CMP in the amount of $1,000.00

per day effective May 7, 2020 until the Facility resumed "substantial compliance" with all applicable regulations.

53. On May 22, 2020, the Facility appealed. The Department held the appeal until after the Informal Dispute Resolution period.

54. On November 17, 2020, by letter, the Department advised that the total CMP imposed was $440,000.00 based, in part, on the Department's conclusion that the Facility was in substantial compliance with the regulations as of July 5, 2020.

55. The Facility is rated as a five-star facility by CMS,[5] and has no prior history of non-compliance.

DISCUSSION

This case involves a CMP assessed by the MDH against the Appellant for alleged deficiencies at its facility. The MDH bears the burden of proving the appropriateness of the CMP imposed. Md. Code Ann., Health-Gen. § 19-1406(c)(2) (2019 & Supp. 2020); COMAR 10.07.02.55B. The standard of proof is by a preponderance of the evidence. Md. Code Ann., State Gov't § 10-217 (2014 & Supp. 2020); COMAR 28.02.01.21K(1).

The Secretary of the Maryland Department of Health (Secretary) regulates nursing homes under Title 19 of the Health General Article, Maryland Code Annotated. Nursing homes[6] are classified as a type of related institution, each of which must be licensed by the State to operate. Md. Code Ann., Health-Gen. §§19-301(o)(1). Pursuant to Health-General sections 19-308(a), the Secretary has adopted regulations that set standards of services for nursing homes. The Secretary has the authority to initiate regular or complaint surveys of nursing homes and to issue CMPs where

[5] CMS rates nursing homes on a number of factors and "five stars" is the top rating a facility can receive.
[6] A "nursing home" is "a comprehensive care facility or extended care facility which offers nonacute inpatient care to residents: (a) who have a disease, chronic illness, condition, disability of advanced age, or terminal disease requiring maximal nursing care without continuous hospital services; and (b) who require medical services and nursing services rendered by or under the supervision of a licensed nurse together with convalescent, restorative, or rehabilitative services." COMAR 10.07.01B (45).

the Department identifies a deficiency or ongoing pattern of deficiencies. Health-Gen. §§ 19-308; 19-1401; 19-1402(a)(4), (b) – (c); 19-1408. A CMP imposed for a serious and immediate threat may not exceed $10,000.00 per instance or $10,000.00 per day for an ongoing pattern of deficiencies until the nursing home is in compliance. Health-Gen. § 19-1404(c); COMAR 10.07.02.70 -.74.

In determining whether to impose a CMP, the MDH must consider the following factors:

> (1) The number, nature, and seriousness of the deficiencies;
> (2) The extent to which the deficiency or deficiencies are part of an ongoing pattern during the preceding 24 months;
> (3) The degree of risk to the health, life, or safety of the residents of the nursing home caused by the deficiency or deficiencies;
> (4) The efforts made by, and the ability of, the nursing home to correct the deficiency or deficiencies; and
> (5) A nursing home's prior history of compliance.

Id. § 19-1402(c).

In this case, the MDH informed the Appellant that it based the CMP on findings following a Focused COVID-19 Infection Control Survey conducted by the OHCQ at the Facility from April 21, 2020 through May 6, 2020. The Department alleges that the Facility's failure to adequately prepare for and respond to the outbreak of the COVID-19 virus within the Facility in April 2020 violated provisions of COMAR 10.07.02.09 that establish infection control, laboratory services, and care planning requirements; and based on those allegations the Department imposed a CMP of $440,000.00. In its Notice to the Facility, the MDH cited COMAR 10.07.02.60D (Facility's failure to develop and implement a comprehensive care plan related to medications); COMAR 10.07.02.28 (Facility's failure to ensure an effective process was in place to obtain lab test results); COMAR 10.07.02.09A-B (Facility Administration's failure to manage the facility effectively and minimize the transmission of COVID-19); COMAR 10.07.02.32A (Facility's failure to maintain a complete and accurate medical record); and COMAR 10.07.02.33 (Facility's failure to

properly prevent and contain COVID-19 by failing to implement and develop an effective infection control program).

Care Planning

COMAR 10.07.02.60D provides as follows:

D. Organization of Care Plan.

(1) Resident's problems and needs shall be identified, based upon the interdisciplinary assessment. The care plan shall address all of the resident's special requirements necessary to improve or maintain the resident's status. The interdisciplinary team shall incorporate resident input into the care plan.

(2) The team shall establish goals for each problem or need identified, or combination thereof. The goals shall be realistic, practical, and tailored to the resident's needs. Goal outcomes shall be measurable in time or degree, or both.

(3) Approaches to accomplishing each goal shall be established. Approaches shall indicate the work to be done, who is to do it, and how frequently it is to be done.

Laboratory and Radiologic Services

COMAR 10.07.02.28

A. Approved Source. Laboratory services provided by the facility shall meet the applicable conditions established under COMAR 10.10.01 Medical Laboratories in Maryland.

B. Provisions of Services. If the facility does not provide laboratory and radiologic services, arrangements shall be made for obtaining these services from a physician's office, a licensed laboratory in a hospital or nursing facility, a licensed independent laboratory, or a State-approved portable X-ray supplier.

C. Physician's Order Required. All services shall be provided only on the orders of the attending physician.

D. Reports of Findings. The nursing home shall notify the attending physician promptly of the findings. The nursing home shall file signed and dated reports of diagnostic services in the resident's medical record.

. . . .

Administration and Resident Care

A. Responsibility

(1) The licensee shall be responsible for the overall conduct of the comprehensive care facility or extended care facility and for compliance with the applicable laws and regulations.

(2) The administrator shall be responsible for the implementation and enforcement of all provisions of the Patient's Bill of Rights Regulations under COMAR 10.07.09.

B. Delegation to the Administrator

. . . .

(3) The administrator shall:
(a) Be responsible for the control of the operation on a 24-hour basis; and
(b) With the exception of §B(3) of this regulation, serve full time.

. . . .

Clinical Records.

A. Records for all Residents. Records for all residents shall be maintained in accordance with accepted professional standards and practices.

. . . .

Infection Prevention and Control Program

A. Infection Prevention and Control Program. The nursing home shall establish, implement, and maintain an effective infection prevention and control program that:

(1) Investigates, controls, and prevents infections in a timely manner through a system that enables the facility to:

(a) Analyze patterns of infected individuals;

(b) Analyze changes in prevalent organisms;

(c) Analyze increases in the rate of infection; and

(d) Obtain surveillance data for the prevention and control of additional cases;

(2) Determine the procedures, such as appropriate precautions, that are to be applied to an individual resident;

(3) Maintains a record of infections in the nursing home and the corrective actions that were taken related to infections; and

(4) Monitors and evaluates the:

(a) Effectiveness of the infection prevention and control program by surveying rates of infection, especially infection rates that are significantly higher than usual; and

(b) Effective implementation of the policies and procedures that are outlined in §E(1) of this regulation.

B. Infection Preventionist.

(1) The nursing home shall assign at least one infection preventionist that has attended training in infection surveillance, prevention, and control to actively mange the nursing home's infection prevention and control program.

(2) The infection preventionist shall attend or have attended a basic infection prevention and control training course that is approved by the:

(a) Office of Health Care Quality; and

(b) Office of Infectious Disease Epidemiology and Outbreak Response for the Department.

(3) This position shall be staffed at a ration of 1.0 Full Time Equivalents for every 200 beds.

C. The nursing home shall have mechanisms for communicating the results of infection control activities to employees and to individuals who are responsible for improving the nursing home's performance.

D. The nursing home's communication mechanism shall ensure that the administrator, director of nursing, and the medical director receive and address reports of infection prevention and control findings and recommendations in a timely manner.

E. Infection Prevention and Control Policies and Procedures.

(1) The infection prevention and control program shall establish written policies and procedures to identify, investigate, control, and prevent infections in the nursing home, including policies and procedures to:

(a) Identify health care-associated infections and communicable diseases in accordance with COMAR 10.06.01;

(b) Report occurrences of certain infectious diseases and outbreaks of infectious diseases to the local health department in a timely manner in accordance with COMAR 10.06.01 and Health General Article §18-202, Annotated Code of Maryland;

(c) Institute appropriate control measures when an infection or outbreak of infections is suspected or identified in order to control infection and prevent spread to other residents;

(d) Perform surveillance for health care-associated and community-associated infections of residents and employees using definitions and methods approved by the infection prevention and control oversight committee to monitor and investigate causes of infection, and the manner in which the infection is spread;

(e) Train employees about infection prevention and control, including:

(i) Standard precautions and hand hygiene;

(ii) Respiratory hygiene and cough etiquette;

(iii) Soiled laundry and line processing;

(iv) Safe handling of needles and sharps and safe injection techniques;

(v) Special medical waste handling and disposal;

(vi) Appropriate use of antiseptics and disinfectants;

(vii) Blood-borne pathogens, including hepatitis B and C and human immunodeficiency virus;

(viii) Tuberculosis exposure; and

(ix) Proper use and wearing of personal protective equipment, such as gloves, gowns, and eye protection;

(f) Train and perform compliance monitoring of employee application of infection prevention and control activities, such as hand hygiene and personal protective equipment used for isolation precautions;

(g) Review the infection prevention and control program elements at least annually and revise as necessary; and

(h) Obtain annual approval of infection prevention and control program activities by the infection prevention and control oversight committee.

(2) The nursing home shall provide information concerning the infectious disease status of any resident being transferred or discharged to any other nursing home, including a funeral home.

(3) The nursing home shall obtain information concerning the infectious disease status of any resident being transferred or admitted to the nursing home from elsewhere.

F. Preventing Spread of Infection.

(1) The facility shall assess any residents with signs and symptoms of an infectious illness for the possibility of transmission to another resident or employee.

(2) The nursing home shall take appropriate infection prevention and control measures to prevent the transmission of an infectious disease to residents, employees, and visitors as outlined in the following guidelines:

(a) 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings; and

(b) Guideline for Infection Control in Health Care Personnel.

(3) The nursing home shall prohibit employees with an infectious disease or with infected skin lesions from having direct contact with residents or their food if direct contact could transmit the disease.

(4) The nursing home shall require employees to perform hand hygiene before and after each direct resident contact for which hand hygiene is indicated by accepted professional practice.

(5) The facility shall handle, store, process, and transport linens so as to prevent the spread of infection.

The Legal Basis for Sanctions

The first question in this case is which substantive standards establish the basis for imposing the proposed sanctions. During the hearing, the Department referenced pieces of various COVID-19 specific guidance that was published by the CDC, the MDH, and CMS in the Spring of 2020, but argued that the sanctions were based on violations of basic standards of care, and laboratory and infection control practices. Specifically, Maryland's nursing home regulations include laboratory and infection prevention and control requirements. COMAR 10.07.02; COMAR 10.07.02.33A(4)(b); COMAR 10.07.02.33E(1)(c). Maryland's nursing home regulations also expressly incorporate the 2007 CDC Guidance. COMAR 10.07.02.02B(4). The CDC updated the 2007 CDC Guidance in July 2019, but the three categories of "transmission-based precautions" set forth in it (contact, droplet, and airborne precautions) have not changed since 1996. Transmission-based precautions are always added in addition to standard precautions, which apply to care of all patients regardless of suspected or confirmed infection. (MDH Ex. 7). During the COVID-19 pandemic, the CDC issued a series of COVID-19 specific guidance explaining how to apply the CDC's long-standing transmission-based precautions, patient placement/cohorting, gown and hand hygiene instructions, among other things, to the new COVID-19 pathogen. Specifically, the guidance issued most recently relative to the survey at the Facility was issued on April 3, 13 and 15, 2020. (MDH Exs. 4, 21 and 23).

Also, the MDH argued that Maryland law provides for the Governor to proclaim a catastrophic health emergency and issue certain orders to the Secretary to take appropriate actions to protect public health. Md. Code. Ann., Pub. Safety § 14-3A-02, -03. On March 5, 2020, Governor Hogan issued a proclamation declaring a state of emergency and catastrophic health emergency in the State due to COVID-19. On April 5, 2020, he issued an

Order Authorizing Various Actions Related to Nursing Homes and Other Health Care Facilities, Order No. 24-04-05-01. Included in that Order, the Governor provided that the Secretary is ordered to issue directives in relation to COVID-19. On April 5, 2020, the Secretary issued an Order requiring that nursing homes "shall immediately ensure that they are in full compliance with all [CDC, CMS and MDH] guidance related to COVID-19." With respect to COVID-19 testing, the Secretary's Order required that nursing homes shall use the most expeditious means available. In respect to cohorting, the Secretary's Order required that nursing homes implement, to the best of their ability, a designated room, unit or floor as an observation area where newly admitted residents would quarantine, and a designated room, unit or floor to care for residents with known or suspected COVID-19.

Nursing homes that accept Medicaid payments, such as the Facility, must also follow federal Medicaid requirements as a condition of participation in the Maryland Medicaid Program. The applicable federal Medicaid requirements include professional standards and levels of service as set forth in all applicable federal and State laws, statutes, rules, and regulations as well as all administrative policies, procedures, transmittals, and guidelines issued by the Department. COMAR 10.09.36.03A. CMS publishes a State Operations Manual that contains guidance for how nursing home surveyors should interpret the federal regulations (Part 483 of Title 42 of the Code of Federal Regulations), including a State Operations Manual Appendix Q that provides guidelines for determining whether residents are in immediate jeopardy. A version of the State Operations Manual is incorporated by reference into Maryland's nursing home regulations. COMAR 10.07.02B(2). Appendix Q provides guidance for how surveyors should assess whether a nursing home deficiency constitutes an immediate jeopardy under federal law. Maryland law defines "serious and immediate threat" in a way that is similar to the federal definition of "immediate jeopardy:" *serious and immediate threat* means

"a situation in which immediate corrective action is necessary because a nursing home's noncompliance with one or more State regulations has caused or is likely to cause serious injury, harm, impairment to, or death of a resident receiving care in the nursing home." Health-Gen. §19-1401(h). The MDH argued that a totality of the various circumstances alleged constitutes a serious and immediate threat.

On March 23, 2020, CMS publicized its plan to utilize State survey agencies to conduct a new Targeted Infection Control Survey to assess compliance with existing infection control requirements amid the pandemic. MDH Ex. 18. They explained that the survey was to "ensure providers are implementing actions to protect the health and safety of individuals to respond to the COVID-19 pandemic." (MDH Ex. 18, pg. 1). CMS disseminated the CMS TIC Survey to educate healthcare facilities on the latest practices and expectations related to COVID-19. CMS made clear that this checklist would be utilized during Targeted Infection Control surveys.

The Respondent argued that in the time just prior and during the survey at the Facility, the guidance was ever changing and confusing or contradictory at times. But most relevant to this case, the OHCQ never explained what guidance would be used in terms of triggering the imposition of sanctions. This case involves a novel virus that was first introduced to the United States only three months prior to the survey. This was the first COVID-19 Focused Infection Control Survey conducted by the OHCQ. It conducted the survey using ad hoc substantive checklists and procedures CMS created for that purpose, rather than the usual survey procedures and substantive criteria described in the CMS Manuals and "Interpretive Guidelines" that are incorporated by reference into COMAR. These COVID-19 survey criteria and procedures were not adopted as regulation or binding directives. Neither CMS nor OHCQ provided specific training and guidance to the Surveyors regarding COVID-19; how to apply the 2007 CDC Isolation Guideline to the COVID-19 emergency; which recommendations CMS or OHCQ

would treat as mandatory; or which specific parts of the various CDC, CMS and MDH guidance established mandatory requirements for purposes of this survey. While some of the plain language of the guidance is clear, the guidance was often changing, taking into consideration the developing knowledge about COVID-19 and the developing challenges posed by the pandemic such as supply chain disruptions. As a result, the guidance includes phrases such as direction to implement suggestions "to the best of your ability," or "in the event of a shortage," and those phrases are not further defined.

The Respondent pointed to several recent court cases making clear that the APA imposes limits against agency deference in enforcement cases. In *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019), and *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), the Court held that deference is limited, at most, to an agency's fair and considered official general interpretations of genuinely ambiguous regulations, and not to a new interpretation, whether or not introduced in litigation, that creates 'unfair surprise' to regulated parties. *Allina*, 139 S. Ct. at 1810-1813; *Kisor*, 139 S. Ct. at 2414-2415. The Court made clear that the APA gives agencies considerable leeway to interpret and apply their regulations prospectively, but not to impose sanctions without giving specific prior notice of the exact standards to which regulated entities will be held. In *Kisor*, the Court made clear that review of an agency enforcement action must take into account whether an agency was purporting to apply a generally-worded regulation to issues it "never thought about" when it promulgated the regulation.

The Respondent argued that OHCQ has done that here. OHCQ could not have anticipated every conceivable fact pattern when designing its regulations, and yet clearly may apply general regulations to new situations. However, as the Court held in *Kisor*, and the Respondent argued, the material issue when considering imposition of sanctions is whether a regulated party is on fair notice that the regulation requires or prohibits specific conduct. It is not

sufficient for the Secretary or OHCQ simply to say, "follow all the latest CMS/CDC/MDH guidance," where, as here, that guidance does not explain, nor allow a reasonably competent Administrator or nurse to determine, what conduct could be the basis for sanction. In conclusion, the Respondent argued, where an agency issues broadly worded regulations, it may not impose sanctions without providing prior notice that a facility must implement the regulation in a certain way. The Respondent suggests that a simple blanket reference to a series of evolving, inconsistent, and even contradictory guidance documents does not constitute sufficient prior notice of the specific conduct for which OHCQ will impose sanctions.

In short, the Department contends that, based on the Governor's Order, the Facility was required to stay up-to-date and in compliance with all of the guidance produced by CDC, CMS and the MDH and therefore, any of that guidance could be a basis for citing a deficiency. The Facility argues that it cannot be expected to comply, to the letter-of-the-law, to a variety of guidance that was confusing and constantly changing in reaction to a real-time healthcare crisis.

I conclude that I do not need to reach the question of which guidance was binding on the Facility during the time of the survey, because the facts presented do not establish a violation regardless of what substantive standard is applied. Assuming that the Department is correct, that the Facility was responsible for following all of the various guidance produced and published by various federal and state agencies during the Spring 2020, I nevertheless do not find a violation. The evidence as presented does not require me to reach a conclusion on this issue, and does not impact my ultimate decision.

The Citations

Laboratory System

It is undisputed that the Facility failed to obtain Resident #[redacted]'s COVID-19 laboratory test result until the resident's relative called to ask about it. Approximately ten days elapsed between when the Facility received the bulk of the tests taken on April 6, 2020, and when they received Resident [redacted]s test result. The purpose of the testing was to identify who had COVID-19, regardless of symptoms, so that the facility could use the information to cohort residents. Surveyor [redacted]testified that he concluded that the Facility's system for tracking lab results was to utilize the line listing. This was an MDH-generated form that provided facilities a vehicle to track residents based on symptoms. The Facility's line listing form included a column for the test results, but not for when the test was returned.

[redacted] testified that he spoke with the Director of Nursing, Ms. Buscher, who explained that, while Resident [redacted] had been in a COVID-19 negative unit, [redacted] had been treated as though [redacted] were infected because prior to testing, [redacted] room was located in an area where a lot of residents were symptomatic or had tested positive. As a result, since the testing, Resident [redacted] had been in a room by [redacted]self with a private bathroom. The surveyors did not agree that Resident [redacted] had been treated as though she were COVID-19 positive. Mr. [redacted] explained that on the first evening of the survey, April 21, 2020 at about 6:30 p.m., they observed a staff member hanging a "droplet precaution" sign on Resident [redacted]'s door. Mr. [redacted] explained that in his conversation with Ms. Buscher, she said she was not aware of the specific facts surrounding the sign on Resident [redacted]'s door but had opined that the surveyors had observed the sign being replaced after it fell.

Surveyor [redacted] elaborated that when she observed Resident #[redacted]'s room, the door was open, there was no doffing station,[7] and Resident #[redacted] who was in her room, was not wearing a mask. Ms. [redacted] testified that she again observed Resident #[redacted] on April 23, 2020. On that date, Ms. [redacted] observed Resident #[redacted] in a small communal space within her unit, being fed by a nursing assistant. At that time, a second resident was also being fed in the communal space, at the opposite end of the table, by a separate staff member. Ms. [redacted] spoke with the nursing assistant and took the handwritten note, "most of the time" in her notebook to reference the nursing assistant's statement that Resident #[redacted] was fed in that way, most of the time.

The OHCQ concluded that this scenario constituted a serious and immediate threat because the Facility failed to comply with a regulation, and the noncompliance created the likelihood that a serious adverse outcome would occur. In her testimony, Dr. Nay underscored the Department's regulations requiring a nursing home to have a system for tracking pending lab results that show when tests were ordered, what results were received, and whether the attending physician has been notified of the results. COMAR 10.07.02.28D. Mr. [redacted] explained that the surveyors tagged this as an immediate threat out of concern that Resident #[redacted] had not been isolated as the Facility claimed, and the laboratory failure signaled the potential for a similar missed test result in the future to lead to unchecked exposure to COVID-19.

Dr. Nay explained that her opinion was informed by a conversation that Facility Administrator Dwyer had with a surveyor during which Ms. Dwyer was alleged to have said that the Facility did not have a system for tracking lab results. However, Ms. Dwyer disputes that conversation, which was alleged to have occurred on April 29, 2020, a day that the surveyors

[7] A "doffing station" is a dedicated receptacle where staff can remove and discard PPE. A "doffing station" can be a trash can.

were not present at the Facility. Instead, April 29 coincides with the date when Ms. Dwyer was communicating back and forth with the OHCQ after concern was raised about the tracking system. She was attempting to alter their existing system for tracking lab results in a way that would be acceptable to the OHCQ. I find Ms. Dwyer's testimony credible that she did not state there was no system for tracking lab results, but rather, that the Facility had a system that failed as to Resident #[redacted]'s COVID-19 lab test result, and the system was therefore updated on April 29, 2020.

Ms. Dwyer testified that immediately after learning of the first COVID-19 positive resident on March 30, 2020, she started reaching out to get approval for Facility-wide testing which, at that point, and for more than a month afterwards, was a practice the MDH discouraged. The volume and nature of the tests required the Facility to utilize two labs and receive lab results in a process that deviated from their standard process. Ms. Dwyer explained that when surveyors inquired about the Facility's standard process for lab results, staff members described the *standard process* rather than the process developed specifically for the April 6, 2020 COVID-19 tests. In that standard process, the lab results come in by phone call or fax, and the nurse taking care of the relevant resident at that time contacts the treating physician about the results, and records everything in a "lab book." There are three shifts for nurses, and each time a nurse comes on duty, he or she checks the lab book so that they are aware of any labs are outstanding for their patients. Ms. Dwyer explained that this is a long-standing practice that has never been cited as deficient, including following the March 3, 2020 annual licensure survey by the OHCQ.

For the Facility-wide COVID-19 tests, which would be coming in from two separate laboratories, both of which were new to the Facility, Ms. Dwyer decided to change the system so that these labs would go to executive nurses rather than to each unit. The lab test results were all documented on the line listing form. Most of the test results were received between

April 9 and 12, 2020. The tests that were completed by [redacted] Lab were uploaded onto a portal. Once a test was uploaded, the lab would inform the Facility and a staff member would log into the portal with a password and specifically retrieve a resident's results. For an unknown reason, [redacted] never called to alert the Facility about Resident #[redacted]'s results. Resident #[redacted] was never symptomatic. Ms. Dwyer explained that during a time when many residents in the Facility were very sick, Resident #[redacted] was stable, bed bound, in an isolated room, and therefore not a high priority for attention, adding to the scenario that allowed for the missed test result. She testified that after the surveyors raised a concern about the Facility process for receiving lab test results, on April 29, 2020, she added a column to the MDH line-listing form for "date of result" and it resolved the concern.

Ms. Dwyer also explained that Resident #[redacted]'s nutrition is her biggest challenge. She said that the staff has better luck feeding Resident #[redacted] outside of her room and agreed that [redacted] was being fed outside of [redacted] room on April 23, 2020. By that date, seventeen days after [redacted] COVID-19 test was taken, because [redacted] remained asymptomatic, [redacted] would no longer be considered contagious.[8] Despite the fact that Resident #[redacted] was not identified as being COVID-19 positive, [redacted] had previously been flagged as potentially positive due to [redacted] room's proximity to other COVID-19 positive residents. Within the system of cohorting the Facility started to implement on or about April 9, 2020, [redacted] had been kept in a single room, with a private bathroom during the time that [redacted] could have been contagious. [redacted] did not wear a mask in [redacted] room, [redacted] was bed-bound, and [redacted] bed was more than six feet from the door which was periodically left open for surveillance due to safety concerns.

[8] There was no consensus during testimony on the exact number of days required for a COVID-19 positive patient to no longer be contagious, but there was a consensus that if a patient was symptom free, that time was not longer than fourteen days.

The MDH citation for laboratory services essentially states that the Facility failed to ensure that an effective process was implemented to obtain and clinically respond to laboratory test results. The cited regulation is COMAR 10.07.02.28D which provides:

> The nursing home shall notify the attending physician promptly of the findings. The nursing home shall file signed and dated reports of diagnostic services in the resident's medical record.

The citation more generally references COMAR 10.07.02.33A(4)(b):

> The nursing home shall establish, implement, and maintain an effective infection prevention and control program that (4) monitors and evaluates the (b) effective implementation of the policies and procedures that are outlined in §E(1) of this regulation.

COMAR 10.07.02.33E(1)(c):

> The infection prevention and control program shall establish written policies and procedures to identify, investigate, control, and prevent infections in the nursing home, including policies and procedures to (c) institute appropriate control measures when an infection or outbreak of infections is suspected or identified in order to control infection and prevent spread to other residents.

The MDH admits that the regulation does not specifically require a system for prompt receipt of results, but that such a requirement is implied by the requirement that the Facility promptly notify the attending physician of lab results and strictly manage infection control practices. Giving the MDH the benefit of the doubt, that all CDC, CMS and MDH guidance about COVID-19 and nursing homes issued during, and just prior to, the relevant timeframe is applicable, I looked to that guidance. There is not much mention of lab test results because at that time, universal testing was not touted as a preferred or recommended form of infection control for COVID-19. The CMS TIC Survey provided to facilities on April 23, 2020, and identified as the document CMS would utilize on Focused Infection Control surveys, does not mention a system for lab test results except in relation to obtaining lab test results from a hospital or other facility if a resident is transferred to the facility from the outside. That survey does have a line item for cohorting that specifically approves the practice of isolating in private rooms.

The survey asks: "Has the facility isolated residents with known or suspected COVID-19 in a private room (if available), or taken other actions based on national, state, or local public health authority recommendations?" (MDH Ex. 18, pg. 014).

The MDH argues that, because a test result was missed, the Facility did not have an effective system in place to receive test results. The Facility argues that it did have a system in place, and that one human error does not invalidate the system's existence or its effectiveness.

There is no question that the missed COVID-19 test was an error – both by [redacted] and the Facility. Health-Gen. § 19-1401(h) defines "serious and immediate threat:"

> A situation in which immediate corrective action is necessary because a nursing home's noncompliance with one or more State regulations has caused or is likely to cause serious injury, harm, impairment to, or death of a resident receiving care in the nursing home.

At the time of the Facility's COVID-19 testing, and at the time of the survey, the MDH did not require surveillance testing as a means of infection control for COVID-19. At that time, the MDH advised and required symptom-based infection control without testing. As of the time of the survey, the MDH was ordering nursing homes to admit COVID-19 positive residents and encouraging them not to test anyone who is asymptomatic. At that time, the State standard for infection control in nursing homes related to COVID-19 did not involve testing, and therefore, a mistake within the lab-test result system could not alone have been a violation of the requisite infection control system within the Facility. Had the Facility not had the foresight it did, and taken the proactive steps to do surveillance testing, Resident #[redacted] would have never been tested, nothing about her care would have changed, and the Facility would not have been cited for a violation in regards to her care or treatment.

On April 29, 2020, the Facility altered its lab-result system in a way that the OHCQ agreed would remedy the problem. As of that date, universal testing was still not required. MDH takes the stance that a facility's failure to obtain the COVID-19 test results of an

asymptomatic resident at that time was likely to cause serious harm, injury, impairment to, or death of a resident receiving care at a nursing home. It would, therefore, also have to agree that its policy at the time of discouraging and preventing nursing homes from testing asymptomatic residents without prior approval was similarly likely to cause serious harm, injury, impairment to, or death of a resident receiving care at a nursing home. The MDH is clearly not taking that latter position and has not shown that the Facility's failure to receive one test result alone resulted in a statutory serious and immediate threat. Further, the March 10, 2020 MDH guidance provided that the MDH would not take regulatory action for non-compliance that arises solely from the good faith implementation of these recommendations during the period in which the Governor has proclaimed a state of emergency related to COVID-19. The Facility was not on notice that the MDH would take regulatory action for a human error that occurred in a process that was not mandated, for which the Facility had no guidance or example to follow because they were the first to do it, when the surveillance testing was the Facility's good faith effort to manage the COVID-19 outbreak to the best of its ability during the state of emergency.

The related second piece of this allegation involves the Facility's treatment of Resident #[redacted] following the date they should have received the positive result of [redacted] COVID-19 test. The MDH argued that because the test result was missed, the Facility allowed Resident #[redacted] to expose others to the virus by keeping [redacted] on a COVID-19 negative unit, leaving [redacted] door open, not requiring that [redacted] wear a mask while in her room, not having appropriate signage on [redacted] door, not having a doffing station at [redacted] door, and feeding [redacted] in a common area where another resident was present. The MDH argued that the totality of this scenario amounted to a statutory serious and immediate threat.

Ms. Dwyer explained that because of Resident #[redacted]'s condition, she required a single room. Prior to receiving [redacted] test results, the Facility was treating [redacted] as having suspected COVID-19, but because [redacted] was in a single room with a private bathroom, and was bed-bound and asymptomatic, at a time when the entire population of the nursing home had to be relocated, [redacted] was not a priority. For the entire time the Facility should have known [redacted] was infected, [redacted] was isolated as described in the CMS TIC Survey described above. (MDH Ex. 18, pg. 14). Dr. Wallace testified that he took measurements at the Facility and no bed was less than six feet from the door. Ms. Dwyer testified that every room at the Facility has at least one trash can, accessible to the door. I found both Ms. Dwyer and Dr. Wallace credible on those points.

The Facility took many steps to best manage the spread of COVID-19 without having the benefit of surveillance testing and retesting, because they were early-adopters of the concept that COVID-19 had asymptomatic spread. They learned this from diligently researching the earlier outbreak in a King County, Washington nursing home, and having regular calls with Dr. [redacted], the MDH State Epidemiologist. As a result, Resident #[redacted] was isolated and treated as being COVID-19 positive despite being asymptomatic and despite the Facility failing to receive [redacted] test results. [redacted] was in [redacted] room alone, bed-bound more than six feet away from the door so even with the door open, [redacted] was "isolated" such that [redacted] was not required to wear a mask. At the time the surveyors observed a sign being hung on her door, [redacted] was no longer contagious. The MDH inferred that, based on those observations, the sign must not have been there prior. The surveyors did observe droplet precaution signs on several other resident's doors who were similarly situated to Resident #[redacted] as they were also isolated in single rooms on Covid-19 negative units. This fact leads me to the conclusion that it was more likely than not that there had also been a sign on Resident #[redacted]'s door. At the time the surveyors observed Resident #[redacted] eating in the community room, [redacted] was no longer contagious.

The MDH inferred that, based on the observation and the nurse assistant's comment that [redacted] ate in that space "most of the time," that [redacted] likely ate in that space, with the other resident, while she was COVID-19 positive. According to Ms. Dwyer, Resident #[redacted] was bed-bound, quite demented and not socializing with any other resident, or eating with another resident by choice. She also stated that she did not believe Resident #[redacted] was fed in the community room between April 6, 2020 and April 20, 2020. Ms. [redacted] testified that the two residents were each in beds, at opposite ends of the table from one another, being fed by separate staff-people and therefore at least six feet apart. There is nothing in the record tending to show that Resident #[redacted] always ate with another resident, and based on Ms. [redacted] notes and testimony, it does not appear she asked that question. A resident who lives in the Facility and eats in the community room 351 days a year would eat in the community room "most of the time," with the exception of a fourteen-day span. The MDH did not meet its burden to show that it was more likely than not that Resident #[redacted] ate in the community room, and even if it had, there is no evidence that the practice caused any harm as the residents were not within six feet of one another.

The laboratory system failure cited by the MDH did not cause a statutory "serious and immediate threat."

Infection Control

Nursing homes in Maryland are required to establish, implement, and maintain an effective infection prevention and control program (ICP). COMAR 10.07.02.33A. The ICP must monitor and evaluate effective implementation of written infection prevention and control policies and procedures that "identify, investigate, control, and prevent infections in the nursing home." COMAR 10.07.02.33E(1). Among other things, the ICP must effectively implement policies and procedures to "[i]nstitute appropriate control measures when an infection or outbreak of infections is suspected or identified in order to control infection and prevent spread

to other residents." COMAR 10.07.02.33E(1)(c). In its Statement of Deficiencies, the MDH alleged that the Facility violated Department "Directives" by failing to cohort residents and staff to the best of their ability; failing to follow CDC Guidelines regarding isolation of infected residents; improper use of PPE; and failure to provide adequate PPE "doffing stations."

a. Doffing Stations

OHCQ generally alleges at page nineteen of the Statement of Deficiencies that the Center "failed to sufficiently establish doffing stations and ensure staff followed isolation precautions." Specifically, the MDH alleged that there was no doffing station set up at the doors of the rooms of Residents #[redacted], #[redacted] and #[redacted] or at the entrance to one of the COVID-19 positive units.

There was no dispute that a doffing station can be a trash can. Ms. Dwyer testified that every patient room had at least one trash can, and while it may not be immediately next to the door, it was located between the patient and the door. Surveyor [redacted]'s notes suggest that she did see trash bins outside every isolation room. (MDH Ex. 25). There was no dispute that the COVID-19 positive units had trash cans at the nursing stations.

The CDC does not use the term "doffing station" in its guidance but rather refers to "designated containers" located convenient to the site of removal. The April 13, 2020 CDC guideline, which was the most recent to the survey, refers to the ability to remove PPE in "patient rooms or areas." As stated above, I find Ms. Dwyer's testimony credible that every patient room contained at least one trash can. The guidance does not require specific placement of the trash cans. Each of the areas mentioned by the MDH contained trash cans within the "patient rooms or care areas." The MDH citation regarding doffing stations does not establish any noncompliance.

b. PPE

The Statement of Deficiencies lists several observations where Facility staff were alleged to have improperly donned PPE. Specifically, on April 21, 2020, on the [redacted] unit, which was designated for COVID-19 positive residents, the Administrator, Ms. Dwyer, and Ms. Buscher, walked through the hallway wearing masks and gloves, but not gowns. On April 23, 2020, a floor tech who was mopping floors walked into the [redacted] unit which was designated for COVID-19 positive patients, without PPE. When [redacted] entered the unit, [redacted] pulled his mask over his face and put on a gown and gloves but did not first wash or sanitize his hands. And on that same day, a nursing assistant who was on a COVID-19 positive unit, removed her gown in the hallway, rolled the exterior of the gown to the inside and carried it thirty to fifty feet to the nursing station to throw it away. Surveyor [redacted] testified that the nursing assistant had rolled the gown to the inside, meaning the exterior of the gown was rolled inwards. She stated that the violation occurred because the staff member then held the rolled gown against [redacted] clothes as [redacted] carried it to the trash can.

The MDH argued that each of these examples illustrated improper usage of PPE that caused a risk of contamination of person and spread. There was no dispute that the Facility was experiencing a gown shortage at the time of the survey and had implemented an extended gown use policy on the COVID-19 positive units. The MDH did not cite the Facility for failure to change gowns between residents on the units designated for COVID-19 positive residents. However, the MDH argued that all staff were required to don full PPE prior to entering the COVID-19 positive unit and cited them for the instances where that practice was not observed. The staff allegedly out-of-compliance were administrators and a janitor. Both Surveyors testified that they did not observe any breaches of CDC PPE guidance by staff who were providing direct resident care.

The Respondent argued that the guidance neither required all staff to wear gowns, nor don PPE prior to entering a COVID-19 positive unit. The April 5, 2020 CDC directive provided that staff who have close patient contact while providing care should wear full droplet precaution PPE, including N95 masks, gloves, gowns and eye shields, but that N95 masks and gowns were not necessary for other staff. The CMS TIC Survey mentions PPE. It recommends that staff wear "all recommended PPE (i.e., gloves, gown, eye protection and respirator or facemask) for the care of all residents…" (MDH Ex. 18, p. 012).[9] The April 9, 2020 MDH guidance illustrated that not all staff are required to wear PPE, including gowns, even when in close contact with residents, but should base the decision to wear PPE on the "procedures being performed and the availability of specific forms of PPE." That guidance also provides that "gowns per se do not necessarily need to be an element of the PPE worn in all interactions with residents; the use of gowns is primarily to prevent infectious droplets from being spread from resident to resident via healthcare providers by direct contact and this risk may not be present for all interactions with residents." Finally, that guidance provided that "nursing homes making a good faith effort at following the gown prioritization guidance…are considered in compliance...of the Secretary's Order…" (Resp. Ex. 37). The CDC guidance published on April 13, 2020 advised that, in cases of gown shortages, they should be prioritized for "high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of [the health care provider.] (Resp., Ex. 46, pg. 7). Many of the CDC's PPE recommendations during the Spring of 2020 relaxed otherwise applicable guidance in order to conserve scarce PPE for such caregivers.

[9] Unlike with other citations, I used the Department's numbering here because the document did not have its own numbering.

The Respondent further argued that the nursing assistant who rolled the gown had done so properly. She rolled the exterior of the gown to the inside such that what had been the interior of the gown was against her clothes as she carried it to the trash can. As the interior of the gown was against her clothes when she was wearing it, it is difficult to see how this practice could result in any harm. The Department did not cite to any guidance specifically discouraging this practice other than general guidance stating the PPE should be discarded in the "patient room or patient care area." As the staff were wearing gowns from room to room on the COVID-19 positive unit in order to conserve them, the entire unit became a "patient care area" and therefore discarding the gown in a room or somewhere else within the unit would have complied with that guidance. The Department likewise failed to provide any guidance stating that one slipped mask would pose any risk of harm to a resident. Dr. Katz stated that a momentary slipped mask poses no plausible risk of harm.

None of these allegations establish noncompliance of any State, CDC or CMS guidance, or any plausible risk of harm to any resident.

c. Cohorting

As described in detail above in relation to Resident # the Surveyors alleged that the Facility failed to properly cohort Residents # # and # Specifically, these residents were kept in individual rooms, with private bathrooms on COVID-19 negative units despite testing positive for COVID-19. Residents # was tested on April 6, 2020 and test came back negative. was tested again on April 17, 2020 when exhibited symptoms, and that test was positive. Similarly to Resident # Resident #'s door was left open at times for observation due to safety precautions. Resident # also first received a negative COVID-19 test, but later received a positive test late on April 21, 2020. Resident # remained in single occupancy room with a private bathroom for the remainder of that day and was moved onto the COVID-19 positive unit

on the morning of April 22, 2020. Surveyor [redacted] testified that the surveyors did not observe Residents #[redacted] or #[redacted] outside of their rooms.

The Statement of Deficiencies alleged that the Facility failed to ensure effective systems to separate COVID-19 negative and COVID-19 positive residents as much as possible. The MDH argued that there were vacant rooms on the COVID-19 positive wings and therefore, these residents should have been moved into those rooms. A fourth resident, Resident #[redacted], was also COVID-19 positive yet remained in a single room on the COVID-19 negative unit and the MDH did not find anything wrong in [redacted] case. The difference between the cases of Residents #[redacted], #[redacted] and #[redacted] seems to be that at times, the door to Resident #[redacted] and #[redacted]'s room was observed open, while the door to Resident #[redacted]'s room was not. Resident #[redacted] is discussed at length above.

Ms. Dwyer testified that immediately upon receiving the first COVID-19 positive results on April 9, 2020, the Center developed and executed a plan to designate specific COVID-19 positive units; and then, within 24 hours, moved and cohorted more than seventy residents based on test results, proximity to COVID-19 positive cases, and symptoms. The MDH did not find fault with that system or execution of cohorting, but with the few residents who were COVID-19 positive but remained in single occupancy rooms on COVID-19 negative units. Ms. Dwyer testified that the logistics of moving residents were extremely difficult to navigate. They had to take into account gender, care requirements, and personal preference. Unlike in a hospital setting, the staff then had to move not only the resident, but all of their belongings. Social factors were also a consideration such as the resident's tendency to wander, become easily agitated, or require an electric wheelchair. After rooms were vacated, the staff had to allow time for airflow and terminal cleaning. Additionally, the guidance suggested limiting the removal of residents from their rooms. Ms. Dwyer added that the rooms that were available on the

COVID-19 positive units were not single rooms. She pointed out that some rooms that appear to be vacant actually have mandatory bed-holds for a resident expected to return. Ms. Dwyer explained that given all of the pieces, isolating Residents #[redacted] - #[redacted] in single occupancy rooms was the best option.

As discussed above, all of the doors in the resident rooms are more than six feet from the beds, so the open doors observed did not vitiate the effectiveness of their isolation. Additionally, the Facility was balancing their residents due to the COVID-19 pandemic with their resident's other medical conditions that necessitated observation that could not be accomplished with closed doors. The Facility was reasonable in their choices that balanced the risks of harm to best care for their fragile patients. The 2007 CDC Guideline recommended isolating residents by placement in a single room, or by cohorting infected residents together in a dedicated unit or area. The April 5, 2020 MDH Order required nursing facilities to cohort known positive residents "to the best of their abilities," and examples of various cohorting possibilities were given including options when facilities were neither able to group residents by location or staff.

The Facility did appropriately cohort residents to the best of their ability as was required.

d. Hand washing

Surveyors also documented several hand hygiene deficiencies allegedly violating the standard of care. Specifically, on April 21, 2020, an LPN on a unit which was designated for COVID-19 positive residents, was wearing full PPE gear including gloves when [redacted] touched a resident's door and then a laptop at the nurses station without changing or sanitizing [redacted] hands or gloves. On April 23, 2020, a registered nurse administered medication to a patient in his or her room, exited the room, returned the medication container to her cart and removed [redacted] gloves. [redacted] then pulled out a new pair of gloves, put them on and then sanitized the exterior of the gloves with alcohol-based hand sanitizer. And on April 23, 3020, a social worker picked up a

food tray from a resident's room, exited the room and placed the food tray on a cart. [redacted] then sanitized the gloves [redacted] was wearing with alcohol-based hand sanitizer and entered another patient room. The MDH argued that the Facility was not experiencing a glove shortage and should therefore not have washed gloves for reuse. MDH did not allege that any staff person reused and sanitized gloves for direct resident care and there is no evidence that anyone did so. The MDH also argued that staff were to perform hand sanitization immediately upon leaving a patient room. However, Surveyor [redacted] conceded that she was not aware of CDC guidance regarding "fomite," or hard surface transmission of COVID-19. The MDH did not offer any specific evidence as to how these particular observations put residents at risk other than evidence that the use of alcohol-based hand sanitizer on the outside of disposable gloves can cause them to break down over time.

The Respondent contested the assertion that they were not experiencing a glove shortage. They pointed to nationwide PPE supply chain disruptions and CDC guidance that sanitizing the outside of gloves for reuse for non-resident care purposes was acceptable infection control practice under these circumstances. The April 30, 2020 CDC Guidance refers to "options for use when glove supplies are stressed, running low, or exhausted," and CMS specifically directed surveyors not to cite to deficiencies where facilities were making good faith efforts to preserve PPE. Ms. Dwyer testified that her supplier had indicated a disruption in their supply chain, and she was unsure about the status of their glove supply. Dr. Katz testified that at the time of the survey no Maryland nursing facility knew where its next supply of any PPE was coming from, and to her, that represented a critical situation. Surveyor [redacted] and Ms. Dwyer testified that a physician from the federal "strike team," who had visited the Facility the day before the survey, specifically approved sanitizing gloves for re-use in non-direct-care circumstances, and

demonstrated to some of the staff how to do it. However, as soon as the Facility learned that the surveyors disagreed with the practice, they advised the staff to immediately discontinue it.

The MDH did not show that the CDC or any other agency specifically prohibited the practice of sanitizing gloves for non-resident care purposes, nor that the Surveyors observed any practice that posed any plausible risk of harm. The individuals observed had touched only hard surfaces and were not involved in direct patient care. The MDH did not show that this specific practice violated any CDC or MDH guidance or posed the risk of any harm.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact and Discussion, I conclude as a matter of law that the Respondent did not have any deficiencies at its Facility that posed a serious and immediate risk to any of its residents. Accordingly, the Respondent is not subject to any Civil Money Penalty. Md. Code Ann., Health-Gen. §§ 19-1406(c)(2); 19-301(o)(1); 19-308; 19-1401; 19-1402(a)(4), (b) – (c); 19-1408 and 19-1404(c) (2019 & Supp. 2020); COMAR 10.07.02.55B; 10.07.02.70 -.74; 10.07.02.09; 10.07.02.60D; 10.07.02.28; 10.07.02.09A-B; 10.07.02.32A; 10.07.02.33

PROPOSED ORDER

I **PROPOSE** that the Maryland Department of Health's imposition of a $440,000.00 Civil Money Penalty on the Respondent be **REVERSED**.

April 2, 2021
Date Decision Mailed

[redacted]
Administrative Law Judge

[redacted]
#191357