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March 26, 2020

Michael Anbesse
IIDR Coordinator
Aging and Long Term Support Administration
Washington Department of Social and Health Services
P.O. Box 45600
Olympia, WA 98504-5600

Re: Request for Independent Informal Dispute Resolution (IIDR)
<u>Life Care Center of Kirkland, CCN 505334</u>

Dear Mr. Anbesse:

Life Care Center of Kirkland, a nursing facility located in Kirkland, WA ("the Center"), respectfully requests independent informal dispute resolution ("IIDR") regarding the deficiencies cited at 42 C.F.R. §§ 483.25 ("F684") ("Quality of Care"), 483.30(d) ("F713") (emergency physician care), and 483.80(b) ("F880") (infection control), all at "severity and scope" "L" ("widespread immediate jeopardy") following the survey that ended on March 16, 2020. A copy of the Statement of Deficiencies is attached hereto as Exhibit 1.

On March 18, 2020 CMS issued a Notice that imposed a civil money penalty in the amount of $14,200 per day effective March 13, 2020, which thus qualifies the Center for independent informal dispute resolution. See Exhibit 2, attached hereto.

Please accept this letter as our request for IIDR, as the amount and detail of information I set forth below would not fit on the usual form.

I am the Center's contact person. I can be reached at 425-823-2323.

Please also copy our counsel Joseph L. Bianculli, email bianculli@healthcarelawyers.com, on any correspondence.

For the reasons outlined below and in the attached exhibits, the Center respectfully requests that the IIDR Committee delete all three citations.

Background

As you are well aware from media reports, the Center was the "index" long term care facility in the United States, if not the world, that illustrated transmission and outbreak of the novel coronavirus that causes the COVID-19 infection. We are particularly concerned that the Statement of Deficiencies does not accurately recite the course of the outbreak at the Center; the Center's response to that outbreak; or even the interviews of key staff supposedly recorded in the Statement of Deficiencies. Please note, for instance, that a federal surveyor interviewed three key staff members, Medical Director Dhirendra Kumar, M.D., his Physician Assistant Christy Carmichael, and the Center's Infection Preventionist ("IP") Nurse Alice Cortez, *while they were at home seriously ill with COVID-19 (and did not have access to Center records).* They all report that the Statement of Deficiencies does not accurately reflect their responses to the surveyor's questions, nor their actual actions during the pertinent time.

The summary attached as Exhibit 3 shows that on February 19, 2020 the Center housed 120 residents and employed about 180 persons. As discussed below, the Center reported a cluster of unusual respiratory infections to the Seattle and King County Public Health Department ("the Department"), the local public health agency, on Wednesday, February 26, 2020. That Department approved the Center's response to the outbreak and did not even send a representative to the Center until the following week. At midnight Saturday, February 29, the Department informed the Center that one of its residents, who had been discharged to a local hospital several days earlier, had tested positive for COVID-19 (evidently the resident did not meet then-prevailing testing criteria in the interim). The following day, representatives of the federal Centers for Disease Control and Prevention arrived at the Center and began widespread testing. That same day the Governor declared a State of Emergency, which opened additional testing and care resources. Eventually CDC and U.S. Department of Health and Human Services relief staff identified 129 cases of COVID-19 among the Center's residents, staff and visitors. See Exhibit 4.

By the time the survey started on March 6, 2020, more than 80 of the Center's employees had become ill, were at home in isolation, or had left their jobs. As discussed below, in the interim, local public health authorities and the Governor promised to provide nursing and other staff on an emergency basis, and such staff began to arrive at the Center to assist with assessments and resident care during the week of March 2. By March 7, various agencies had provided 24-hour physician coverage. Notably, the survey team informed us that the presence and actions of such outside staff

– triggered by the State of Emergency, which was the entire reason for their presence – "did not count" when evaluating the Center's compliance with the regulations at issue, since they were not "facility staff."

As is now well-known, the novel coronavirus is so contagious that responsible authorities have called nursing facilities "petri dishes" for its spread. Many public health authorities indicate that the most effective means to control spread of infectious disease is universal testing and contact tracing, yet neither the Center nor any of its residents' physicians had (and still do not have) the authority or capability to conduct such testing for the coronavirus. Moreover, so far as we know, no public health authority conducted contact tracing of the first cases in the State, nor, so far as we know, contact tracing of anyone else, including any of the Center's residents or staff. But the Center's Medical Director, Dr. Kumar, says that he has learned that the genetic fingerprint of every case from the Center is identical to that of the first "index case" in the State, an individual who presented with COVAD-19 in early February following travel in China; according to Dr. Kumar, while the vector to the Center is unknown, that index individual must have infected others in the community, who then spread the virus until it eventually reached the Center. Had the public health authorities isolated and traced the contacts of that index individual, the tragedy at the Center might have been avoided.

As of today, there is no known effective treatment for the disease, which has a very high mortality rate among frail elderly persons. Of the 120 residents at the Center on February 19, 2020, 66 were transferred to hospitals by March 20. Of these 66 residents, 57 had tested positive for the virus by that date. Eleven residents died at the Center during that time (in recent months between 3 and 7 residents typically died each month); of those eleven residents, eight tested positive (and two were not tested; that is, only one tested negative). Of the 42 residents remaining at the Center on March 20, 2020, 31 had tested positive as of that date. See Exhibit 3.

These facts – all of which are absent from the Statement of Deficiencies – provide context for the discussion below.

The Statement of Deficiencies essentially alleges that the Center "failed to recognize all possible systemic risks and concerns related to" this outbreak; "did not anticipate the need to develop contingency plans to address how the outbreak may affect their ability to provide consistent provision [sic] of quality goods and services;" and "failed to notify public health authorities and seek assistance from infection control experts." According to the Statement of Deficiencies, *as the direct result of these supposed failures, numerous acutely ill residents required hospital treatment, and many died.* The latter allegation was necessary to support the "immediate jeopardy" allegations, which require evidence that some act or omission by a facility *that was a regulatory violation* "caused or was likely to cause" death or serious harm to residents.

As discussed below, the Center did not violate any of the cited regulations. In fact, many of the allegations of noncompliance do not even track the plain regulatory language. But more important, the allegations in the Statement of Deficiencies disregard the critical context that the Center was the first long term care facility in the United States to face an outbreak of this novel infection, and that during the time period addressed in the Statement of Deficiencies, no public authority – not CMS, the CDC, nor any State or local public health authority – had promulgated any guidance, much less requirements for enhanced or specific additional infection control policies and procedures, that the Center violated. For instance, in early February, 2020, CMS promulgated a memorandum that simply reminded nursing facilities to review and implement existing infection control policies and protocols in the case of an infectious disease outbreak. In fact, neither the CDC nor the State promulgated specific COVID-19 guidance until early March, 2020. See Exhibit 5. As has been well-reported in the media, the CDC and CMS response to the coronavirus pandemic has been, and continues to be even today, late, inconsistent and even flawed.

Finally, even if every allegation in the Statement of Deficiencies is factually correct – and many are at best incomplete – none describes how any act or omission by the Center caused any resident to develop COVID-19, or exacerbated the course of any resident's illness.

The Center certainly understands its legal and moral obligations to establish and maintain effective infection control policies and procedures, and to protect residents from avoidable illness. As described below, we respectfully suggest that we have done so. Likewise, we appreciate the role of CMS to assure that nursing facilities are doing so. But part of the context of the cited deficiencies is that surveyors descended on the Center *during the height of the outbreak, when staff already were overwhelmed by an emergency*. Surveyors nevertheless demanded production and scanning of thousands of pages of documents, and interviewed numerous line staff at length, diverting more than 400 hours of staff time – that is, more than ten full time staff equivalents over the course of a week – from resident care to survey management. As noted, surveyors interviewed key witnesses while they were acutely ill, and when they had no access to Center records. While these facts may not determine whether or not the Center was or was not in compliance, they certainly are pertinent to consideration of the evidence we outline below.

Moreover, you might consider that the survey could have been conducted equally as effectively after the immediate crisis had passed. As noted, by the time the survey was underway, numerous agencies had dispatched assistance, including 24-hour physician coverage.

Note also that the surveyors did not have the COVID-19 survey protocol CMS released on March 20, 2020, but that protocol makes clear that surveyors should have been focused on the direct interaction between staff and residents, and not statistical and paperwork issues highlighted in this Statement of Deficiencies.

We address each citation in turn.

F684

The Statement of Deficiencies generally alleges that the Center's IP Nurse, Alice Cortez, first became concerned about a "cluster of respiratory infections," including several cases of pneumonia, about February 20, 2020; that Nurse Cortez discussed the matter with Medical Director Kumar's Physician Assistant ("PA") Christy Carmichael; that at least some of the affected residents tested negative for influenza and were treated with antibiotics; and that the Center did not report the "cluster" of infections to the local public health authority until February 26, 2020 (after conferring with Dr. Kumar and others).

The Center respectfully suggests that nothing about these facts implicates any regulatory violation, or any violation of the Center's resident care or infection control policies and procedures.

Again, context is critical. Respiratory infections in nursing facilities, and in the community, commonly spike during the winter, and it is not unusual for "clusters" of pneumonia to follow respiratory infections in compromised frail elderly persons (and also to occur for other reasons, for instance, aspiration). As summarized below, the Center has typical infection control policies and procedures that address such outbreaks. But because such outbreaks of seasonal respiratory disease and pneumonia are neither unusual or unexpected, the State does *not* require nursing facilities to report such cases. At the pertinent time, the State did require reports of certain infections diseases, but *not* COVID-19 (the State subsequently did begin requiring such reports); likewise, the residents' illnesses did *not* appear to fall within any other reportable category (for instance health care facilities must report certain "unexplained critical illnesses and deaths," but only for persons under age 50). See Exhibit 6.

As discussed in further detail below, the Center did establish and maintain appropriate infection control policies and procedures that incorporate or reflect all applicable CMS and CDC guidance regarding identification, treatment, cohorting and isolation when necessary, reporting to public health authorities, and quality assurance analysis. Pertinent excerpts of those policies and procedures, which total several hundred pages, are attached as Exhibit 7.

First, the Center's Infection Control Program provides for surveillance for all possible infections and outbreaks of infectious disease (which can, in some cases, consist of only one unexpected case). The pertinent protocol provides for, among other things, consideration of a resident's new acute symptoms and presentation (fever, acute change in mental status, acute functional decline and the like); microbiologic and radiologic findings where appropriate; and specific diagnostic criteria for various infections (common cold, influenza, pneumonia, urinary tract

infection, cellulitis, scabies, gastrointestinal infection, etc.; COVID-19 was added in early March, 2020).

The Program then provides that when an infection or outbreak is identified, the IP Nurse and interdisciplinary care planning team ("IDT") must identify the illness; determine the number and distribution of cases; formulate a hypothesis regarding the mechanism of transmission; and design and evaluate control measures.

The Center's staff followed these steps. Moreover, the allegation in the Statement of Deficiencies that Nurse Cortez failed to review or familiarize herself with the Center's Infection Control Program and Protocols during this time is an outrageous slander; she says that – while confined at home ill – she actually recited large portions of the Protocols to the surveyor, and told him that she did not need to review them again because she knew them by heart.

Indeed, Nurse Cortez is a very experienced nurse, and she says that she actually did consider the possibility that the cluster of new infections might be COVID-19. She says that in early February, 2020 she did internet research, and saw no guidance or bulletins from CDC or the local public health authorities for long term care facilities; and saw that every reference to the one confirmed case in the State at the time indicated that the person had been isolated and was recovering uneventfully. But she remained suspicious, and began questioning visitors and staff about foreign travel and unusual symptoms. See Exhibit 8. In fact, in mid-February she informed two kitchen staff (husband and wife) who recently had traveled to Korea and the Philippines that they could not return to work until they self-quarantined for 10 days (they chose to quit instead and never returned to the Center).

Nurse Cortez also created and updated line listings of new infections on a daily basis per the Center's Protocol. See Exhibit 9. As the Statement of Deficiencies recites, nurses did assess residents who presented with upper respiratory illnesses throughout February – the typical season for such infections – and Dr. Kumar or PA Carmichael then who ordered influenza tests and chest X-rays, and started each on Duoneb, an antibiotic, and, if needed, oxygen, pending receipt of test results, which is the ordinary clinical response.

We note that the Statement of Deficiencies is at best misleading to the extent that it suggests that Dr. Kumar, who served as attending physician for most residents, was not physically present at the Center through this time. In fact, Dr. Kumar customarily does rounds and assesses new admissions at the Center nearly every day, and he continued to do so through February, 2020. During that time he continued to see residents, perform assessments, provide orders, and consult with the Center's staff. About March 2, he became ill with COVID-19, so he stayed away after that date, but he never was so sick that he could not consult by phone with PA Carmichael and the Center's staff, and he continued to do so several times every day. PA Carmichael likewise was present at the

Center nearly every day (except Wednesday, her day off), until she also became ill about March 8. By that time various public authorities had provided backup practitioners (as noted, the survey team stated that these practitioners, who actually were providing assessments and care, "don't count" when assessing the Center's compliance)..

As the Statement of Deficiencies recites, no resident tested positive for influenza during February, 2020, so it was not necessary for the Center to implement every aspect of its Influenza Protocol (for instance, prophylactic Tamiflu, which Nurse Cortez, Dr. Kumar and PA Carmichael actually did consider, but decided against because they concluded that the risk of side effects outweighed any potential benefit). However, the Center nevertheless *did* implement many provisions of that Protocol that were not specific to influenza. For instance, the Center always has a notice on the door requesting visitors to limit visits if they are experiencing fever or respiratory symptoms, and reminding visitors to sanitize their hands frequently. See Exhibit 10. Additional sanitizer stations were added, including outside the front door. Face masks were available at the front desk. The Center already had instituted flu-season increased cleaning of common areas, door handles, hallway railings, and the like. Nurse Cortez conducted inservice education of the nursing staff to reinforce the Center's infection control protocols. The Center followed CDC Infection Control protocols and enforced standard precautions for ill residents, including physical separation of at least 6 feet, and use of personal protective equipment ("PPE") by caregivers, for residents who were exhibiting respiratory symptoms (at that time, single room isolation and PPE for residents and visitors was not recommended).

Likewise, Nurse Cortez advised all Department Heads to coordinate with her, and to send home any staff member who was coughing, or who had a fever or respiratory symptoms beyond allergic runny nose or the like (and staff could not return to work until they produced a negative influenza test result). See Exhibit 11. Nurse Cortez says that during February, she personally sent home a handful of workers from the housekeeping, therapy and dietary departments, and two nursing students from a nearly technical school. (Media reports that staff were permitted to work while sick are not accurate.)

As the Statement of Deficiencies suggests, Nurse Cortez *did* become concerned about the increasing trend of respiratory infections in mid-February. That is why she conferred with Dr. Kumar and PA Carmichael regarding the matter. By mid-February, numerous residents had been sent to hospitals with pneumonia and other serious respiratory illnesses, *but no hospital had informed the Center that any of these cases involved COVID-19.* Both Dr. Kumar and PA Carmichael say that in these circumstances, and because there was no evidence that any resident had been exposed to any COVID-19 patient, they believed that the outbreak was *not* COVID-19, but likely was a routine respiratory virus, and/or a cluster or bacterial or aspiration pneumonia cases.

In fact, until late February, 2020 the media continued to report that the only local COVID-19 cases appeared to involve persons who recently had traveled in Asia; that all infected persons had recovered; that there were no reported cases in health care facilities; and that no one had yet died of COVID-19 anywhere in the United States. For instance, on February 26, President Trump publicly announced that there were only fifteen confirmed COVID-19 cases in the entire country, and that he anticipated that the number would be reduced to zero in the coming week. As noted, Dr. Kumar observes that, in retrospect, this information was dangerously flawed.

More important, as noted, before the end of February, no public health authority had recommended, much less ordered, that the Center (or, for that matter, any other nursing facility in the United States) restrict admissions or otherwise change operating or clinical policies due to COVID-19, so the point of the critique that the Center continued to admit residents during February is unclear. It is not unusual for the local public health authorities to restrict admissions during outbreaks of diseases that are known to be contagious in health care facilities, but there was no such order or even guidance at that time. Moreover, as noted above, neither the Center nor any resident's physician had the authority or ability to order COVID-19 testing, so in a very real sense the Center was flying blind into a storm (as was much of the nation at the time).

As the Statement of Deficiencies suggests, the Center's IP Nurse, Medical Director, Director of Nursing and others *did* become increasingly concerned as the number of non-influenza respiratory infections and hospitalizations increased. More specifically, they say that they were concerned by a cluster of unexplained fevers on one particular nursing unit, and the fact that some residents sent to the hospital had decompensated and died within hours, which was very unusual, and so on February 26, 2020 – ironically, the same day President Trump announced that the pandemic was easing in the United States – they met and decided to request assistance from the local County public health authorities. *Again, to their knowledge there still were no confirmed COVID-19 cases at or from the Center at that time.*

On the same day, the Center closed the Center to visitors; informed all families of the closure; closed its dining and therapy rooms; and began providing meals and therapy only in resident rooms. All group activities were canceled. The Center canceled nursing student clinical rotations. The Center increased bleach cleaning of all public areas, doorknobs, hallway railings, bathrooms, and the like. Nurse Cortez instructed Central Supply to order additional PPE, and she provided an inservice education session to all Department Heads and staff about these measures, and a refresher on proper use of PPE.

Nurse Cortez called the County Health Department at 9 A.M. Wednesday, February 26 – and she also called and left messages several times thereafter during the next two days, as no one returned her calls. She also filed an online report with the State Department of Health. Finally, on the afternoon of Thursday, February 27, Sauna Clark, a County Health Department investigator

called back; Nurse Cortez described the circumstances and the Center's responses; and Ms. Clark told Nurse Cortez that the Center was doing everything right (Ms. Clark also suggested using disposable plates and forks, which the Center started doing). The following day Nurse Cortez faxed line listings and lists of recent admissions and discharges to Ms. Clark. No one from the County Public Health authority actually came to the Center until late the following week.

During the call on February 28, Ms. Clark told Nurse Cortez that a local hospital had just obtained authority to test a resident who had been discharged to the hospital several days earlier with respiratory symptoms for COVID-19 (according to the investigator, the protocol at the time had been *not* to test patients with comorbidities, which seems exactly backward). As noted above, the Center was notified of a positive result at midnight that night. By Monday, March 2, two investigators from the CDC arrived at the Center (they again complimented the Center's response to date), and widespread testing commenced shortly thereafter.

As noted, the Governor declared a State of Emergency on March 1; the State promised immediate help to fill in for sick or quarantined staff; and such staff, including physicians, trickled in over the next week. In the meanwhile, the Center's nurses and PA Carmichael worked nearly round the clock assessing residents, providing care, providing orders, and the like. PA Carmichael actually worked nearly round the clock for a week, until she also became ill about March 8. In response, the Statement of Deficiencies critiques the fact that the Center's staff and PA Carmichael did not complete all of their nursing notes, complete transfer paperwork, and other documentation during that time (a Center representative told the surveyors that PA Carmichael was trying to complete her progress notes while she was sick at home, yet the Statement of Deficiencies nevertheless includes this unfair critique).

The Center suggests that nothing about this chronology illustrates substandard quality of care, or failure to provide necessary goods or services. It is very unfortunate that the novel coronavirus attacked the residents and staff of the Center, but such spread of a new unknown pathogen is *characteristic of* pandemic, not evidence that the Center's staff, or Dr. Kumar or PA Carmichael, somehow failed their responsibilities to identify the pathogen, to perform appropriate assessments, or to diagnose or treat a novel disease. With due respect, that conclusion is a parody of the regulatory process.

Moreover, as CDC and the media have reported, within a few days the number of confirmed COVID-19 cases among the Center's residents, staff and visitors exploded. So far as we are aware, CDC was unable to determine how or when the virus first invaded the Center, but, as noted, Dr. Kumar surmises that it is likely that many of the Center's residents and staff were exposed by unknowing visitors or even staff who somehow had been infected by the State's index case, well before any public health authority confirmed its presence in the community, much less at the Center. Indeed, media reports indicate that families of some residents who died from respiratory ailments

during the weeks before testing confirmed COVID-19 at the Center believe that such residents also might have died from the disease. But it is unclear how any act or omission by the Center – much less any regulatory violation – caused any of these results.

F713

This regulation requires that "the facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency." According to the Interpretive Guideline that accompanies the regulation, the intent of the regulation is that facilities must assure that "if a resident's attending physician is unavailable, the facility should attempt to contact the physician covering for the attending physician before assuming the responsibility of contacting another physician." According to the Interpretive Guideline, examples of noncompliance include a resident's attending physician leaving for an extended overseas vacation without designating a covering practitioner, and the facility thereafter being unable to find someone with whom to confer in an emergency; or a physician being away and not providing a prompt response to a lab test. See Exhibit 12.

The regulation does *not* require a facility to assure that a physician or practitioner must be physically present at the facility 24 hours per day, even during an emergency such as this COVID-19 outbreak.

The Statement of Deficiencies does not allege anything like any of these situations. As noted, Dr. Kumar – who attended most of the Center's residents – actually was at the Center, and available 24 hours per day at all times – even while he was ill after March 2 -- and his PA actually was in the Center nearly every day until she became ill about March 8. At all pertinent times, PA Carmichael and the Center's staff actually were in ongoing communication with Dr. Kumar – and other physicians, including physicians at local emergency rooms – multiple times per day. During the week of March 2, various public agencies supplied on-site physicians, and after March 7, the Center had 24-hour per day physician coverage (although the surveyors said that such coverage "doesn't count," a bizarre interpretation of the supposedly resident-centered survey process).

Most important, the Statement of Deficiencies does not cite, or even suggest, that there ever was any time or circumstance where the Center's staff was *not* able to obtain prompt or effective guidance or orders because of the lack of immediate availability of a physician or practitioner. In fact, there was none.

In short, this citation does not even describe a violation of this regulation.

F880

The crux of the Statement of Deficiencies is the suggestion that residents became ill and died because the Center failed to "establish and maintain" appropriate infection control procedures. There is no factual or legal basis for that allegation or conclusion, and the evidence shows that the Center was in substantial compliance with the regulatory requirement at all times.

This regulation has several pertinent provisions. First, the regulation requires that "the facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections."

The Center had such a Program, and the Statement of Deficiencies does not allege otherwise. See pertinent excerpts of the several-hundred page document at Exhibit 7.

The regulation goes on to describe the specific required elements of the Program:

First, the Program must include "a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals . . . "

The Center's Program includes such customary standards, and the Statement of Deficiencies neither critiques those standards, nor suggests any reason why they were ineffective. For instance, CDC and Center protocols provide for use of personal protective equipment, including gloves, gowns, masks and "red bags" by caregivers (but not, at that time, by infected residents or visitors), and physical separation which the Center meticulously maintained. At no time before the Center acted on February 26, 2020 did any authority recommend or order closure of the common dining room, therapy department or other clinical areas.

Second, the infection control program must include "written standards, policies, and procedures for the program," including surveillance, reporting, transmission-based precautions, isolation, and hygiene standards. Again, as outlined above, the Center's Program includes such standards, and the Statement of Deficiencies does not critique their content or implementation.

Moreover, it is important to note that at the pertinent time, neither CMS, CDC, nor any other public health authority had provided specific guidance or directions regarding cohorting or isolating residents of long term care facilities who presented with signs or symptoms of what appeared to be seasonal respiratory ailments. Likewise, the data summarized above show that the Center routinely transferred to hospitals (consistent with the usual practice) all residents who presented with signs or symptoms of serious respiratory ailments. Again, at that time, neither the Center nor its residents'

physicians had the authority or ability to test for the novel coronavirus, but even had they done so and residents tested positive, treatment and transfer protocols would not have changed.

Third, the infection control program must include a system for identifying and documenting infections. As noted, the Center did create routine line listings of infections, and those data assisted the Center's IP Nurse and IDT to address the outbreak.

Instead, the allegation of noncompliance is to the effect that the Center's staff did not anticipate "the need to develop contingency plans," and "all possible systemic risks and concerns related to" the COVID-19 outbreak. With due respect, no one in any position of authority in the United States provided guidance *in January and February, 2020* regarding such "risks and concerns" or "contingency plans." Indeed, as late as late February, when the Center *did* contact local public health authorities – a month after the first case of COVID-19 was identified in the State – local authorities *still* provided no guidance or assistance. More important for this IIDR process, as discussed above, *the Center* did establish and maintain its infection control process.

Conclusion

The Center recognizes that CMS has a significant role to play in the nation's response to the COVID-19 pandemic. But scapegoating the first nursing facility in the nation to confront the outbreak is not appropriate, and, more to the point, imposing sanctions based on retrospective critiques of clinical decisions, actions, and responses to illnesses that were unremarkable at the time does not satisfy the "remedial" purpose for enforcement sanctions.

The Center suggests that the COVID-19 survey protocol CMS released on March 20, 2020 – a month after the events at issue here, yet intended, by its terms, to guide surveys of nursing facilities experiencing infectious disease outbreaks – actually is a useful guideline for evaluating not only regulatory compliance, but also the appropriate clinical and infection control responses to a potential or actual outbreak in a long term care facility. The Center respectfully suggests that had the survey team used that new survey guidance in this case, it would have focused upon – and found that – the interactions between the Center's staff and residents met all standards and criteria CMS describe in that tool as necessary and appropriate to protect residents from *avoidable* COVID-19 infection.

The reality is that the preparation for,.and response of, every governmental authority and healthcare provider to the COVID-19 pandemic will be analyzed and critiqued during the coming months and years (and that much of the contemporaneous commentary will be found to be flawed, incomplete, inappropriate or unfair). It is extremely unfortunate that numerous residents and staff of the Center became among the first victims of the pandemic in the United States, and even more

so that many died, but that result is the quintessential Act of God, and not evidence of a significant regulatory violation that requires monetary and other sanctions.

For that reason, and the reasons outlined above, the Center respectfully requests that the citations, and the resulting sanctions CMS imposed, be set aside.

Respectfully submitted,

Ellie Basham /by JLB

Ellie Basham
Executive Director