GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

June 12, 2019

In the Matter of:

McLaren Flint
Chad M. Grant, President and CEO
401 South Ballenger Hwy
Flint, MI 48532

ORDER

Conditions at McLaren Flint Hospital concerning low level persistence of *Legionella* bacteria in the McLaren Flint Hospital's water system has come to the attention of the Department of Licensing and Regulatory Affairs (DLARA). Steps taken by McLaren Flint ("the Facility") to date are not sufficient to resolve these issues that impair the ability of the Facility to deliver an acceptable level of care and services for the health, safety and welfare of the public. Therefore, after review I find, as the Director of the Michigan Department of Licensing and Regulatory Affairs (DLARA), that additional steps must be taken by the hospital to ensure compliance with the Public Health Code, 1978 PA 368, MCL 333.20101 *et seq.*, as amended, related to the persistent level of *Legionellosis* and the continued identification of healthcare associated Legionnaires' disease cases.

Findings:

This *Order* is based upon the Michigan Department of Health and Human Services' (MDHHS), Communicable Disease Division, *Ongoing Legionellosis Investigation, McLaren Flint Hospital* (dated June 10, 2019). The MDHHS investigation report is included as *Attachment A*.

The MDHHS investigation makes findings related to *Legionellosis* that includes, among other items: five cases of Legionnaires' disease with health care associated exposure at McLaren Flint Hospital were reported to public health officials in 2018 and 2019; review by the Centers for Disease Control and Prevention (CDC) and MDHHS review of all medical records attached to the case files entered into the Michigan Disease Surveillance System by Genesee County Health Department (GCHD) supports the assertion that these five cases represent Legionnaires' Disease (LD) cases with exposure histories that classify them as possible (4) and/or definite (1) health care association with McLaren Flint Hospital.

As a result of MDHHS's investigation and this report, MDHHS recommended the following non-inclusive steps be taken:

- immediately impose water restrictions for patients (filters or reduction in patient water use) on all areas serviced by the impacted monochloramine unit (F tower, floors 4 and up),

- advise current and recently released patients (as of April 1, 2019) of potential exposure, symptoms of Legionnaires' disease and recommendations to seek immediate care if symptomatic,

- evaluate trends in water quality and testing measures over time, particularly in light of Legionnaires' disease cases, and

- continue to identify and remediate underlying issues (fixtures, systemic) that are the source of the persistent positivity and continuation of associated cases.

MDHHS further recommended a facility evaluation by subject matter experts from the CDC, which would include unfettered access to review records, assess current implementation of the facility water management plan, and to obtain water and biofilm samples from the facility at any locations the CDC deems to be appropriate.

MDHHS anticipated the Facility's good faith cooperation with the recommendations and site evaluation by the CDC team. However, efforts by DLARA to secure the Facility's full cooperation have not been successful. Thus, in light of dangers to current and future patients posed by the *Legionellosis* reviewed in the DHHS investigation and report, and pursuant to the DLARA's authority under the Public Health Code, 1978 PA 368, *et. seq.*, DLARA makes the following findings:

1. The DLARA has the obligation and authority to "[p]rotect the health, safety, and welfare of individuals receiving care and services in or from a health facility . . . [.]" MCL 333.20131(1)(a).
2. The DLARA has the further authority "to control communicable diseases" and can "take immediate action necessary to protect the public health, safety, and welfare of individuals receiving care and services in or from a health facility or agency." MCL 333.20132(2).
3. The Facility has the mandatory obligation to "cooperate with the department in carrying out its responsibility under this article." MCL 333.20151.
4. The Facility has the further mandatory obligation to provide DLARA with "access to books, records, and other documents maintained by a health facility . . . to the extent necessary to carry out the purpose of" Article 17 of the Public Health Code. MCL 333.20155(17).

5. The Facility also "shall endeavor to carry out practices that will further protect the public health and safety, prevent the spread of disease, alleviate pain and disability, and prevent premature death." MCL 333.21521.
6. The Facility further must "assure that the hospital develops and maintains a plan for biohazard detection and handling." MCL 333.21513.
7. The Public Health Code authorizes the DLARA to issue an order concerning a licensee's operations according to the Code's requirements. MCL 333.20162(6).

Considering the foregoing findings, and based on the MDHHS investigation report, it is hereby ordered that:

ORDER

Now therefore, pursuant to the DLARA's foregoing statutory authority and McLaren Flint Hospital's statutory obligations and duties, and in light of the Public Health Code's clear intent that its provisions "be liberally construed for the protection of the health, safety, and welfare of the people of this state." MCL 333.1111, it is hereby ordered that:

1. McLaren Flint shall immediately implement and maintain water restrictions for patients in areas used by health care associated Legionnaires' disease cases, as directed by the Department, including water restrictions on the fifth floor of B/C building. Water restrictions, including those currently in place on all floors of F tower served by monochloramine unit one, will be maintained until MDHHS, in consultation with CDC, states the imminent threat from building water system has been mitigated.
    a. Water Restrictions include:
        i. Restricting showers (using sponge baths instead);
        ii. Avoiding exposure to jetted tubs;
        iii. Installing 0.2-micron biological point-of-use filters on any showerheads or sink/tub faucets intended for use;
            1. Understand and comply with manufacturer's recommendations regarding the temperature, pressure, and chemical levels that filters can withstand and suggested frequency for replacement.
        iv. Provision of an alternate potable water supply for patients;
        v. Any other potential source of patient exposure that are identified during the investigation.

2. McLaren Flint shall immediately notify current patients and all patients discharged since April 21, 2019 of potential exposure to *Legionella* at this facility, symptoms of Legionnaires' disease and recommendations to seek immediate care if symptomatic, using notification templates already provided by MDHHS. McLaren

Flint shall provide the Department written confirmation this has been accomplished by 5:00p.m. on June 14, 2019.

3. McLaren Flint shall provide MDHHS complete test results with raw data for all water tests including, but not limited to, bacteriologic, temperature, pH, monochloramine, chlorine residuals, and free ammonia testing within seven (7) days of testing. Results should be provided for a period not less than twelve (12) months for purpose of public health investigation into the source of *Legionella* exposure in the facility. This twelve-month investigatory period will reset following the diagnosis of a definite health care-associated Legionnaires' disease case or a second possible health care associated case. Data for period April 1 to June 7, 2019 shall be provided by Friday June 14, 2019.

4. McLaren Flint shall perform an evaluation of trends in water quality and testing measures over time, particularly in response to incident Legionnaires' disease cases and also for areas occupied by patients with healthcare associated Legionnaires' disease in the past.

5. McLaren Flint shall continue to identify and remediate underlying issues (fixtures, systemic) that are the source of the persistent positivity and continuation of associated cases.

6. McLaren Flint shall allow MDHHS and cooperating public health agencies such as the CDC to conduct a public health investigation of the health threat. This shall include unfettered access to:
    a. the facility to conduct a risk assessment and test water quality parameters, water and biofilm samples at any locations deem to be appropriate by the Department in the public health investigation.
    b. records and appropriate staff to assess current implementation of the facility's water management plan and enhanced clinical surveillance.

7. McLaren Flint will preserve isolates from all positive *Legionella* results from clinical and environmental testing in accordance with MDHHS and CDC recommendations. Isolates from environmental samples are needed to assess the genetic variability of *Legionella* within the facility's system. All isolates that result from this testing must be promptly shared with MDHHS using shipping method as described in attached "Legionellosis Guidance for Clinicians" from MDHHS.

8. McLaren Flint must provide DHHS with all information requested by the Department related to *Legionella*, its water system, the revision and implementation of its infection control protocols, and the revision and implementation of its water management plan. McLaren Flint shall also promptly comply with all requests for

information related to its investigations, evaluations, and responses to Legionnaires' disease cases.

9. McLaren Flint must carry out the recommendations from the MDHHS, the CDC, and the GCHD to assess and reduce risk of Legionnaires' disease in its facility.

This **ORDER IS EFFECTIVE IMMEDIATELY.**

Conclusion:

1. This *Order* is issued under the authority provided to the DLARA under the Public Health Code including, but not limited to, the statutory provisions cited above.

2. This *Order* does not relieve the McLaren Flint Hospital, its owners, officers, directors, employees and/or agents from any requirement under state or federal laws or regulations governing hospitals or similar health facilities.

3. Nothing in this *Order* shall be construed to limit the Michigan Department of Licensing and Regulatory Affairs' authority, or that of any other state entity or department, to take additional action or issue further orders based upon on-going investigations.

Pursuant to MCL 333.20162(7) and 333.20168, the Facility may request a hearing within 5 days of the issuance of this Order.

This *Order* is made and dated this 12th day of June 2019, in Lansing, Michigan.

Orlene Hawks, Director
Michigan Department of Licensing and Regulatory Affairs

ATTACHMENT A

INTEROFFICE MEMORANDUM

TO: LARRY HORVATH
DIRECTOR, LARA BUREAU OF HEALTH CARE FACILITY LICENSING

FROM: JIM COLLINS
DIRECTOR, MDHHS COMMUNICABLE DISEASE DIVISION

SUBJECT: ONGOING LEGIONELLOSIS INVESTIGATION, MCLAREN FLINT HOSPITAL

DATE: JUNE 10, 2019

CC: SARAH LYON-CALLO, MDHHS BUREAU OF EPIDEMIOLOGY
ROBERT GORDON, MDHHS DIRECTOR
DR. JONEIGH KHALDUN, MDHHS CHIEF MEDICAL EXECUTIVE
ORLENE HAWKS, LARA DIRECTOR
KIM GAEDEKE, LARA DEPUTY DIRECTOR

This memorandum serves as an update on MDHHS engagement with McLaren Flint Hospital regarding cases of Legionnaires' disease associated with the facility, and to clarify our specific asks of the facility given our concerns about ongoing risk.

MDHHS had recommended that McLaren Flint Hospital provide water restrictions in patient areas of floors 4 through 12 of the F Tower and allow the Centers for Disease Control and Prevention (CDC) to conduct an environmental investigation. It is important that McLaren Flint Hospital be cooperative with the site evaluation by this CDC team and that the team be offered unfettered access to review records, assess current implementation of the facility water management plan, and to obtain water and biofilm samples from the facility at any locations they deem to be appropriate. It is also important to re-state that there are public health and safety concerns with low level persistence of *Legionella* bacteria in the McLaren Flint Hospital's water system particularly in the context of continued identification of healthcare associated Legionnaires' disease cases.

MDHHS Legionellosis staff review case referrals and local public health response to reported cases of legionellosis, including Legionnaires' Disease. Records gathered for reported cases in the Michigan Disease Surveillance System are reviewed for timely follow-up, completion and indications of common exposures for cases, including healthcare settings. Responses to identified issues, including investigation into possible healthcare associated cases of Legionnaires' disease, are coordinated with local public

health jurisdiction staff. MDHHS staff look for guidance in evaluation of cases and conduct of investigations from the CDC Legionella program (https://www.cdc.gov/legionella/index.html) and frequently obtain technical assistance from subject matter experts from that program. Standard protocols promulgated by the CDC include assessment for a full investigation of hospitals that have two or more possible healthcare associations, or one or more definite health care associations, within a twelve-month period (https://www.cdc.gov/legionella/health-depts/healthcare-resources/cases-outbreaks.html). Investigation includes implementation of enhanced clinical review of cases, full risk assessment and investigatory water testing, possible water restrictions, and identification/remediation of potential source(s) of exposure.

During 2018 and 2019, five cases of Legionnaires' disease with healthcare associated exposure to McLaren Flint Hospital were reported to public health. CDC and MDHHS staff have reviewed all available medical records attached to the case files in the Michigan Disease Surveillance System by Genesee County Health Department (GCHD) staff. That review supports the assertion that these five cases represent Legionnaires' disease cases with exposure histories that classify them as possible (4) and/or definite (1) healthcare association with McLaren Flint Hospital (see attachment One). Among these five cases with exposure at McLaren Flint, two clinical *Legionella* isolates were recovered from patient specimens. Whole genome sequencing (WGS) on these two clinical isolates demonstrated that they were highly similar to a known cluster of environmental isolates collected at McLaren Flint Hospital during 2016-2019 and four other clinical specimens collected during 2008-2016 from healthcare associated case-patients with exposure to McLaren Flint Hospital. Further, environmental specimens collected in 2019 include one collected from an ice machine that was located near the definite healthcare associated case in 2019. These clinical and environmental specimens were also, genetically, highly similar to each other and the rest of the McLaren Hospital patient and environmental specimens. Overall, this cluster demonstrates not only great similarity within, but also represents a very distinct pool when compared to other Michigan and national isolates.

Resultant from these cases and ongoing concerns with persistent, low level positivity of *Legionella* testing in the hospital water system, MDHHS, CDC, and GCHD have been actively engaged with McLaren Hospital administration and contracted consultants to minimize risk to current and recent patients. The hospital is in process with updating their water management plan, continues to maintain monochloramine secondary water treatment units, has reported to have installed appropriate filters on the fixtures on floors 4-12 of F Building, has imposed limited additional water restrictions while filter installation occurred, and has conducted limited patient notification of current patients and staff.

To protect the public against this threat, MDHHS is specifying that:

1) McLaren Flint Hospital shall immediately implement water restrictions for patients in areas used by health care associated Legionnaires' disease cases, as directed by public health, including water restrictions on the fifth floor of B/C building. Water restrictions, including those currently in place on floors of F tower served by

monochloramine unit one, will be maintained until MDHHS, in consultation with CDC, states the source of exposure has been identified and remediated.

a) Water Restrictions include, but are not limited to:
   i) Restricting showers (using sponge baths instead)
   ii) Avoiding exposure to jetted tubs
   iii) Installing 0.2 micron biological point-of-use filters on any showerheads or sink/tub faucets intended for use
      (1) Understand manufacturer's recommendations regarding the temperature, pressure, and chemical levels that filters can withstand and suggested frequency for replacement
   iv) Provision of an alternate potable water supply for patients
   v) Restrictions around any other potential sources of patient exposure that are identified during the investigation.

2) McLaren Flint Hospital shall immediately notify all current patients and all patients discharged since April 21, 2019, using the templates provided by MDHHS, of potential exposure to *Legionella*, symptoms of Legionnaires' disease and recommendations to seek immediate care if symptomatic.
3) McLaren Flint Hospital will provide MDHHS complete test results with raw data for all water tests including, but not limited to, bacteriologic, temperature, pH, monochloramine, and free ammonia testing within seven (7) days of receipt. Results should be provided for a period not less than twelve (12) months for purpose of public health investigation into the source of Legionella exposure in the facility. This twelve-month investigatory period will reset following the diagnosis of a definite health care-associated Legionnaires' disease case or a second possible health care associated case in a twelve-month period. Data for period April 1 to June 7, 2019 shall be provided by Friday June 14, 2019.
4) McLaren Flint Hospital shall demonstrate evaluation of trends in water quality and testing measures over time, particularly in response to incident Legionnaires' disease cases.
5) McLaren Flint Hospital shall continue to identify and remediate underlying issues (fixtures, systemic) that are the source of the persistent positivity and continuation of associated cases.
6) McLaren Flint Hospital shall allow MDHHS, GCHD, and the CDC to conduct a public health investigation of the health threat. This shall include unfettered access to:
   a) the facility to conduct a risk assessment and test water quality parameters, water and biofilm samples at any locations deemed to be appropriate by the Department in the public health investigation.
   b) records and appropriate staff to assess current implementation of the facility water management plan and enhanced clinical surveillance.
7) McLaren Flint Hospital will preserve isolates from all positive Legionella results from clinical and environmental testing in accordance with MDHHS, GCHD and CDC recommendations. Isolates from environmental samples are needed to assess the genetic variability of *Legionella* within the hospital system. All isolates that result from this testing must be shared with MDHHS using shipping method as described in attached "Legionellosis Guidance for Clinicians" from MDHHS.

8) McLaren Flint Hospital must cooperate with all requests for information from the Department related to Legionella, its water system, the revision and implementation of its infection control protocols, and the revision and implementation of its water management plan. McLaren Flint shall also comply with all requests for information related to its investigations, evaluations, and responses to Legionnaires' disease cases.
9) McLaren Flint Hospital must cooperate with recommendations from public health to assess and reduce risk of Legionnaires' disease.

Attachment One: Case Summaries

Case 1:

The first case involved an exposure history that included an inpatient stay at the hospital between December 11-16, 2017. The Genesee County Health Department (GCHD) reported an onset of symptoms on 1/2/2018, The patient was re-admitted to McLaren Flint on January 8, 2018 and transferred to another hospital on January 12, 2018.

In April 2018, the results of whole genome sequencing of the patient's clinical *Legionella* isolate and environmental *Legionella* isolates from the hospital demonstrated that the two bacteria were highly related. This analysis was requested by GCHD.

Case 2:

The second case was admitted to McLaren Flint on November 5, 2018 for an elective procedure (bariatric surgery). Onset of Legionnaire's disease symptoms was identified 72 hours following admission on November 8, 2018 when the patient was transferred to ICU for respiratory failure and tested positive by urine antigen test for *Legionella*. On November 14, the patient died. The patient's onset of pneumonia was >48 hours after admission, meeting the Infectious Diseases Society of America criteria for a clinical case of "hospital-acquired pneumonia". An episode of pneumonia not associated with mechanical ventilation that develops 48 hours or more after admission and did not appear to be incubating at the time of admission (https://www.idsociety.org/practice-guideline/hap_vap/).

Case 3:

The third case was initially hospitalized at McLaren Flint from November 12, 2018 to November 25, 2018, discharged to a skilled nursing facility (11/25/2018- to 12/2/2018) and readmitted to McLaren Hospital with pneumonia on December 7, 2018. Urine antigen test collected on 12/12/2018 was reported to public health as positive on 12/13/2018. GCHD recorded an onset date of December 5, 2018.

On February 5, 2019, GCHD indicated that this is not a case of legionellosis, contrary to the classification of possible healthcare associated Legionnaires' disease supported by the CDC.

Case 4:

The fourth health care associated case includes an inpatient stay during the entirety of the patient's 10-day incubation period, meeting the case classification of "Definite Health Care Association". The patient onset

date was determined to be May 1, 2019. Prior to that onset date, this patient was admitted to McLaren Hospital as an in-patient on April 21, 2019 and did not leave before Legionnaires' disease onset. Onset date was determined through careful review of medical records that indicated patient status based on patient vitals, blood chemistry and radiologic information. The results of whole genome sequencing of this patient's clinical *Legionella* isolate demonstrated that the bacteria isolated from this case were highly related to previous environmental isolates from McLaren Hospital as well as clinical isolates from other patients with an exposure history that included McLaren Hospital.

Case 5:

The fifth health care associated case was admitted to McLaren Flint on May 31st, 2019 for difficulty breathing and confusion. This was this patient's 3rd admission to McLaren Flint in less than a month. As a resident of Heritage Manor skilled nursing facility since this patient experienced in stroke in early April 2019 and was initially transferred to McLaren Flint on May 15, 2019 following a seizure. The patient was discharged back to Heritage Manor on May 22, 2019 but readmitted to McLaren Flint less than 24 hours later following another seizure event. The patient was discharged back to Heritage Manor on May 29th. Upon readmission on May 31st, the patient was tested for Legionnaires' disease with a urinary antigen test and collection of sputum for culture while still in the Emergency Room. The urinary antigen test result came back positive early on June 1st. As part of patient work-up, the patient was found to have increased pleural effusions and a worsening pericardial effusion. Based on limited records received to date, the plan was to take the patient for a pericardial window procedure to help drain the pericardial effusion on May 5th, however the patient passed away on May 4th. When GCHD contacted McLaren on May 3rd to request records, they were informed that there had been "none since admission" other than some nursing progress notes that were shared. On June 6th, GCHD received some limited additional information, including lab results, radiographic information, a cardiology consult note from June 3rd and pulmonary consult note from June 4th noting that ID was evaluating the positive Legionella urinary antigen test result.

** Unlike documentation available from McLaren Flint Hospital around previous cases, there are currently no records of treatment for Legionnaires' disease. However, GCHD has requested and is still awaiting further medical records to better understand the patient's clinical course including the events leading up to the patient's death on June 4th. Based on GCHD's tentative onset determination of May 23rd, the patient would have spent 8 of the 10 days prior to onset at McLaren Flint.