STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

GRETCHEN WHITMER
GOVERNOR

ROBERT GORDON
DIRECTOR

ORDER REQUIRING MCLAREN REGIONAL MEDICAL CENTER IN FLINT TO CORRECT CONDITIONS

The Michigan Department of Health and Human Services (the "Department" or "MDHHS") has a duty "to prevent the spread of diseases and the existence of sources of contamination." MCL 333.2226. Further, "[t]o assure compliance with laws enforced by the department, the department may inspect, investigate... any matter, thing, premises, place, person, record, vehicle, incident, or event." MCL 333.2241. And, the Department may issue an order to "correct, at the owner's expense, a building or condition which violates health laws or which the local health officer or director reasonably believes to be a nuisance, unsanitary condition, or cause of illness." MCL 333.2455. The Department also has authority to order the correction of conditions posing an imminent danger to the public health. MCL 333.2251.

McLaren Regional Medical Center in Flint ("McLaren Flint") has been the subject of Legionnaires' disease outbreak investigations due to having health-care associated cases of Legionnaires' disease in multiple years, including 2014 and 2015 (52 cases), 2016 (2 cases), 2017 (1 case), 2018 (3 cases) and 2019 (2 cases to date). In 2018 and 2019 alone, five cases of Legionnaires' disease were identified as having health care associated exposure as an inpatient to McLaren Flint. One of these cases is a definite health care associated case, as the individual spent ten days at the facility during their disease incubation period. Two of the five health care

associated cases have died. In comparison, during this two-year period, no other hospital in the state has had more than three cases with in-patient exposure. Despite best efforts, the Department has been unable to obtain satisfactory assistance from McLaren Flint in investigating the continued occurrence of cases.

The Department has attempted to work with McLaren Flint to assure that all appropriate steps are being taken to protect the health, safety and welfare of patients, staff and visitors within the health facility. McLaren Flint has a duty to cooperate with this Department in matters affecting the public health. MCL 333.2231(1). McLaren Flint also has an obligation to carry out practices to prevent the spread of diseases. MCL 333.21521. But the history of Legionnaires' disease cases in this facility, coupled with McLaren Flint's resistance to the Department's public health assurance efforts, leave concerns about McLaren Flint's practices and patient health at the hospital. The Department may assure compliance with laws enforced by the Department, and may inspect, investigate, or authorize an inspection or investigation to be made of any matter, thing, premises, place, person, record, vehicle, incident, or event. MCL 333.2241(1). This Order is issued because the Department has sought assurance of legal compliance from McLaren Flint but not received it, and because the Director has determined a nuisance, unsanitary condition, and a possible cause of illness rising to the level of an imminent danger to the public health exist in this facility.

The facts giving rise to the issuance of this Order are as follows:

1. McLaren Flint was the subject of Legionnaires' disease outbreak investigations for 2014, 2015, and 2016. Concerns flowing from those investigations led the Department to issue a correction order on February 14, 2017. While there was disagreement between the Department and McLaren Flint regarding the issuance of that order, that disagreement was resolved through a collaboration agreement between the parties that took effect on May 17, 2017.

2. By its terms, the collaboration agreement expired on December 31, 2017.

3. Following expiration of the collaboration agreement, the Department issued a Close-out Report on July 11, 2018, through which the Department evaluated McLaren Flint's compliance with the agreement. The Department also articulated concerns about McLaren Flint's implementation of its water management plan and offered recommendations for public health assurance improvements.

4. During 2018, three patients at McLaren Flint experienced conditions the Department believes to be Legionnaires' Disease with a possible association with their stays in McLaren Flint. As McLaren Flint is aware based on its participation in discussions with the Department and the Centers for Disease Control and Prevention ("CDC"), the CDC agrees with the Department's determinations in this regard. Nonetheless, McLaren Flint has disputed the factual determinations related to all three of these patients. McLaren Flint has declined to fully implement recommendations made by both the CDC and the Department on

how to investigate suspected cases in the future, and on the steps to be taken regarding the water system to better assure public health.

5. During 2018, McLaren Flint also failed to provide timely and complete documentation or information about its corrective actions to address problems (reflected in testing data) arising in its implementation of its water management plan.

6. As McLaren Flint provided poorly scanned testing data, the Department enlisted the assistance of the Michigan Department of Licensing and Regulatory Affairs ("LARA") in early 2019 to facilitate the receipt of water system testing data. On February 11, 2019, McLaren Flint provided LARA water system testing data from November 1, 2018 through February 7, 2019. The Department also asked LARA to secure documentation describing McLaren Flint's process for corrective measures arising from the data, such as Water Management Team meeting minutes and Corrective Action reports described in McLaren Flint's Water Management Plan, McLaren Flint did not supply documentation.

7. A review of the testing data from July of 2018 through February 7, 2019, showed anomalies in the provided data that included evidence of Legionella bacteria in water in patient areas and monochloramine measurements that often fell outside control limits. Because of these continuing anomalies, the Department requested a collaborative agreement through which McLaren Flint would send information directly to the Department. Despite several lengthy communications, efforts to come to such an agreement were not successful.

8. On April 5, 2019, I sent McLaren Flint's Chief Executive Officer a letter requiring McLaren Flint to provide the Department specified documentation needed for public health assurance purposes. A deadline for providing this material was set for April 10, 2019.

9. On April 10, 2019, Chad Grant, McLaren Flint's Chief Executive Officer, responded to my letter making various commitments. This letter objected to MDHHS attention to cases associated with McLaren Flint and stated that attention focused exclusively on McLaren Flint biases resulting data against McLaren Flint. McLaren Flint agreed to provide the revised edition of its water management plan when it is completed. Mr. Grant's April 10, 2019 letter also agreed to make corrective action logs available to MDHHS or the Genesee County Health Department ("GCHD") only after a public health investigation of Legionellosis conducted in accordance with MDHHS's "Legionellosis Surveillance and Investigation Protocol", limiting conditions for public health investigation. Not accepting my request that it provide water system parameter testing data on a routine ongoing basis, McLaren Flint only agreed to provide data for water testing for February and March 2019 only, which Julie Borowski provided under a separate cover on April 10, 2019. In the cover letter to these data, Ms Borowski stated that their expert consultant, Dr. David Krause, felt that overall the data "reflects a water management program that is actively managing the supplemental treatment of its higher risk systems and responding to varying conditions and validation sample results in a rapid, conservative, and effective manner. Sporadic detection of

low Legionella concentrations does not indicate amplification, nor does it correlate with risk of disease." CDC has documented the importance of maintaining a high index of suspicion for healthcare-associated LD, even in the setting of a long-term disinfection program (Demirjian A, Lucas CE, Garrison LE, et al. *Clin Infect Dis.* 2015; 60:1596–602).

11. Meanwhile, during 2019, two more Legionnaires' disease cases with association to McLaren Flint have been reported. This means that, during 2018 and 2019, five cases of Legionnaires' disease were identified as having health care associated exposure as an inpatient to McLaren Flint. One of these cases is a definite health care associated case, as the individual spent ten days at the facility during their disease incubation period. Two of the five health care associated cases have died. In comparison, during this two-year period, no other hospital in the state has had more than three in-patient cases with this exposure.

12. Two of the 2018 and 2019 cases had *Legionella* bacteria from their lungs available for genetic testing, including the 2019 definite health care associated case. These cases with exposure to McLaren Flint during the incubation period are highly similar genetically to environmental samples taken from water in McLaren Flint between 2016 and 2019, from both hot and cold-water systems. These *Legionella* are also highly genetically similar to *Legionella* from four other patients with health care associated exposure to McLaren Flint from 2008, 2015 (2 cases) and 2016.

13. On May 10, 2019, MDHHS recommended to McLaren Flint that, due to the definite health care associated case of Legionnaires' disease, immediate water restrictions were needed in F Building, as well as notification of risk to current patients and patients discharged from impacted areas of the facility since April 21, 2019. Ms Borowski shared a patient notification on May 10, 2019 that did not adequately notify patients to the potential *Legionella* exposure at McLaren Flint. MDHHS has provided suggestions and templates for patient notification that have been disregarded by McLaren Flint.

14. On May 10, 2019, McLaren Flint also stated that it would not be able to pull a report of past discharged patients and begin mailing notices until the following Monday. MDHHS issued a press release on May 10, 2019, disclosing to the public that MDHHS is investigating a case of Legionnaires' disease in a patient at McLaren Flint and alerting people to signs and symptoms of the disease and that people with pneumonia should be tested for Legionnaires' disease if they were recently hospitalized. On Wednesday, May 15, 2019, Ms Borowski informed MDHHS that McLaren Flint would not be restricting water usage or sending notification to previously discharged patients at this time, as no *Legionella* was detected in water from locations where that recent patient had stayed, and they felt the MDHHS press release advised the public of ongoing issues with Flint water.

15. In a June 5, 2019 email to LARA, Chad Grant, McLaren Flint CEO said he welcomed the involvement of CDC but then attempted to set conditions for a public health investigation. McLaren Flint requested that the visit occur during

normal business days, limiting the time of the investigation to three days. They also required that CDC or MDHHS provide a written report to McLaren Flint within 30 days of the completion of the site visit. CDC will provide a report to MDHHS once the work is completed and cleared review. McLaren Flint also attempted to restrict the use of the information obtained as part of this visit. McLaren Flint also tried to set conditions regarding MDHHS ability to inform the public about this visit or the findings from this visit.

McLaren Flint's approach to this CDC site visit is consistent with its past efforts to restrict the public health assurance activities generally, and the CDC specifically. During a CDC and GCHD site visit on August 25-26 of 2016, McLaren Flint also placed time and location restrictions on CDC's ability to investigate a health care associated case in that facility. CDC was advised of these restrictions in a letter from Cline, Cline and Griffin on August 25, 2016. Although CDC and GCHD staff were given one day to take samples from areas where the patient had stayed, the agencies were only able to conduct a limited environmental assessment of other areas of the McLaren Flint facility and could therefore only collect a few representative points to describe the water management system. If additional time had been available, CDC and GCHD would have expanded the environmental assessment to include additional control points and inspection of all cooling towers, decorative fountains, whirlpool therapy spas, and ice machines, which is usual investigation practice.

16. Rooms, drinking fountains, and ice machines in McLaren Flint have continued to test positive for *Legionella* on multiple occasions. McLaren Flint has stated these levels of positivity are to be expected, but repeated positive tests in water systems serving patients who later became sick with Legionnaires' disease is an indicator of health risk.

On these grounds, I reasonably believe McLaren Flint's water system is a nuisance, in an unsanitary condition, and a possible source of illness rising to the level of being an imminent danger. Acting on this reasonable belief, I, under the authority granted by sections 2241, 2251 and 2455 of the Public Health Code, order McLaren Flint to comply with the following:

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 Department, the CDC, and the GCHD to assess and reduce risk of Legionnaires' disease in its facility.

This **ORDER IS EFFECTIVE IMMEDIATELY.**

Date: June 12, 2019

Robert Gordon, Director
Michigan Department of Health and Human Services