Notice of Statewide Surveillance for COVID-19/SARS CoV-2 under the Minnesota Communicable Disease Rule (4605.7080)

Section: COVID-19 Epidemiology Section

Under part 4605.7080 of the Communicable Disease Reporting Rule, the Commissioner of Health ("commissioner") shall select new or emerging diseases/syndromes for reporting if certain criteria are met. Specifically, 4605.7080 says:

> "Subpart 1. Disease selection. The commissioner shall, by public notice, require reporting of newly recognized or emerging diseases and syndromes suspected to be of infectious origin or previously controlled or eradicated infectious diseases if:
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> A. the disease or syndrome can cause serious morbidity or mortality; and
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> B. report of the disease or syndrome is necessary to monitor, prevent, or control the disease or syndrome to protect public health.
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> Subp. 2. Surveillance mechanism. The commissioner shall describe a specific, planned mechanism for surveillance of the disease or syndrome including persons and entities required to report, a time frame for reporting, and protocols for the submission of test results and clinical materials from cases and suspected cases to the Minnesota Department of Health, Public Health Laboratory."

I. DISEASE SELECTION

The commissioner shall, by public notice, require reporting of newly recognized or emerging diseases and syndromes suspected to be of infectious origin or previously controlled or eradicated infectious diseases if:

A. The disease is newly recognized or emerging

Based on the following information, the Commissioner of Health finds that COVID-19 is a newly recognized or emerging infectious disease.

COVID-19 is an infectious disease caused by the SARS-CoV-2 virus. An emerging infectious disease is one that is newly recognized, newly introduced, newly evolved, or that is increasing in incidence or geographic range. COVID-19 was first identified in China in late 2019, with the first U.S. case identified in January 2020 and the first Minnesota case identified in March 2020. Since its identification, the SARS-CoV-2 virus has caused distinct waves of disease in Minnesota and globally and has shown the ability to evolve rapidly. The World Health Organization has named five variants of concern to date, with some of these variants resulting in subvariants. Variants have had different characteristics including in transmissibility, virulence of disease, and in clinical presentation. Variants may also show (and have shown) the ability to evade vaccine immunity, infection-induced immunity, and certain treatments. Each new variant of

concern, to some extent, constitutes a newly emerging infectious disease due to its own defining set of characteristics.

Variants of concern have caused temporal but significant increases in disease incidence in Minnesota. An example is the recent wave that began in December 2021 caused by the highly transmissible Omicron variant. Since the week of December 26, 2021, the majority of SARS-CoV-2 case specimens that could be sequenced in Minnesota have been Omicron. Over 400,000 cases were identified in Minnesota from that week through February 2022, representing approximately 26% of all cases in the pandemic.

While much has been learned, COVID-19 remains a new disease epidemiologically, and knowledge is evolving and must continue to evolve in order to understand each new SARS-CoV-2 variant. Because of the short time since its initial recognition; the continuing, rapid, and unpredictable changes in the virus; continued evolution of scientific and epidemiologic knowledge; and significant (though periodic) increases in case incidence due to variants and subvariants, COVID-19 continues to be an emerging infectious disease.

B. The disease or syndrome can cause serious morbidity or mortality

Based on the following information, the Commissioner of Health finds that COVID-19 can cause serious morbidity or mortality.

Most people with COVID-19 suffer mild to moderate illness. However, the highly consequential toll due to serious illness and death from COVID-19 has been experienced in Minnesota and worldwide. COVID-19 has a well-documented spectrum of illness and can cause serious morbidity resulting in hospitalization including the need for ICU care. It can result in death, especially in people over 65 years and those with often common medical conditions (e.g., obesity) that place them at higher risk for severe disease. Since January 2020, the U.S. has had more than 96 million COVID-19 cases and more than 1 million deaths. Minnesota has had over 1.6 million cases and more than 13,000 deaths. More than 73,000 Minnesota cases have been hospitalized, with over 12,000 spending time in a hospital ICU.

COVID-19 can result in post-COVID conditions known as “long COVID.” Though we still are learning how often long COVID occurs and the duration of symptoms, studies show that 10-30% or more of people who have had COVID-19 have symptoms for months, a year, or longer after their initial infection. Long COVID symptoms can range from mild to debilitating.

COVID-19 can also cause severe illness in children. After a COVID-19 infection, some children develop multisystem inflammatory syndrome (MIS-C), a rare but serious condition. Children with MIS-C suffer inflammation, which can occur in the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. Children and teens under age 18 who have had COVID-19 are up to 2.5 times more likely to be newly diagnosed with diabetes a month or more after infection.

Multiple studies have shown adverse pregnancy outcomes associated with a SARS-CoV-2 infection in the pregnant person. SARS-Cov-2 infection increases the likelihood of the infant being born preterm (earlier than 37 weeks). CDC has identified an increase in

stillbirth since COVID started, especially while Delta was the dominant variant. In Minnesota, the number of stillbirths occurring among people who had had a COVID-19 infection during pregnancy almost tripled between 2020 and 2021. Additional work is needed to understand whether this increase was driven by COVID-19 infections during the Delta period or some other reason.

The longer-term effects of COVID-19 in both adults and children can occur even if a person's acute COVID-19 disease was mild or moderate. Therefore, serious morbidity cannot be defined solely by the severity of the illness a person experiences during the infectious period.

With the advent of pharmaceutical interventions (e.g., vaccination, out-patient and in-patient treatment) to combat the severe effects of COVID-19, a newer set of factors will affect morbidity and mortality. These factors include the percent of the population that is up to date on vaccination, the efficacy of vaccines in preventing severe illness and death from the circulating variant, waning vaccine immunity, the durability of infection-induced immunity, and the effectiveness and availability of treatment for the variant. The characteristics of variants will continue to play a critical role.

C. Report of the disease or syndrome is necessary to monitor, prevent, or control disease or syndrome to protect public health

Based on the following information, the Commissioner of Health finds that reporting of COVID-19 cases is necessary to monitor, prevent, and control the disease to protect the public's health.

On March 3, 2020, the Commissioner issued a notification letter pursuant to her authority under Minn. Rules 4605.7050 requiring all mandated reporters to report any cases, suspected cases, carriers, and deaths due to SARS-CoV-2 to MDH within one working day. The letter also required medical laboratories to submit test results and clinical materials upon request.

The federal Coronavirus Aid, Relief, and Economic Security (CARES) Act, which became law in March 2020, contains additional reporting requirements for laboratories. Under the CARES Act, "[e]very laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" is required to report the results from each test to the U.S. Department of Health and Human Services (HHS). Laboratories are entities that conduct SARS-CoV-2 testing under a Clinical Laboratory Improvement Amendments (CLIA) certificate or certificate of waiver, which range from sophisticated laboratories in medical environments to settings exclusively authorized to perform simple tests that do not require specialized equipment or expertise (e.g., rapid antigen testing by staff at schools, correctional facilities, or long-term care facilities) HHS has published regular guidance defining federal reporting requirements for each setting and test type, the current version of which is available at COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 (www.cdc.gov/coronavirus/2019-ncov/downloads/lab/HHS-Laboratory-Reporting-Guidance-508.pdf).

From the start of the pandemic, the data from mandated reporting of COVID-19 infections have been at the heart of the public health response across the United States and in Minnesota. These data are necessary to monitor, prevent, and control disease. The data have allowed for the characterization of the epidemiology of COVID-19 including identifying groups at highest risk of severe outcomes (characteristics of people hospitalized, admitted to the ICU, and deaths) and understanding the circumstances under which SARS-CoV-2 is more likely to spread. Knowledge of the epidemiology of COVID-19 has in turn informed public heath recommendations for the general population and for specific settings, such as long-term care facilities, schools, childcare, shelters, and correctional facilities. Reporting has also allowed for the identification and rapid initiation of public health interventions to contain outbreaks in specific settings and prevent further spread. The data also helped inform the initial prioritization of vaccine administration and eligibility for treatment. Data from mandated reporting made clear racial and ethnic disparities in morbidity and mortality from COVID-19, emphasizing the critical need to ensure resources for harder hit groups. The data have also been critical in monitoring fluctuations in disease transmission across the state so that Minnesotans know when to exercise caution. Further, disease reporting allowed for case interviews and notification of contacts, and for recommendations for isolation and quarantine to limit spread.

The nature of the pandemic is changing with vaccinations, effective treatments, and increased infection-induced immunity. However, the emergence of new variants of SARS-CoV-2 illustrates the critical need for disease reporting to quickly identify changes in the epidemiology of COVID-19 including changes in vaccine and treatment efficacy. Data from disease reporting are also critical to identifying changes in groups at high risk, disease severity, and transmissibility. In addition, data are important for monitoring the durability of vaccine and infection-induced immunity. Further, reporting helps MDH to identify outbreaks or clusters so that appropriate intervention measures can be quickly implemented. COVID-19 has disproportionately impacted specific populations beyond health-associated risk factors such as chronic conditions and age. COVID-19 has resulted in disproportionate morbidity and mortality among historically disadvantaged communities including the American Indian, Black, Hispanic, and Asian and Pacific Islander communities. Programs were put into place during the pandemic to help mitigate this disproportionate impact, but continued data monitoring is necessary to assess the effect of COVID-19 on these populations.

With the changes in the pandemic, MDH has determined that changes in disease reporting are appropriate. We will continue to require case-based reporting from health care providers to monitor the epidemiology of COVID-19 in the state. However, we are simplifying COVID-19 reporting requirements for community settings such as Pre-K through Grade 12 schools and child care programs. The reporting required for these settings will largely shift to focus on aggregate reporting of cases. The Commissioner will request more detailed information from community settings on individual cases when needed to prevent and control disease. The simplified reporting will still allow for identification of epidemiologic changes, monitoring trends, identification of outbreaks, and prompt intervention to help stop disease transmission in these settings. As required

by Minn. Rules 4605.7080, the surveillance mechanism for each category of reporter is provided below.

II. SURVEILLANCE MECHANISM

The commissioner shall describe a specific, planned mechanism for surveillance of the disease or syndrome including persons and entities required to report, a time frame for reporting, and protocols for the submission of test results and clinical materials from cases and suspected cases to the Minnesota Department of Health, Public Health Laboratory.

A. Overview

MDH is continuing the current case-based reporting[1] for SARS-CoV-2 infections/COVID-19 by health care practitioners, health care facilities, and all other licensed health care providers (the persons and entities required to report under 4605.7030 of the Communicable Disease Reporting Rule, hereafter "state reporting rule").[2] The mechanism for surveillance for these reporters is described in Section II.C.4.a. below.

Medical laboratories[3] must continue to report test results for SARS-CoV-2 infection in accordance with federal and state requirements and, upon request of MDH, to submit clinical materials for reported cases to the MDH Public Health Laboratory.[4] The mechanism for surveillance for medical laboratories under the state reporting rule is described in Section II.C.4.b. below. In section II.B. below, we also reference the federal requirements for laboratory reporting for SARS-CoV-2 infections since laboratories must meet both federal and state reporting requirements.

The significant change in this notice is for reporting of SARS-CoV-2 infection/COVID-19 by community settings. MDH is shifting from individual case-based reporting to aggregate (case count) reporting for SARS-CoV-2 infection/COVID-19 for most of these settings. MDH will request more detailed information (person-level information) on cases in community settings when needed to prevent and control disease, including for characterization of the epidemiology of new variants of SARS-CoV-2. When entities in these settings conduct point of care (POC) testing under a CLIA certificate or certificate of waiver, they must continue to report individual test results per the federal HHS guidelines. The surveillance mechanisms for these settings are described in Sections D-H below as follows (all settings should refer to Section II.B. for federal reporting

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[1] On March 3, 2020, the Commissioner of Health required reporters to initiate case-based reporting of COVID-19 under the authority of Minn. Rules 4605.7050. In issuing this notice, MDH is requiring health care reporters to continue case-based reporting but now under the authority of Minn. Rules 4605.7080.

[2] MDH is citing Minn. Rules 4605.7030 in order to reference the reporters described in that section of the rule. These same health care reporters are required to report COVID-19 in accordance with Section II.C.4.a. of this notice. MDH is also incorporating into this notice the definitions of these reporters in Minn. Rules 4605.7000.

[3] "Medical laboratory" in this notice is defined in Minn. Rules 4605.7000.

[4] Medical laboratories are required to report SARS-CoV-2 test results in accordance with CARE Act/HHS requirements. In addition, they have been required to submit clinical materials for cases to the MDH Public Health Laboratory upon request of the Commissioner of Health under the authority of Minn. Rules 4605.7050 pursuant to the Commissioner's letter of March 3, 2020. These reporting requirements are continuing under this notice but now the requirement to submit clinical materials upon request is under the authority of Minn. Rules 4605.7080.

requirements when they conduct POC testing under a CLIA certificate or certificate of waiver):

- SECTION D: Long-term care facilities including skilled nursing facilities, assisted living facilities, DHS- licensed residential facilities
- SECTION E: Pre-K through grade 12 schools, certified child care centers, licensed child care centers, and licensed family child care
- SECTION F: Institutions of higher education
- SECTION G: Correctional facilities
- SECTION H: Shelters and other high-risk congregate living settings serving people with temporary or transitional housing needs

B. Federal reporting requirements for laboratories (entities conducting SARS-cov-2 testing under a CLIA waiver or certificate of waiver)

The federal CARES Act establishes minimum requirements for laboratories to report SARS-CoV-2 test results. These requirements apply to entities conducting testing under a CLIA certificate or certificate of waiver. The current federal requirements are set forth in federal HHS guidance available at COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 (www.cdc.gov/coronavirus/2019-ncov/downloads/lab/hhs-laboratory-reporting-guidance-508.pdf). In addition, MDH has resources on the federal reporting requirements which include specifications for methods of submission to MDH at COVID-19 Test Reporting Requirements (www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html). These federal reporting requirements are separate from and in addition to reporting requirements under the state's reporting rule.

The HHS guidance makes clear that federal laboratory reporting requirements do not prohibit or limit state health departments from requesting or requiring additional SARS-CoV-2 test result and/or data element reporting. Though the state reporting rule authorizes MDH to set requirements for medical laboratory reporting for SARS-CoV-2, we have determined that HHS requirements (including the requirement that results are reported directly to MDH) fulfill our needs for laboratory reporting of results at the present time with two exceptions. The exceptions are (1) requirements to submit clinical materials to the MDH Public Health Laboratory upon request and (2) requirements to report results of SARS-CoV-2 genomic sequencing. These two exceptions are discussed in section II.C.4.b. below. Entities conducting POC testing under a CLIA certificate of waiver are not required to submit clinical specimens or to report results of genomic sequencing.

If reporting requirements under the federal CARES Act are repealed or modified, MDH will communicate with entities conducting tests for SARS-CoV-2 about any changes in their reporting requirements under the state reporting rule.

C. Health care practitioners, health care facilities, medical laboratories, and other reporters enumerated in Minn. Rules 4605.7030.

1. **Disease or syndrome**

   This notification describes reporting requirements for SARS-COV-2 infection/COVID-19 as evidenced by a positive viral test. Viral tests include nucleic acid amplification tests (NAATs) and antigen tests.

2. **Reporting entities**

   The entities required to report are listed in Minn. Rules 4605.7030. These reporters include health care practitioners,[5] health care facilities, medical laboratories, and every other licensed health care provider who provides care to any patient who has COVID-19.[6]

   Health care facilities such as hospitals and clinics must either designate that individual health care practitioners report under this notice or the facility can designate an infection preventionist or other staff to report to MDH for the individual practitioners at the facility.

3. **Reporting time frame**

   Unless otherwise specified in the protocols for submission below, the time frame is as follows:

   - Reporters must submit case reports within one working day of receiving a positive result of a viral test for SARS-CoV-2 or of knowledge of a death.
   - Hospitals must submit reports on hospital admissions (including the associated events of transfer to/discharge from the ICU and death in the hospital) as soon as possible, but no later than three working days after admission, ICU transfer, ICU discharge, and within one working day of death.

4. **Protocol for submission**

   a. **Health care practitioners, health care facilities, and other licensed health care providers**: There is no change in current reporting[7] for these reporters under this notice. When attending a case of or death from COVID-19, reporters are required to submit a report to MDH by electronic transmission or fax. Reporters should use the report form that corresponds to the method of submission.[8]

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[5] Health care practitioners include medical examiners and coroners.

[6] The definitions for these reporters and reporting entities are in Minn. Rules 4605.7000.

[7] On March 3, 2020, the Commissioner of Health required reporters to initiate case-based reporting of COVID-19 under the authority of Minn. Rules 4605.7050. In issuing this notice, MDH is requiring health care reporters to continue case-based reporting but now under the authority of Minn. Rules 4605.7080.

[8] There are multiple ways to submit a case or death report: to fax a report, reporters should use the form located at COVID-19 Case Report Form (www.health.state.mn.us/diseases/coronavirus/hcp/covidreportform.pdf); to submit an individual report electronically, reporters should go to COVID-19 Patient Reporting Form (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=9XMX7WKRTM); and to upload a spreadsheet for submitting reports, reporters should go to COVID-19 Provider Portal (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=J3AH4M7W7D) .

Hospitals are required to submit reports on hospitalizations.[9] They are required to submit reports on patients who had a positive viral test for SARS-CoV-2 when the test occurred in the 14 days prior to admission or during their hospital stay.

- The report form for hospitalized cases is located at the COVID-19 Provider Portal (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=J3AH4M7W7D) and can be submitted through the REDCap platform, direct electronic transmission, or fax.
- Reporters can use the report form or another format that provides MDH the same data elements.
- Hospitalization reports must be updated to reflect the following changes for a previously reported patient: transfer to the ICU, discharge from the ICU, and death in accordance with the reporting timeframes specified above.
- There are exclusions pertaining to reporting of hospitalizations. The current exclusions are for patients who are: admitted to the hospital for observation for less than 24 hours; seen in the emergency room or urgent care only (not admitted); or not a Minnesota resident.

Each reporting health care provider or facility, upon request of the Commissioner, must provide access to additional information on cases from all medical, pathological, and other pertinent records including information related to COVID-19 diagnosis, treatment, severity of disease, outcome (which may include outcome of pregnancy and infant follow-up information) and follow-up per Minn. Rules 4605.7090. MDH epidemiologists review patient medical records using a standardized case report form to collect basic demographic information, risk factors, and other pertinent information of epidemiologic or infection prevention concern.

b. Medical laboratories

There is no change in current reporting requirements[10] for medical laboratories under this notice. Medical laboratories are required to:

- Meet their reporting requirements under the federal CARES Act as referenced in section II.B. of this notice.

[9] The reporting of hospitalizations referred to in this notice is case-based reporting of hospitalized patients who have tested positive for SARS-CoV-2. This notice does not address or affect the separate reporting requirements for hospitals to submit data through MNTrac for TeleTracking and bed information purposes. Hospitals are currently required to perform both types of reporting (case reporting and MNTrac reporting).

[10] Medical laboratories are required to continue their reporting under the CARES Act/HHS guidelines. They are also required to continue to submit clinical materials for cases upon the Commissioner's request. In issuing this notice, MDH is relying on its authority under Minn. Rules. 4605.7080 instead of Minn. Rules 4605.7050, which was the basis for the Commissioner's letter requiring submission of clinical materials on March 3, 2020.

- Submit to the MDH Public Health Laboratory the results of genomic testing on SARS-Cov-2 specimens.[11] Medical laboratories with the capability to identify the lineage of SARS-CoV-2 specimens must submit all such test results (variant lineage number) to MDH through the test results submission methods specified at COVID-19 Test Reporting Requirements - Minnesota Dept. of Health (state.mn.us). If a medical laboratory has test results that identify the actual genomic sequence for a SARS-CoV-2 specimen, the laboratory must submit the actual sequence to the MDH Public Health Laboratory upon request. Laboratories must submit the actual sequence in an electronic format by a means that is feasible for both the submitting laboratory and the MDH Public Health Laboratory. For both reports of lineage number and actual sequence, medical laboratories must also include as much disease report information as is known, as provided for in Minn. Rules 4605.4090.
- Upon request of the Commissioner, submit clinical materials for reported cases of SARS-CoV-2/COVID-19 to the MDH Public Health Laboratory. The term "clinical materials" is defined in Minn. Rules 4605.7000, subpart 3.

c. Other reporting

Nothing in this notice affects the operation of any other provisions of the reporting rule.[12]

D. Long-term care facilities including skilled nursing facilities, assisted living facilities and other MDH-licensed residential facilities, and DHS-licensed residential facilities

1. Disease or syndrome

This notification describes reporting for SARS-CoV-2 infection/COVID-19 as evidenced by a positive viral test. Viral tests include nucleic acid amplification tests (NAATs) and antigen tests.

2. Reporting entities

Skilled nursing facilities, assisted living facilities and other MDH-licensed residential facilities, and DHS-licensed residential facilities.

3. Reporting time frame

[11] The HHS guidance states that requirements to report results of SARS-CoV-2 genomic sequencing are outside the scope of the federal mandate. Further, the HHS guidance notes that timelines and processes for reporting lineages determined through viral genomic sequencing to state health departments should be established in accordance with state laws.

[12] Provisions of the state reporting rule that may be of particular relevance to SARS-CoV-2/COVID-19 include Minn. Rule 4605.7050, Subp. 2 (requiring reporting of an unexplained death or critical illness in a previously healthy individual that may be caused by an infectious agent by the attending health care practitioner, medical examiner or coroner, or by the person having knowledge about the death or illness), and Minn. Rule 4605. 7030, Subp. 5 (requiring reporting by veterinarians and veterinary medical laboratories upon the request of the Commissioner for diseases that may be transmitted directly or indirectly to and between humans and animals).

Weekly unless otherwise specified in the protocols for submission below.

4. Protocols for submission

The following requirements apply to all facilities:

- Facilities should report according to their category below in a-c. If a facility is dually licensed by MDH and DHS, it must report as an MDH-licensed facility.
- When facilities are required to report on staff cases, they should include only staff who worked or interacted with others in the facility while infectious with COVID-19. Staff includes all staff regardless of number of hours worked or position type (i.e., includes full time, part time, contract staff, and volunteers).
- All facilities, upon request of the Commissioner, are required to provide to MDH individual case information for cases reported in the aggregate counts described below per Minn. Rules 4605.7090 in order to identify or characterize an outbreak, a cluster of cases, an unusual pattern of cases, or the epidemiology of a new variant of SARS-CoV-2.
- If a facility is operating under a CLIA certificate or certificate of waiver[13] to conduct point of care (POC) testing (without the use of a medical laboratory), it must report test results to MDH per the federal HHS reporting guidelines. For further information on federal reporting requirements, refer to Section II.B. of this notice.

a. Skilled nursing facilities

- Facilities must report in accordance with Centers for Medicare and Medicaid Services (CMS) reporting requirements for COVID-19, which include submission of reports to the Center for Disease Prevention and Control's (CDC) National Healthcare Safety Network (NHSN). MDH has access to NHSN reporting data from skilled nursing facilities in Minnesota and is not requiring duplicate reporting to MDH.
- Facilities must report directly to MDH on deaths of residents due to COVID-19. For reporting of deaths, facilities must submit the COVID-19 Long-Term Care Report Form (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=HH47NMERJHJX7CJF) and provide case-specific information. A reportable death is one where a resident has previously tested positive for SARS-CoV-2 infection. Facilities must submit reports of death within one working day of the death.
- Facilities should include deaths based on a positive viral test (including NAATs or antigen) regardless of where the test is performed (by the facility, at a clinic, at home, at resident's apartment).

[13] In general, any organization that administers a COVID-19 test onsite or interprets or processes results must have a CLIA certification or certification of waiver. CLIA certificates of waiver provide non-laboratory settings like schools, childcare, and congregate-living settings an option to offer and administer certain COVID-19 tests.

b. Assisted living facilities and other MDH licensed residential facilities

- Facilities must report weekly aggregate case (positive viral test) counts of COVID-19 for staff and residents separately to MDH through submission of the form COVID-19 Long-Term Care Report Form (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=HH47NMERJHJX7CJF).
- Facilities must also report to MDH on deaths of residents due to COVID-19. For reporting of deaths, facilities must submit the COVID-19 Long-Term Care Report Form (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=HH47NMERJHJX7CJF) and provide case-specific information. A reportable death is one where a resident has previously tested positive for SARS-CoV-2 infection. Facilities must submit reports of death within one working day of the death.
- For aggregate reporting of cases and for reporting of deaths, facilities should include cases and deaths based on either a positive NAAT or antigen test regardless of where the test was performed (by the facility, at a clinic, at home, at resident's apartment).
- When facilities identify positive cases through on-site testing programs, they should include those cases both in the aggregate case counts and in the individual test result reporting required by the federal CARES Act/HHS reporting guidelines. See Section II.B. for information on the federal HHS reporting guidelines.

c. DHS-licensed residential facilities (if licensed only by DHS)

- Facilities must follow the reporting instructions for aggregate cases and deaths due to COVID-19 as provided in the COVID-19 Long-Term Care Report Form (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=HH47NMERJHJX7CJF). They should follow the instructions in effect at the time they make the report.

E. Pre-K through grade 12 schools, certified child care centers, licensed child care centers, and licensed family child care

1. Disease or syndrome

This notification describes reporting for SARS-CoV-2 infection/COVID-19 as evidenced by a positive viral test. Viral tests include nucleic acid amplification tests (NAATs) and antigen tests.

2. Reporting entities

All pre-K through grade 12 schools (public and private), all certified child care centers, all licensed child care centers, and all licensed family child care (hereinafter "child care providers").

3. Reporting time frame

Weekly unless otherwise specified in the protocol for submission below.

4. Protocol for submission

- The following requirements apply to all schools and child care providers:
- Schools and child care providers must report according to their category below.
- All pre-K through grade 12 schools and child care providers must, upon request of the Commissioner, provide individual information on cases reported in the aggregate counts described below per Minn. Rules 4605.7090 to identify or characterize an outbreak, a cluster of cases, an unusual pattern of cases, or the epidemiology of a new variant of SARS-CoV-2.
- If a pre-K through grade 12 school or child care provider is operating under a CLIA certificate or certificate of waiver[14] to conduct point of care (POC) testing (without the use of a medical laboratory), it must report POC test results to MDH per the federal HHS reporting guidelines. For further information on federal reporting requirements, refer to Section II.B. of this notice. When entities identify positive cases through on-site testing programs, they must include these cases in both the aggregate case counts described below and in the individual test result reporting required per the federal CARES Act/HHS guidelines.

a. All pre-K through grade 12 schools, all certified child care centers, and licensed child care centers serving 40 or more children:

- These entities must report aggregate case counts of COVID-19 (as evidenced by a positive viral test) weekly to MDH for staff and for students separately who tested positive during the reporting period.
- All cases of COVID-19 of which the school or child care center has knowledge must be included in the weekly reports regardless of where the viral test occurred (e.g., clinic, testing site, at school or child care, at home).
- When reporting aggregate cases, schools and child care centers should not include cases among staff in school/childcare administrative buildings or offices, children/students or staff who are working fully remote, children/students or staff participating in an online-only program, or anyone who is otherwise not engaging in an in-person setting.
- Entities must report cases through the MDH REDCap platform. Each school and child care center will be set up in the REDCap platform to receive a weekly email with a unique link to report their COVID-19 data. Schools and child care centers should email health.schools.covid19@state.mn.us if they are not enrolled in this reporting system.
- These entities are also required to report on the weekly form on any hospitalizations or deaths potentially due to COVID-19 that occurred during

[14] In general, any organization that administers a COVID-19 test onsite or interprets or processes results must have a CLIA certification or certification of waiver. CLIA certificates of waiver provide non-laboratory settings like schools, child care, and congregate-living settings an option to offer and administer certain COVID-19 tests.

the reporting period for staff and for students separately. If a death or hospitalization occurred, they are also required to provide the name and date of birth for the staff person or the student/child.

- Upon request of the Commissioner, these entities must provide individual case information per Minn. Rules 4605.7090 on observed clusters of COVID-19 cases (e.g., children from the same classroom). The requested information may include individual data on cases and/or a line list of cases.

b. Licensed child care centers serving fewer than 40 children and licensed family child care:

- These entities are required to follow the same reporting requirements as larger child care centers under II.E.4.a. above with the exception that weekly reporting is not required. These child care centers should only report a case(s) (count only), deaths(s) and hospitalization(s) when these events occur.
- Entities should report through the COVID-19 Case Report Form for Child Care Programs (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=DJK4AN48FRANDHML).
- Upon request of the Commissioner, these child care centers must provide individual case information per Minn. Rules 4605.7090 on observed clusters of COVID-19 cases (e.g., children from the same classroom). The requested information may include individual data on cases and/or a line list of cases.

F. Institutions of higher education (IHE)

1. Disease or syndrome

This notification describes reporting for SARS-CoV-2 infection/COVID-19 as evidenced by a positive viral test. Viral tests include nucleic acid amplification tests (NAATs) and antigen tests.

2. Reporting entities

All institutions of higher education (IHE), specifically the COVID-19 Coordinator for the institution or other administrator.

Campus health care services and the health care providers they employ are required to follow the same case-based reporting as for other Minn. Rules 4605.7030 reporters under this notice (refer to section II.C.4.a.). Similarly, medical laboratories operated by IHE must follow the same reporting requirements as other medical laboratories in the state (see section II.C.4.b.).

3. Timeframe for reporting

Weekly unless otherwise specified in the protocol for submission below.

4. Protocols for submission

- IHE must report aggregate case counts of COVID-19 (as evidenced by a positive viral test) weekly to MDH through the College and University COVID-19 Reporting (https://redcap.health.state.mn.us/redcap/surveys/?s=KWF3TMAX7E).
- IHE must report aggregate case counts for staff and for students separately who tested positive during the reporting period. Student workers should be included in the student case counts only. When reporting aggregate counts, IHE should not include cases among students or staff who are working remotely full time, students or staff participating in an online-only program, or anyone who is otherwise not engaging in an in-person setting.
- IHE must include in the weekly aggregate case count all cases identified for staff and students from all sources available to the institution including : campus health services, POC testing conducted by the IHE under a CLIA certificate of waiver, POC testing conducted by the IHE and sent to an off-campus laboratory for processing, and student or staff self-reports using at-home tests or an off-campus clinic for testing.[15] IHE must specify the source(s) used to report aggregate cases on the reporting form. IHE must include in the weekly aggregate count all cases of COVID-19 of which the institution has knowledge from the source(s) it specifies on the reporting form.
- IHE are also required to indicate on the weekly reporting form whether any hospitalizations or deaths due to COVID-19 occurred during the reporting period for staff and for students separately. If a death or hospitalization occurred, IHE are required to provide name and date of birth for the staff person or the student.
- If an IHE is operating under a CLIA certificate or certificate of waiver[16] to conduct point of care (POC) testing (without the use of a medical laboratory), they still must report test results to MDH per the federal HHS reporting guidelines. For further information, on the HHS reporting guidelines refer to Section II.B of this notice.
- For all IHE, upon request of the commissioner, the institution must provide individual case information on cases reported in the aggregate counts described above per Minn. Rules 4605.7090 to identify or characterize an outbreak, a

[15] IHE is not required to collect the results of home tests or test results from off-campus clinics if they do not routinely collect these results already. Similarly, if an IHE does not have health services, that source of data is not available to them.

[16] In general, any organization that administers a COVID-19 test onsite or interprets or processes results must have a CLIA certification or certification of waiver. CLIA certificates of waiver provide non-laboratory settings like schools, child care, and congregate-living settings an option to offer and administer certain COVID-19 tests.[17] In general, any organization that administers a COVID-19 test onsite or interprets or processes results must have a CLIA certification or certification of waiver. CLIA certificates of waiver provide non-laboratory settings like schools, childcare, and congregate-living settings an option to offer and administer certain COVID-19 tests.

cluster of cases, an unusual pattern of cases, or to characterize the epidemiology of a new variant.

G. Correctional facilities

1. Disease or syndrome

This notification describes reporting for SARS-CoV-2 infection/COVID-19 as evidenced by a positive viral test. Viral tests include nucleic acid amplification tests (NAATs) and antigen tests.

2. Reporting entities

All correctional facilities including jails, prisons (state and federal), juvenile detention centers and other facilities licensed by the Minnesota Department of Corrections.

3. Timeframe for reporting

Weekly unless otherwise specified in the protocol for submission below.

4. Protocols for submission

- Facilities must report individual cases of COVID-19 (as evidenced by a positive viral test) to MDH by submitting weekly either a case report form for each case or a line list of cases through the MDH Case Reporting for Congregate Living Settings (https://redcap.health.state.mn.us/redcap/surveys/?s=WDCFYJD3YD34X83J) (with the exception of cases referenced in bullet 4 below).
- Facilities must provide reports on both staff and residents who tested positive during the reporting period. All cases of COVID-19 of which the facility has knowledge must be included in the weekly reports regardless of where the viral test occurred. For staff, this includes a positive test at an outside medical facility, a testing site, or at home. For residents, this includes a positive test at an outside medical facility, or a self-report of a positive result from a test distributed by the facility and self-administered by the resident.
- State-operated prisons may designate the Minnesota Department of Corrections to submit weekly reports to MDH on staff cases for tests conducted outside the prison as currently done.
- An exception to reporting of cases through the case report form/line list are staff and resident cases identified through facility-administered (point of care) SARS-CoV-2 test(s) or tests conducted by a third-party contract laboratory. These cases should not be reported through the weekly REDCap reporting mechanism since the results of those tests are already required to be reported to MDH under the federal HHS reporting guidelines. For reporting of results from facility-administered POC tests conducted under a CLIA certificate or certificate of

waiver,[17] correctional facilities should refer to the HHS guidelines and Section II.B. of this notice.

- Facilities are required to report within one working day any death in a staff person or resident suspected to have died due to COVID-19. Deaths should be reported using the MDH Case Reporting for Congregate Living Settings (https://redcap.health.state.mn.us/redcap/surveys/?s=WDCFYJD3YD34X83J). When reporting a death, facilities are required to provide the name and date of birth for the staff person or resident.
- Facilities also must report within one working day any outbreak or unusual cluster of COVID-19 cases. Upon request of the Commissioner, facilities must provide individual information on cases per Minn. Rules 4605.7090 for an outbreak or unusual cluster.
- Third-party healthcare providers that operate onsite at a corrections facility fall under case-based reporting requirements for health care reporters who are listed in Minn. Rules 4605.7030. Those requirements are described in Section II.C.4.a.

H. Shelters

1. Disease or syndrome

This notification describes reporting for SARS-CoV-2 infection/COVID-19 as evidenced by a positive viral test. Viral tests include nucleic acid amplification tests (NAATs) and antigen tests.

2. Reporting entities

Shelters and other high-risk congregate living settings serving people with temporary or transitional housing needs. These entities are collectively referred to in this document as “shelters.”

3. Timeframe for reporting

Weekly unless otherwise specified in the protocol for submission below.

4. Protocols

- Shelters must report individual cases of COVID-19 (as evidenced by a positive viral test) to MDH by submitting weekly either a case report form for each case or a line list of cases through the MDH Case Reporting for Congregate Living Settings (https://redcap.health.state.mn.us/redcap/surveys/?s=WDCFYJD3YD34X83J) (with the exception of cases referenced in bullet 4 below).

[17] In general, any organization that administers a COVID-19 test onsite or interprets or processes results must have a CLIA certification or certification of waiver. CLIA certificates of waiver provide non-laboratory settings like schools, childcare, and congregate-living settings an option to offer and administer certain COVID-19 tests.

- Shelters must submit reports on both staff and residents who tested positive during the reporting period and spent time in the facility while infectious.
- A shelter must report all cases of COVID-19 of which the shelter has knowledge regardless of where the viral test occurred. For staff, this includes a positive test at an outside medical facility, a testing site, or at home. For residents, this includes a positive test at an outside medical facility, or a self-report of positive result from a test distributed by the facility and self-administered by the resident.
- An exception to reporting of cases through the case report form/line list are staff and resident cases identified through facility-administered testing (point of care SARS-CoV-2 test) or tests conducted by a third-party contract laboratory. These cases should not be reported through the weekly REDCap reporting mechanism since the results of those tests are already required to be reported to MDH under the federal HHS reporting guidelines. For reporting of results from facility-administered POC tests conducted under a CLIA certificate or certificate of waiver,[18] shelters should refer to the HHS guidelines and Section II.B. of this Notice.
- Third-party healthcare providers that operate onsite at a shelter fall under the case-based reporting requirements for health care reporters who are listed in Minn. Rules 4605.7030. Those requirements are described in Section II.C.4.a.
- Shelters are required to report within one working day any death in a staff person or resident suspected to have died due to COVID-19. Deaths can be reported using the MDH Case Reporting for Congregate Living Settings (https://redcap.health.state.mn.us/redcap/surveys/?s=WDCFYJD3YD34X83J). When reporting a death, shelters are required to provide the name and date of birth for the staff person or resident.
- Shelters must report within one working day any outbreak or unusual cluster of COVID-19 cases. Upon request of the Commissioner, shelters must provide individual information on cases per Minn. Rules 4605.7090 for the outbreak or unusual cluster.

NOTICE ISSUED BY: /s/
Commissioner Jan K. Malcom, Minnesota Department of Health

DATE: November 18, 2022

[18] In general, any organization that administers a COVID-19 test onsite or interprets or processes results must have a CLIA certification or certification of waiver. CLIA certificates of waiver provide non-laboratory settings like schools, childcare , and congregate-living settings an option to offer and administer certain COVID-19 tests.