

# THIRD AMENDED PUBLIC HEALTH ORDER 21-02 CONCERNING ACCESS TO CARE January 31, 2022

#### PURPOSE OF THE ORDER

I am issuing this Public Health Order (PHO or Order) in response to recent increases in hospital admissions as well as hospital staffing shortages that threaten the availability and accessibility of hospital level of care to those in the State of Colorado in need of such care. This Order sets forth eligibility terms of COVID-19 patients for access to COVID-19 therapeutics and requires providers to do all they can to provide such therapies.

#### **FINDINGS**

- 1. On March 10, 2020, Governor Jared Polis verbally declared a disaster emergency regarding COVID-19 in Colorado, and on March 11, 2020 Governor Polis issued **Executive Order D 2020 003**, memorializing the disaster declaration. The Governor's verbal declaration of a disaster emergency is now memorialized in **Executive Order D 2021 122**, as amended and extended by **D 2021 124**, **D 2021 125**, **D 2021 129**, **D 2021 132**, **D 2021 136**, **D 2021 139**, and **D 2021 141**. The Governor has taken numerous steps to implement measures to mitigate the spread of disease within Colorado.
- 2. I have issued public health orders in response to the conditions of the pandemic since March 2020, which included previously implementing standards to reduce the types of elective and surgical procedures that were permitted based on the staff bed capacity of individual hospitals. By reducing the spread of disease, these requirements help to preserve the medical resources needed for those in our communities who fall ill and require medical treatment, thus protecting both the ill patients and the healthcare workers who courageously continue to treat patients. That prior public health order expired in May 2021 as cases of COVID-19 were declining.
- 3. As of January 30, 2022, there have been 1,240,361 Coloradans diagnosed with COVID-19, 56,733 have been hospitalized and 11,434 Coloradans have died from COVID-19. There are 1,363 individuals currently hospitalized due to COVID-19, and only 699 hospital beds remain unoccupied across the state. At this time, 90% of Colorado's intensive care beds are occupied and 92% of medical/surgical beds are occupied.
- 4. Despite the significant progress the State of Colorado has made over the course of the COVID-19 pandemic in curbing disease transmission, we have seen recent increases in cases due

in large part to the circulation of the highly contagious Delta and Omicron variants. Colorado faces a severe staffing shortage in hospitals due to COVID-19 that can have significant repercussions on the availability of necessary health care services for all in need.

5. The U.S. Food and Drug Administration (FDA) has authorized the use of several COVID-19 therapeutics, including sotrovimab, Evusheld, molnupiravir, and Paxlovid, for the treatment or prevention of COVID-19 for certain patients who are at high risk for progression to severe COVID-19, including hospitalization or death. Providing information regarding and access to these authorized therapeutics may reduce a patient's need for hospitalization and assist the state in managing hospital bed capacity.

#### **INTENT**

This Order outlines access to COVID-19 therapeutics for eligible COVID-19 patients and requires all providers to do all they can to provide such therapies.

#### **ORDER**

### I. ACCESS TO COVID-19 THERAPEUTICS

- A. All healthcare providers such as hospitals, urgent care clinics, community health clinics, pharmacies, and free standing emergency departments shall take all necessary steps to provide all eligible Coloradans access to life-saving COVID-19 therapeutics. As available hospital beds are in limited supply, healthcare providers are encouraged to provide COVID-19 therapeutics in outpatient settings, or refer patients who are appropriate candidates for such therapeutics to outpatient settings.
- **B.** Providers who are approved for enrollment in the COVID-19 Therapeutics Program administered by CDPHE are required to submit weekly electronic reporting regarding their administration of sotrovimab, and daily electronic reporting for Evusheld, molnupiravir, and Paxlovid into a federal reporting database made available through CDPHE.
  - 1. Enrolled providers will be included in a provider locator tool that patients may use to find COVID-19 therapeutic providers.

<sup>&</sup>lt;sup>1</sup> https://www.fda.gov/media/149534/download

<sup>&</sup>lt;sup>2</sup> https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Evusheld/Pages/default.aspx

<sup>&</sup>lt;sup>3</sup> https://www.phe.gov/emergency/events/COVID19/investigation-MCM/molnupiravir/Pages/default.aspx

<sup>4</sup> https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Paxlovid/Pages/default.aspx

- C. Eligibility for COVID-19 Therapeutics
  - 1. In accordance with the FDA Emergency Use Authorization (EUA) for sotrovimab, eligible individuals include individuals who:
    - a. Are high risk for developing severe COVID-19,
    - b. Have a positive COVID-19 test and have not yet been admitted to the hospital, and
    - c. Are at least 18 years old or 12-17 years of age and weigh at least 88 pounds.
  - 2. In accordance with the FDA EUA for <u>Evusheld</u>, eligible individuals for the pre-exposure prophylaxis of COVID-19 include individuals:
    - a. who are at least 18 years old or 12-17 years of age and weigh at least 88 pounds,
    - b. who are not currently infected with COVID-19 and who have not had a known recent exposure to an individual infected with COVID-19, **and**
    - who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination or
    - d. for whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).
  - 3. a. In accordance with the FDA EUA for the oral antiviral <u>molnupiravir</u>, eligible individuals for treatment of mild to moderate COVID-19 include individuals:
    - i. who are at least 18 years of age or older with positive COVID-19 test results,
    - ii. who are at high risk for progressing to severe COVID-19, including hospitalization or death, and
    - iii. for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
    - b. Note that warnings regarding the use of this oral antiviral include the following conditions and specific populations:
      - i. Embryo-Fetal Toxicity: Molnupiravir is not recommended for use during pregnancy.
      - ii. Bone and Cartilage Toxicity: Molnupiravir is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth.

See full Emergency Use Authorization for additional information.

- 4. a. In accordance with the FDA EUA for the oral antiviral <u>Paxlovid</u>, eligible individuals for treatment of mild-to-moderate COVID-19 include individuals who:
  - i. are 12 years of age and older weighing at least 40 kg or 18 years of age or older,
  - ii. have a positive COVID-19 test result, and
  - iii. are at high risk for progression to severe COVID-19, including hospitalization or death.
  - b. Note that a warning regarding the use of this oral antiviral includes the concomitant use of Paxlovid and certain other drugs may result in potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions. See full Emergency Use Authorization for additional warnings and contraindications.
- 5. High risk includes any of the following:
  - a. 65 years of age or older,
  - b. overweight (body mass index over 25),
  - c. pregnancy,
  - d. chronic kidney disease,
  - e. Diabetes (Type 1 and Type 2),
  - f. weakened immune system,
  - g. currently receiving immunosuppressive treatment,
  - h. cardiovascular disease/hypertension,
  - i. chronic lung disease,
  - j. sickle cell disease,
  - k. neurodevelopmental disorders, and
  - 1. medical-related technological dependence.

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization of these therapeutics under their EUAs is not limited to the medical conditions or factors listed above.

6. Individuals who meet these criteria for treatment with COVID-19 therapeutics may seek such treatment from any authorized healthcare provider without the need for a healthcare provider referral for care. Appropriate screening to confirm eligibility for this therapy shall be conducted by the treating healthcare provider.

### III. ENFORCEMENT

This Order will be enforced by all appropriate legal means. Local authorities are encouraged to determine the best course of action to encourage maximum compliance. Failure to comply with this order could result in penalties, including jail time, and fines, and may also be subject to discipline on a professional license based upon the applicable practice act.

### IV. SEVERABILITY

If any provision of this Order or the application thereof to any person or circumstance is held to be invalid, the remainder of the Order, including the application of such part or provision to other persons or circumstances, shall not be affected and shall continue in full force and effect. To this end, the provisions of this Order are severable.

### V. DURATION

This Order shall become effective on January 31, 2022 and will expire at 12:01 AM on March 1, 2022 unless extended, rescinded, superseded, or amended in writing.

Jill Hunsaker Ryan, MPH

Executive Director

January 31, 2022

Date