

**ONTARIO REGULATION 560/22**

made under the

**REGULATED HEALTH PROFESSIONS ACT, 1991**

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**AMENDING O. REG. 107/96**

**(CONTROLLED ACTS)**

**1. Ontario Regulation 107/96 is amended by adding the following section:**

**16.** (1) Subject to subsections (2) and (3), a Part A pharmacist is exempt from section 27 (1) of the Act for the purpose of prescribing Nirmatrelvir/ritonavir if,

- (a) the patient to whom the drug is being prescribed presents the pharmacist with the results of a positive COVID-19 test;
- (b) the prescribing occurs within five days of onset of symptoms of COVID 19; and
- (c) the patient is not on supplemental oxygen and is,
  - (i) 60 years of age or older,
  - (ii) 18 years of age or older but less than 60 years of age, and is,
    - (A) immunocompromised,
    - (B) at high risk of severe COVID-19 because the individual has one or more comorbidities, or
    - (C) at high risk of severe COVID-19 because the individual has inadequate immunity due to being unvaccinated, having an incomplete series of primary COVID-19 vaccination or not having had a COVID-19 vaccine dose or SARS-CoV-2 infection within the past six months.

(2) The Part A pharmacist shall make a determination as to the patient's risk for any drug interactions that cannot be properly managed or that prevent Nirmatrelvir/ritonavir from being prescribed and shall not prescribe the drug if such an interaction exists.

(3) The Part A pharmacist shall notify the patient's primary care provider, if any, within a reasonable time that the pharmacist prescribed Nirmatrelvir/ritonavir to the patient and provide details respecting the prescription.

(4) The following are examples of persons who are immunocompromised for the purposes of this section:

- 1. Individuals receiving dialysis, such as hemodialysis or peritoneal dialysis.
- 2. Recipients of solid-organ transplant who are taking immunosuppressive therapy.
- 3. Individuals receiving active treatment 3, such as chemotherapy, targeted therapies or immunotherapy, for solid tumour or hematologic malignancies.

4. Recipients of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant, who received transplantation within the past two years or who are taking immunosuppression therapy.
5. Individuals with moderate to severe primary immunodeficiency, such as DiGeorge syndrome or Wiskott-Aldrich syndrome.
6. Individuals who have experienced HIV with AIDS-defining illness in the last 12 months before starting their vaccine series or severe immune compromise with CD4 count <200 cells/uL or CD4 percentage <15%, or without HIV viral suppression.
7. Individuals receiving active treatment with the following categories of immunosuppressive therapies:
  - i. Anti-B cell therapies such as monoclonal antibodies targeting CD19, CD20 and CD22.
  - ii. High-dose systemic corticosteroids.
  - iii. Alkylating agents.
  - iv. Antimetabolites.
  - v. Tumour-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.

(5) In this section,

“comorbidities” include, without being limited to,

- (a) cancer,
- (b) cerebrovascular disease,
- (c) chronic kidney disease,
- (d) chronic liver diseases, where the disease is cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease or autoimmune hepatitis,
- (e) chronic lung diseases, where the disease is bronchiectasis, chronic obstructive pulmonary disease, interstitial lung disease, pulmonary hypertension or pulmonary embolism,
- (f) cystic fibrosis,
- (g) diabetes mellitus, type 1 or type 2,
- (h) disabilities such as Down syndrome, learning, intellectual or developmental disabilities, ADHD, cerebral palsy, congenital disabilities or spinal cord injuries,
- (i) heart conditions such as cardiomyopathies, coronary artery disease, heart failure and similar conditions,
- (j) HIV infection,
- (k) mental health disorders, where the disorder is a mood disorder, including depression, or a schizophrenia spectrum disorder,
- (l) obesity,
- (m) pregnancy or recent pregnancy,
- (n) primary immunodeficiency diseases,
- (o) smoking, current or former,
- (p) solid organ or blood stem cell transplant,
- (q) tuberculosis, and
- (r) use of corticosteroids or other immunosuppressive medication; (“comorbidités”)

“Part A pharmacist” means a member of the Ontario College of Pharmacists who holds a certificate of registration as a pharmacist and who is listed in Part A of the College’s register. (“pharmacien inscrit à la partie A”)