ST. CLAIR COUNTY HEALTH DEPARTMENT

220 Fort Street, Port Huron, MI 48060
Phone: 810.987.5300
www.scchealth.co

August 29, 2025

Dear Physician or Health Care Provider,

As medical director of the St. Clair County Health Department (SCCHD), I am writing to advise you of recent developments in the indications for active immunization against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, or "coronavirus").

Please review the enclosed information to facilitate your patient accessing coronavirus vaccine at SCCHD facilities in Port Huron, including our Main Clinic at 220 Fort Street, and our Teen Health Center at 2215 Court Street.

This year, in recognition of FDA warnings of increased risk of myocarditis and related adverse events from mRNA-based coronavirus vaccines, particularly among healthy male adolescents and young adults,[i] SCCHD will be offering only the non-mRNA, protein-based vaccine (Nuvaxovid™) to our patients aged 12 and older.

Although the Michigan Department of Health and Human Services (MDHHS) has recommended continued universal vaccination against coronavirus infection,[ii] this recommendation is now at odds with the new U.S. Food and Drug Administration (FDA) approved indications for the coronavirus vaccines, which are now limited to use in high-risk patient populations.[iii] As the MDHHS recommendation is not supported by current Advisory Committee on Immunization Practices (ACIP) recommendations, such use may also not be covered by the broad liability protections of the 1986 Vaccine Injury Act. Accordingly, coronavirus vaccine will be offered as a single dose under standing orders only for the following high-risk patients, consistent with FDA-approved product labelling:

- **All adults aged 65 and older**
- **Older children and adults aged 12 through 64, who have at least one underlying condition that puts them at high risk for severe outcomes from coronavirus disease**

At the time of writing this letter, the U.S. Centers for Disease Control and Prevention (CDC) supports the following physical health conditions placing individuals at high risk for severe outcomes from coronavirus disease:[iv] obesity, current or former smoking status, asthma and chronic lung disease; hematologic malignancies; cerebrovascular disease; heart conditions; chronic kidney or liver disease; diabetes; dementia and Parkinson's disease; HIV infection or tuberculosis; solid organ or blood stem cell transplantation; primary immunodeficiencies; and use of corticosteroids and immunosuppressive medications.

As use outside of these patient groups may now constitute "off-label" use, SCCHD will be administering coronavirus vaccine to non-high-risk patients by documented physician or other health care provider (i.e., physician assistant, or nurse practitioner) recommendation only.

Although recommended by several medical specialty associations, the U.S. Department of Health and Human Services (HHS) does not currently recommend use of coronavirus vaccine in healthy pregnancies.[v] The FDA notes that "[p]regnant women were excluded from enrollment in all clinical studies" of Nuvaxovid™, and that "[d]ue to the exclusion of pregnant women from trial participation and the limited clinical trial data from participants who became pregnant after vaccination, available data on the [o]riginal monovalent vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."[vi] As further evidence is reviewed or further recommendations are made, this information may be updated.

If you are recommending your patient obtain coronavirus vaccine at an SCCHD facility absent a history of these conditions, or if you are recommending a pregnant patient receive this vaccine, please provide a written prescription or written physician recommendation to your patient to facilitate administration under our standing orders. Administration to these patient groups absent such recommendation may require a scheduled SCCHD nurse practitioner or physician encounter to verify indication and ensure informed consent, which may delay administration.

Nuvaxovid™ is not approved for use in pediatric populations aged 6 months to 11 years, and no other protein-based vaccine appears likely to receive FDA approval for use this year. Of the existing pediatric mRNA-based vaccines, the Pfizer vaccine COMIRNATY® was recently granted full FDA approval, but only for those aged 5 and older,[vii] which makes stocking this vaccine less desirable. Only Moderna has received full FDA approval for their formulation, under the brand name SPIKEVAX®, for use across all pediatric age groups aged 6 months and older.[viii] As with other newly approved coronavirus vaccines, both mRNA-based vaccines are now indicated for use only in patients with at least one underlying condition that puts them at high risk for severe outcomes from coronavirus disease.[ix]

Subject to its availability, we will offering only SPIKEVAX® to our pediatric patients. Given the limited indications for SPIKEVAX® and the relatively low prevalence of conditions which place pediatric patients at high risk for severe outcomes from coronavirus disease, parental self-referral for SPIKEVAX®, absent physician or health care provider recommendation, will require a scheduled nurse practitioner or physician encounter to verify indication and ensure informed consent, which may delay administration.

If you are recommending your patient obtain this vaccine at one of our facilities, please provide a written prescription, or a written physician recommendation to your patient, such as in a note or letter, to facilitate administration without requiring a nurse practitioner or physician encounter.

Remington Nevin, MD, MPH, DrPH
Medical Director

---

[i] Prasad V, Makary MA. US FDA Safety Labeling Change for mRNA COVID-19 Vaccines. *JAMA*. Published online July 14, 2025. doi:10.1001/jama.2025.12675.
[ii] https://www.michigan.gov/mdhhs/inside-mdhhs/newsroom/2024/09/12/respiratory-virus.
[iii] Prasad V, Makary MA. An Evidence-Based Approach to Covid-19 Vaccination. *N Engl J Med*. 2025;392(24):2484-2486. doi:10.1056/NEJMsb2506929.
[iv] https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html.
[v] https://www.acog.org/news/news-releases/2025/05/acog-statement-on-hhs-recommendations-regarding-the-covid-vaccine-during-pregnancy.
[vi] U.S. Food and Drug Administration. BLA Clinical Review Memorandum, STN BL 125817/0, April 1, 2025. Available at: https://www.fda.gov/media/187145.
[vii] Pfizer. COMIRNATY Package Insert, August 2025. Available at: https://www.fda.gov/media/151707.
[viii] Moderna. SPIKEVAX Package Insert, August 2025. Available at: https://www.fda.gov/media/155675.
[ix] U.S. Food and Drug Administration. Supplement Approval, STN: BL 125752/276, July 9, 2025. Available at: https://www.fda.gov/media/187511.