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KAITLAN BASTON, MD, MSc, DFASAM Commissioner

To: Health Care Facilities Licensed by the Department of Health

From: Michael Kennedy, J.D.

Executive Director, Certificate of Need & Licensing Program

Date: May 15, 2024

Subject: Guidance Regarding Routine Human Immunodeficiency Virus Screening

The Department of Health (Department) has received inquiries from healthcare facilities, including hospitals, seeking guidance on whether separate written consent is necessary to initiate human immunodeficiency virus (HIV) testing for a patient. Specifically, the Department was asked whether an "opt out" approach to HIV testing, where the consent for such testing is included in a healthcare facility's general consent to treatment rather than obtaining a separate written informed consent specific for HIV testing from the patient, is permissible. In response, the Department is issuing this guidance memorandum.

After reviewing the request, the Department was unable to identify a statutory or regulatory prohibition to routine HIV testing in the healthcare setting, provided that the healthcare facility advises their patient that an HIV test will be administered as part of the facility's routine care and pursuant to the patient's general consent to treatment, which offers the patient an opportunity to decline the test. As such, the Department's review of this question did not reveal a bar to "opt-out" HIV testing in this State, provided that the healthcare facility follows the general rules for informed consent.

Moreover, the Centers for Disease Control and Prevention (CDC) recommends routine HIV testing in healthcare settings. As set forth in the CDC's Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in

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<sup>&</sup>lt;sup>1</sup> Note that N.J.A.C. 8:111-9.1 requires residential substance use disorder treatment facilities to perform HIV testing for newly admitted clients and are required to obtain a separate written consent for the testing. Although this rule requires an "opt-in" approach to HIV testing, it only applies to residential substance use disorder treatment facilities and does not establish a general prohibition to the "opt-out" testing approach in other healthcare settings.

Health-Care Settings (2006) ("CDC Recommendations")², the CDC recommends an "optout" approach to HIV testing for all patients in a healthcare setting who are 13 to 64 years old. Under the "opt-out" approach, the CDC recommends the administration of HIV testing as part of a healthcare facility's routine care and diagnostic screening of a patient and pursuant to the patient's general consent to treatment unless the patient specifically declines to receive HIV testing. Thus, the CDC Recommendations provide further support for "opt out" HIV testing in healthcare facilities and are consistent with the Department's guidance set out above.

Based upon the foregoing, the Department encourages healthcare facilities, including hospitals, to incorporate routine HIV testing into their general informed consent for treatment and standard of care procedures. Incorporating routine HIV testing into a healthcare facility's standard of care will provide earlier diagnosis and treatment for those patients who are unaware that they are HIV positive and, in turn, assist with reducing the transmission risks of the disease and contribute to ending the HIV epidemic in New Jersey.

While the Department is encouraging healthcare facilities, including hospitals, to include routine HIV testing into their general informed consent for treatment and standard of care procedures for their patients, healthcare facilities, as applicable, are reminded of their obligation to adhere to the HIV testing requirements for newborns and pregnant persons, as set out in N.J.S.A. 26:2-111.2 and N.J.S.A. 26:5C-15 through 20, and the rules the Department has promulgated pursuant thereto at N.J.A.C. 8:61-4.

If you have any questions concerning this matter, please contact Stephanie Rose Orlando at Stephanierose.Orlando@doh.nj.gov.

14):1-17; https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

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<sup>&</sup>lt;sup>2</sup> Centers for Disease Control and Prevention. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. MMWR (September 22, 2006) 55(No. RR-