Practice Information: Non-Patient Specific Orders and Protocols

Professions: RNs, LPNs, CNSs & NPs

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General Information

In most cases, New York law requires a registered professional nurse (RN) to execute medical regimens (i.e., administer drugs, medical treatments, or tests) that are prescribed for a specific patient by a physician or other qualified health professional who has examined the patient. RNs cannot execute medical orders or protocols that allow the RN to make medical diagnoses, determine medical treatments, or perform other medical services that are outside the scope of practice of the RN.

However, New York law allows RNs to execute written non-patient specific orders and protocols, issued by a physician or nurse practitioner (NP), for specific medical services described below:

- (1) administration of U.S. Food and Drug Administration (FDA) approved immunizing agents, anaphylaxis treatments, and opioid related overdose treatments;
- (2) the administration of FDA approved laboratory or point of care tests to detect COVID-19, Influenza, TB, HCV, HIV, pregnancy, and other specified conditions;
- (3) medical screening of at-risk persons for syphilis, chlamydia and/or gonorrhea infections, which may include the administration of FDA approved tests to detect syphilis, gonorrhea, and chlamydia; (4) emergency medical services that facilitate the immediate medical diagnosis and treatment of
- three potentially life-threatening medical conditions; and (5) in hospitals with newborn nurseries, the administration to newborn patients of certain laboratory tests, immunizations, and prophylactic medical treatments.

The physician or NP who issues the written non-patient specific order and protocol, as described above, is not required to examine or have a treatment relationship with the recipient of the ordered medical services.

Requirements for Non-Patient Specific Orders and Protocols

All non-patient specific orders and protocols must be in writing. Non-patient specific orders should include, at a minimum, the following:

- The name, license number and signature of the physician or NP authorizing the non-patient specific order and protocol;
- Information concerning: (1) the name, dose and route of administration of the specific vaccine(s) or medication(s), pr laboratory or point of care test(s) to be administered, or a specific description of the medical services to be performed; (2) the time period that the order will be in effect, including start and end dates; and, (3) the group of persons to be treated pursuant to the order (i.e., students at X college, pediatric patients at X medical practice, employees of X corporation, residents of X nursing home, etc.);
- Identification of the RNs authorized to execute the orders by: (1) including the name(s) and license number(s) of RNs authorized to administer the ordered tests, treatments or screening services; or (2) identifying the health care provider that employs or contracts with the RNs who implement the order (i.e., X medical practice, X hospital's inpatient newborn nursery); and, A protocol for executing the order or a specific reference to a separate written protocol for executing the order.

Protocols should, at a minimum, address the following:

- **Initial Screening** The protocol must include criteria for screening or assessing potential recipients for eligibility for (and contraindications to) the ordered medical service(s).
- **Pre-Test/Pre-Treatment/Pre-Screening Counseling** The protocol must include information regarding the health risks and benefits of the ordered medical service(s), which must be disclosed to potential recipients (or legally responsible person for a child or other potential recipient who lacks capacity to consent to the ordered medical service(s)).
- **Informed Consent** The protocol must define criteria for obtaining informed consent from the potential recipient (or legally responsible person for a potential recipient who lacks capacity to consent to the ordered medical service(s)). In some cases, such as HCV screening in a hospital, a protocol may permit documentation of informed consent for testing be covered under a "general consent" form. An RN is not required to obtain informed consent during an emergency in order to

- provide emergency care, anaphylactic treatment or opioid overdose related treatment to a person who is not capable of consenting.
- **Clinical Instructions** The protocol should include instructions necessary for performing the ordered medical service(s). It should also address relevant storage and handling requirements for equipment and supplies needed to provide the ordered medical service(s).
- **Documentation** The protocols must describe record keeping and medical documentation requirements that apply to recipients as well as to potential recipients who do not qualify for, or who refuse the ordered medical service(s). The medical record of a recipient of the ordered medical service (s) should include: the non-patient specific order and protocol; the recipient's name; applicable documentation informed consent; the date, time and type of medical service(s) provided and the name of the nurse who provided it.
- **Post-Test, Post-Treatment or Post-Screening Actions** The protocol must describe follow up actions to be taken by an RN such as, post-test counseling, disclosing test results, referring patients for follow-up care, procuring emergency transport to a hospital, or disclosing information to other health care providers.

Information for Nurses

An RN who is responsible for implementing a non-patient specific order and protocol may assign licensed practical nurses (LPNs) to help (i.e., administer the ordered vaccine, recordkeeping), provided that the assistance is within the scope of practice of an LPN and the LPN is competent to provide the service. The RN must provide on-site direction to the LPN, except in emergency situations. A ratio of no more than three LPNs to one RN should be maintained. If an RN is self-employed and is the "provider of record" of the ordered medical service(s), the RN shall be responsible for complying with applicable documentation, recordkeeping, reporting and other relevant requirements set forth in law.

Note: Additional guidance for specific types of non-patient specific orders and protocols are described in the following sections.

Immunizations

Immunizing agents are vaccines and immunoglobulin drugs approved by the FDA to provide immunity against diseases caused by infectious agents. An RN may administer immunizing agents pursuant to a non-patient specific order and protocol (issued by a physician or NP) to provide immunity against diseases identified in the charts below. The charts were updated in February 2024.

Immunizing Agents for Adults (Age 18 or Older)	
Pertussis	Measles
Diphtheria	Meningococcus
Hepatitis A	Mumps
Hepatitis B	Pneumococcus
Herpes Zoster vaccine	Rubella
Human Papilloma Virus (HPV)	Tetanus
Polio	Varicella
Influenza	COVID-19
Respiratory Syncytial Virus (RSV)	

Immunizing Agents for Children (Younger than Age 18)	
Pertussis	Measles
Diphtheria	Meningococcus
Haemophilus Influenza Type b (HIB)	Mumps
Hepatitis A	Pneumococcus
Hepatitis B	Rotovirus
Human Papilloma Virus (HPV)	Rubella
Polio	Tetanus
Influenza	Varicella
COVID-19	Respiratory Syncytial Virus (RSV)

An RN may administer additional immunizing agents pursuant to a non-patient specific order: (1) against an infectious disease that causes an epidemic or community wide outbreak as part of a public health program established by the New York State Commissioner of Health, a New York county health commissioner or a county public health director; or, (2) as recommended by the New York State Board of Regents in accordance with recommendations from the US Centers for Disease Control and Prevention or the New York State Department of Health.

All nurses involved in administering immunizing agents pursuant to a non-patient specific order and protocol must meet the criteria listed below:

- RNs who administer immunizing agents (or who direct LPNs to administer immunizing agents) must be currently certified in CPR by the American Red Cross, American Heart Association, or other organization acceptable to the New York State Education Department or have received CPR training by health facility in-service departments.
- The RN should ensure that an appropriate non-patient specific order and protocol for the administration of anaphylactic treatment is in place and that the anaphylactic treatment agents, syringes and needles and other necessary supplies are available at the immunization site.

In addition to other issues described above, immunization protocols must address the following:

- Prior to immunization, each potential recipient (or legally responsible person for a child or other
 potential recipient who lacks capacity to consent to immunization) must receive a Vaccine
 Information Statement (VIS) developed by the US Centers for Disease Control and Prevention
 (CDC) that relates to the vaccine(s) to be administered.
- Each immunization recipient (or legally responsible person for a child or other potential recipient who lacks capacity to consent to immunization) must receive with a signed certificate of immunization with the recipient's name, immunization agent, date, administering nurse, immunizing agent, manufacturer and lot number, and recommendations for future immunizations.
- Each immunization recipient's primary care provider should be informed of the immunization if the recipient has one. An adult influenza vaccine recipient may: (1) fill out a postcard that is sent by the RN or agency to the recipient's primary care provider, or (2) agree to provide his or her primary care provider with a copy of the certificate of immunization.
- Adverse immunization outcomes are reported to the Vaccine Adverse Event Reporting System (VAERS), which is operated by the CDC.
- A record should be made of all potential immunization recipients, including those who were not immunized. The record for each immunization recipient must include: the non-patient specific standing order and protocol utilized, recipient's name, date, address of immunization site, immunizing agent, manufacturer and lot number of administered vaccine(s) and any recommendations for future immunizations. With respect to adult influenza vaccine recipients only,

an RN may maintain a log of the names, addresses and phone numbers the recipients in a dated file with a copy of the influenza order and the influenza protocol attached to the log.

Anaphylaxis Treatment

When administering anaphylaxis treatment pursuant to a non-patient specific order and protocol, the RN should:

- Administer anaphylaxis treatment in an emergency, if the recipient of the anaphylaxis treatment is not capable of giving informed consent.
- Arrange for immediate follow-up care (i.e., by contacting an emergency medical service provider and reporting the recipient's name, and the name, time, doses, and strength of the anaphylactic treatment agent[s] administered and route of administration).
- Ensure that a record is maintained of all recipients of anaphylaxis treatments, which includes, at a minimum: the non-patient specific order and protocol, the recipient's name, date, the address of administration site, the name of the administering nurse, and the anaphylactic treatment agent administered and its manufacturer and lot number.
- Report the anaphylaxis treatment to the recipient's primary care provider, if possible.

Tuberculosis (TB) Tests

TB tests are laboratory or point of care tests approved by the FDA to detect or screen for tuberculosis infections, such as Purified Protein Derivative Mantoux Tuberculin Skin Tests (PPD tests) and Interferon Gamma Release Assays (IGRAs).

In addition to complying with criteria described in the General Information section, RNs who administer PPD tests pursuant to a non-patient specific order and protocol should ensure that:

- The protocol requires the documentation of the name of the PPD test recipients, the manufacturer and lot number of the PPD administered, and test results.
- The protocols specifically describe to whom the PPD test results are sent (i.e., the recipient's health care provider or employee health office).
- An appropriate non-patient specific order and protocol for the administration of anaphylactic agents is in place and that the anaphylactic agents, syringes, and needles are available at the PPD testing site.
- Prior to administering the PPD injection, the potential test recipient or his or her authorized representative is informed of the need for a test evaluation within 48 to 72 hours after the injection is administered.

An RN may assign an LPN to administer the intra-dermal injection of PPD and also direct an LPN to observe and report the recipient's physical response to the PPD injection, provided that the LPN is trained to do so. For example, the LPN may observe the test site and report the observations to the RN (i.e., no area of induration, 1 mm area of induration). However, New York Law requires that an RN determine whether the test result is positive or negative.

Human Immunodeficiency Virus (HIV) Tests

HIV tests are laboratory or point of care tests approved by the FDA to detect the presence of antibodies or antigens to HIV virus or the HIV virus. RNs may administer screening and confirmatory HIV tests pursuant to a non-patient specific order and protocol.

In cases where a confirmatory or diagnostic HIV test is positive, an RN must inform a qualified physician, physician assistant or NP of the test result and must obtain a **patient specific order** from a physician, physician assistant or NP to disclose the test result to the test recipient. There are many laws and

regulations that govern HIV testing, including specific requirements for obtaining informed consent, pre-test and post- test counseling, test result reporting, referrals for follow up care, confidentiality, record keeping and contact tracing. Information about HIV testing and counseling is available on the New York State Department of Health website. www.health.ny.gov.

Hepatitis C Virus (HCV) Tests

HCV tests are laboratory or point of care tests approved by the FDA to detect the presence of antigens or antibodies to the hepatitis C virus or the hepatitis C virus. RNs may administer screening and confirmatory HCV tests pursuant to a non-patient specific order and protocol.

In cases where a confirmatory or diagnostic HCV C test is positive, an RN must inform a physician, NP or physician assistant of the test result and must obtain a **patient specific order** from a physician, NP or physician assistant to disclose the test result to the test recipient. There are many laws and regulations that govern HCV testing, including specific requirements for offering HCV tests, test result reporting, referrals for follow up care, and record keeping.

Additional information regarding HCV testing is available on the New York State Department of Health website. www.health.nv.gov.

Influenza and COVID 19 Tests

Influenza tests are laboratory or point of care tests approved by the FDA to detect to presence of antigens and antibodies to influenza viruses or influenza viruses. COVID-19 tests are laboratory or point of care tests approved or authorized by the FDA to detect to presence of antigens to COVID 19 viruses or COVID 19 viruses.

RNs may administer screening and confirmatory Influenza or COVID 19 tests pursuant to a non-patient specific order and protocol. The RN should disclose test results if specifically authorized in the protocols to do so (as prescribed by the physician or NP). In cases where the protocol does not explicitly authorize the RN to disclose the test results, the RN must inform a physician, NP or physician assistant of the test result and must obtain a **patient specific order** from a physician, NP or physician assistant to disclose the test result to the test recipient.

Pregnancy Tests

Pregnancy tests are laboratory or point of care tests approved by the FDA to detect pregnancy. RNs may administer pregnancy tests pursuant to a non-patient specific order and protocol. The RN may disclose test results to the test recipient or third parties if authorized in the protocols to do so (as prescribed by the physician or NP). In cases where the protocol does not explicitly authorize the RN to disclose the test results, the RN must inform a physician, NP or physician assistant of the test result and must obtain a **patient specific order** from a physician, NP or physician assistant to disclose the test result to the test recipient.

Screening for Syphilis, Gonorrhea and/or Chlamydia Infections

Screening for syphilis, gonorrhea and/or chlamydia infections includes an assessment of an individual to ascertain the individual's risk of having a syphilis, gonorrhea and/or chlamydia infection and may include the administration of one or more laboratory or point of care tests approved by the FDA to detect or screen for syphilis, gonorrhea, or chlamydia infections. RNs may administer screening, confirmatory or diagnostic tests or tests that aid in the diagnosis of syphilis, gonorrhea and/or chlamydia infections pursuant to a non-patient specific order and protocol.

New York law does **not** authorize RNs to determine medical diagnoses, presumptive medical diagnoses or medical treatments for patients who are screened for syphilis, gonorrhea and/or chlamydia infections. A

physician, NP or physician assistant must make these determinations for each patient. In cases where the result of an ordered screening indicates that the screening recipient may be infected (including positive confirmatory or diagnostic laboratory tests for syphilis, gonorrhea and/or chlamydia) an RN must inform a physician, NP or physician assistant and obtain a **patient specific order** from the physician, NP or physician assistant in order to disclose the results or the physician's, NP's or physician assistant's diagnosis or presumptive diagnosis to the screening recipient.

Opioid Related Overdose Treatment

Opioid related overdose treatment includes the urgent or emergency administration of naloxone or another drug approved by the FDA to treat opioid related overdose to a person who is experiencing an opioid related overdose or is suspected of experiencing an opioid related overdose. RNs who administer opioid related overdose treatment (or who direct LPNs to administer opioid related overdose treatment) should be currently certified in CPR or BCLS or have received CPR training by health facility in-service departments.

When administering opioid related overdose treatment pursuant to a non-patient specific order and protocol, the RN should:

- Administer the ordered opioid related overdose treatment in an emergency if the recipient of the treatment is not capable of giving informed consent.
- Arrange for immediate follow-up care (i.e., by contacting an emergency medical service provider and reporting the recipient's name, and the name, time, dose[s] and strength of the opiate antagonist drug administered and route of administration).
- Ensure that a record is maintained of all recipients of opioid related overdose treatment, which
 includes, at a minimum: the non-patient specific order and protocol, the recipient's name, date, the
 address of administration site, the name of the administering nurse, and the opiate antagonist drug
 administered.

Additional information regarding opioid related overdose treatment is available on the New York State Department of Health website. www.health.ny.gov.

Hospital "Standing Orders" for Newborn Patients

In hospitals with newborn nurseries, an RN may execute a written non-patient specific order and protocol (also referred to as a standing order) issued by a physician or NP for providing medical services that prevent or screen for diseases in newborn patients less than 3 days old, as described below:

- The administration of New York State mandated newborn screening tests pursuant to section 2500-a of the public health law;
- The administration of laboratory or point-of-care tests that are approved by the FDA and indicated for use in neonates;
- The administration of vaccines that are approved by the FDA and indicated for use in neonates;
- The administration of prophylactic medications that are approved by the FDA and indicated for use in neonates.

New York law does **not** authorize RNs to determine medical diagnoses, presumptive medical diagnoses, or medical treatments for patients. A qualified physician, NP, midwife or physician assistant must make these determinations for each newborn patient. An RN may disclose the results of ordered tests as authorized by the protocol. If the protocol does not authorize the RN to disclose test results, the RN must obtain **patient specific order** from the qualified midwife, physician, physician assistant or NP to disclose the test result to the test recipient's parent or other person legally responsible for consenting to medical care for the newborn patient.

Emergency Medical Care

Emergency medical care is medical services that are ordered to expedite the detection and/or medical intervention for emergency medical conditions, as described below:

- (A) administering electrocardiogram tests to detect signs and symptoms of acute coronary syndrome;
- (B) administering point-of-care tests that are approved by the FDA to determine blood glucose levels for the purpose of evaluating acute mental status changes;
- (C) administering tests, which may include laboratory or point-of-care tests that are approved by the FDA, to patients who meet criteria for severe sepsis and septic shock; and,
- (D) establishing peripheral venous access on patients who meet criteria for severe sepsis and septic shock.

When ordered emergency medical care is provided outside of a hospital, the recipient of the medical care must be transferred to a general hospital for follow-up care in accordance with criteria in the protocol. The RN should not delay patient access to physician care or emergency transportation to a hospital. New York law does **not** authorize RNs to determine medical diagnoses, presumptive medical diagnoses, medical treatments for patients. A qualified physician, NP, or physician assistant must make these determinations for each patient.

Information for Pharmacists

Pharmacists may provide syringes, needles, medications, and other supplies needed by RNs to execute non-patient specific orders and protocols. The sale of these immunization agents, medications, needles, and syringes may be considered a wholesale transaction. However, a wholesale registration from the State Board for Pharmacy will not be necessary for these transactions.

In addition, qualified pharmacists may execute a non-patient specific regimen prescribed or ordered by a physician or NP for:

- (a) dispensing up to a 7-day supply of drugs to prevent HIV infections in person who may have been exposed to HIV;
- (b) dispensing certain self-administered oral hormonal contraceptives (i.e., hormonal contraceptive vaginal rings, hormonal contraceptive patches, birth control pills);
- (c) administering certain immunizations; and,
- (d) providing other medical services.

For more information, please visit the New York State Pharmacy Board website. http://www.op.nysed.gov/prof/pharm/

References: Education Law §6909, §6801 and 8 NYCRR §64.7, §64.5.