AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6801, 6806, 6902 and 6909 of the Education Law and Chapter 128 of the Laws of 2023.

1. The Regulations of the Commissioner of Education are amended by adding a new section 63.16 to read as follows:

Section 63.16 Dispensing Self-Administered Hormonal Contraceptives

(a) Definitions. As used in this section, self-administered hormonal contraceptives, means self-administered contraceptive medications or devices approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation, and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings and hormonal contraceptive patches.

(b) Pursuant to sections 6527, 6801, and 6909 of the Education Law, a pharmacist licensed and located in this state may execute a non-patient specific order to dispense self-administered hormonal contraceptives provided that:

(1) the pharmacist has successfully completed training in the dispensing of self-administered hormonal contraceptives, satisfactory to the commissioner;

(2) the non-patient specific order is prescribed or ordered by the commissioner of health, a physician licensed in this state, or a nurse practitioner certified in this state; and

(3) the self-administered hormonal contraceptive is approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation and includes oral hormonal contraceptives, hormonal contraceptive vaginal

rings and hormonal contraceptive patches and is being dispensed to the patient for such purpose.

(c) Requirements.

(1) A pharmacist licensed and located in this state shall not dispense self-administered hormonal contraceptives to patients pursuant to a non-patient specific order without receiving training satisfactory to the commissioner. Training that is satisfactory to the commissioner shall entail the completion of instruction in the dispensing of self-administered hormonal contraceptives that provides:

(i) knowledge of the menstrual cycle, including the different menstrual cycle phases and hormonal functions;

(ii) knowledge of the various contraceptive methods, medications and devices, including both self-administered and non-self-administered contraceptives and devices. Such overview shall also include the pharmacology and mechanisms of actions for the various contraceptives and devices available on the market;

(iii) knowledge of the precautions and contraindications in the use of hormonal contraceptives; and

(iv) knowledge of the various techniques required to counsel and adequately screen patients for the dispensing of an appropriate self-administered hormonal contraceptive if applicable.

(2) Pharmacists that dispense self-administered hormonal contraceptives to patients pursuant to a non-patient specific order are required to maintain documentation of their successful completion of the training prescribed in paragraph (1) of this

subdivision. Such documentation shall be available for review by the department upon request.

(d) Standards, procedures and reporting requirements for the dispensing of self-administered hormonal contraceptives pursuant to a non-patient specific order.

(1) Prior to dispensing self-administered hormonal contraceptives to a patient and at a minimum of every twelve months thereafter for each returning patient, the licensed pharmacist shall:

(i) Provide the patient with a self-screening risk assessment questionnaire, developed by the commissioner of health in consultation with the commissioner, to be reviewed by the pharmacist to identify any known risk factors and assist the patient's selection of an appropriate self-administered hormonal contraceptive; and

(ii) Provide the patient with a fact sheet, developed by the commissioner of health, that includes, but is not limited to, the clinical considerations and recommendations for use of the self-administered hormonal contraceptive, the appropriate method for using such self-administered hormonal contraceptive, information on the importance of follow-up health care, health care referral information, and the ability of the patient to opt out of practitioner reporting requirements.

(2) A licensed pharmacist shall notify the patient's primary health care practitioner, unless the patient opts out of such notification, within 72 hours of dispensing a self-administered hormonal contraceptive, that such self-administered hormonal contraceptive has been dispensed. Such notification may occur via electronic transmission or facsimile. If the patient does not have a primary health care practitioner or is unable to provide contact information for their primary health care practitioner, the

pharmacist shall provide the patient with a written record of the self-administered hormonal contraceptives dispensed and advise the patient to consult an appropriate health care practitioner.

(3) A licensed pharmacist shall:

(i) maintain records of the dispensing of the self-administered hormonal contraception, in accordance with section 6810(5) of the Education Law; and

(ii) maintain or ensure the maintenance of a copy of the non-patient specific order which authorizes the pharmacist to dispense self-administered hormonal contraception in accordance with the requirements of this section.

(4) Nothing in this section shall prevent a pharmacist from refusing to dispense a non-patient specific order of self-administered hormonal pursuant to this section if, in their professional judgment, potential adverse effects, interactions or other therapeutic complications could endanger the health of the patient

2. The Regulations of the Commissioner of Education are amended by adding a new section 60.14 to read as follows:

Section 60.14 Non-patient specific orders to dispense self-administered hormonal contraceptives

(a) As used in this section, self-administered hormonal contraceptives means self-administered oral hormonal contraceptive medications or devices approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation, and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings and hormonal contraceptive patches.

(b) A licensed physician may issue a written non-patient specific order and protocol for a licensed pharmacist to dispense self-administered hormonal contraceptives to patients in New York State, provided that the requirements of this section are met.

(c) Order and protocol.

(1) The non-patient specific order shall include, at a minimum, the following:

(i) the name, license number and signature of the licensed physician who issues the non-patient specific order and protocol;

(ii) the name and dose of the specific drug(s) or the name of specific medical device to be dispensed;

(iii) a protocol for dispensing the self-administered hormonal contraceptives or a specific reference to a separate written protocol for dispensing the self-administered hormonal contraceptives, which shall meet the requirements of paragraph (2) of subdivision (c) of this section.

(iv) the period of time that the order is effective, including the beginning and ending dates;

(v) a description of the group(s) of persons who may receive the dispensed self-administered hormonal contraceptives; and,

(vi) the name and license number of each licensed pharmacist authorized to execute the non-patient specific order and protocol or the name and address of the New York State licensed pharmacy that employs or contracts with the licensed pharmacist(s) to execute the non-patient specific order and protocol.

(2) The written protocol, incorporated into the order prescribed in paragraph (1) of subdivision (c) of this section shall, at a minimum, require the licensed pharmacist to:

(i) provide the patient with a self-screening risk assessment questionnaire, developed by the commissioner of health in consultation with the commissioner, to be reviewed by the pharmacist to identify any known risk factors and assist the patient's selection of an appropriate self-administered hormonal contraceptive;

(ii) provide the patient with a fact sheet, developed by the commissioner of health, that includes but is not limited to, the clinical considerations and recommendations for use of the self-administered hormonal contraceptive, the appropriate method for using such self-administered hormonal contraceptive, information on the importance of follow-up health care, health care referral information, and the ability of the patient to opt out of practitioner reporting requirements;

(iii) notify the patient's primary health care practitioner, unless the patient opts out of such notification, within seventy-two hours of dispensing a self-administered hormonal contraceptive, that such self-administered hormonal contraceptive has been dispensed. Such notification may occur via electronic transmission or facsimile. If the patient does not have a primary health care practitioner or is unable to provide contact information for their primary health care practitioner, the pharmacist shall provide the patient with a written record of the self-administered hormonal contraceptives dispensed and advise the patient to consult an appropriate health care practitioner;

(iv) offer or provide in writing, the names and addresses of hospitals or other health providers that offer follow-up care, which shall be identified in the protocol; and

(vi) document the pharmacy services provided as described in this paragraph and maintain the documentation in accordance with sections 29.2(a)(3), 63.6(b)(7), and 63.6(b)(8) of this Title.

3. Section 64.5 of the Regulations of the Commissioner of Education is amended by adding a new subdivision (d) to read as follows:

(d) Non-patient specific orders to dispense self-administered hormonal contraceptives

(1) As used in this subdivision, self-administered hormonal contraceptives means self-administered oral hormonal contraceptive medications or devices approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation, and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings and hormonal contraceptive patches.

(2) A certified nurse practitioner may issue a written non-patient specific order and protocol for a licensed pharmacist to dispense self-administered hormonal contraceptives, provided that the requirements of this subdivision are met.

(3) Order and protocol.

(i) The non-patient specific order shall include, at a minimum, the following:

(a) the name, license number and signature of the certified nurse practitioner who issues the non-patient specific order and protocol;

(b) the name and dose of the specific drug(s) or the name of specific medical device to be dispensed;

(c) a protocol for dispensing the self-administered hormonal contraceptives or a specific reference to a separate written protocol for dispensing the self-administered

hormonal contraceptives, which shall meet the requirements of subparagraph (ii) of this paragraph;

(d) the period of time that the order is effective, including the beginning and ending dates;

(e) a description of the group(s) of persons who may receive the dispensed self-administered hormonal contraceptives; and,

(f) the name and license number of each licensed pharmacist authorized to execute the non-patient specific order and protocol or the name and address of the New York State licensed pharmacy that employs or contracts with the licensed pharmacist(s) to execute the non-patient specific order and protocol.

(ii) The written protocol, incorporated into the order prescribed in subparagraph (i) of this paragraph, shall, at a minimum, require the licensed pharmacist to:

(a) provide the patient with a self-screening risk assessment questionnaire, developed by the commissioner of health in consultation with the commissioner, to be reviewed by the pharmacist to identify any known risk factors and assist the patient's selection of an appropriate self-administered hormonal contraceptive;

(b) provide the patient with a fact sheet, developed by the commissioner of health, that includes but is not limited to, the clinical considerations and recommendations for use of the self-administered hormonal contraceptive, the appropriate method for using such self-administered hormonal contraceptive, information on the importance of follow-up health care, health care referral information, and the ability of the patient to opt out of practitioner reporting requirement;

(c) notify the patient's primary health care practitioner, unless the patient opts out of such notification, within seventy-two hours of dispensing a self-administered hormonal contraceptive, that such self-administered hormonal contraceptive has been dispensed. Such notification may occur via electronic transmission or facsimile. If the patient does not have a primary health care practitioner or is unable to provide contact information for their primary health care practitioner, the pharmacist shall provide the patient with a written record of the self-administered hormonal contraceptives dispensed and advise the patient to consult an appropriate health care practitioner;

(d) offer or provide in writing, the names and addresses of hospitals or other health providers that offer follow-up care, which shall be identified in the protocol; and

(e) document the pharmacy services provided as described in this subparagraph and maintain the documentation in accordance with sections 29.2(a)(3), 63.6(b)(7), and 63.6(b)(8) of this Title.