GEORGIA DEPARTMENT OF PUBLIC HEALTH

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June 19, 2020

NOTICE OF PROPOSED RULEMAKING
Proposed New Public Health Regulations
Chapter 511-2-9
"Syringe Services Program"

The Department of Public Health proposes to promulgate Chapter 511-2-9, "Syringe Services Program," pursuant to its authority under O.C.G.A. § 16-13-32.

During the 2019 legislative session of the Georgia General Assembly, Chapter 13 of Title 16 of the Official Code of Georgia Annotated was amended to authorize the Department to promulgate rules and regulations to supervise the activities of Syringe Services Programs, including the registration of such programs.

The proposed amendments have been posted to the Department's website at https://dph.georgia.gov/regulationsrule-making. Interested persons may submit comments on these proposed revisions in writing addressed to:

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Written comments must be submitted on or before July 20, 2020. Comments may also be presented in person at a public meeting scheduled for 10:00 a.m. on July 17, 2020, in Room 9-260, "Adina's Room," at 2 Peachtree Street, NW, Atlanta, Georgia 30303. To dial in, please call 877-873-8018 and enter access code 3529045. The Commissioner of Public Health will consider the proposed rules for adoption on or about July 21, 2020, to become effective on August 20, 2020.

Kristin L. Miller
General Counsel
Georgia Department of Public Health

RULES OF THE
DEPARTMENT OF PUBLIC HEALTH

CHAPTER 511-2-9
Syringe Services Programs

Rule 511-2-9-.01 Definitions.

(1) **"Administrator"** means the person who signs an application for registration of a Syringe Services Program and bears the ultimate responsibility for ensuring that the Program operates in compliance with O.C.G.A. § 16-13-32 and these rules and regulations.

(2) **"Consumer"** means a person who receives assistance through a Syringe Services Program.

(3) **"Commissioner"** means the Commissioner of Public Health.

(4) **"Department"** means the Georgia Department of Public Health.

(5) **"Policies and Procedures Manual"** means a written manual detailing the policies and procedures for the safe and lawful operation of a Syringe Services Program.

(6) **"Site"** means the location(s) or venue(s) where Syringe Services Programs are offered to Consumers.

(7) **"Staff"** means a person who works for or acts as an agent of a Syringe Services Program, whether compensated or not.

(8) **"Syringe Services Program" or "Program"** means an organization which provides substance abuse and harm reduction counseling, education, and referral services for substance abuse disorder treatment; training and provision of naloxone to reverse opioid overdoses; screening for HIV, viral hepatitis, sexually transmitted diseases, and tuberculosis; referrals and linkage to HIV, viral hepatitis, sexually transmitted diseases, and tuberculosis prevention, treatment, and care services; safer injection supplies; and evidence-based interventions to reduce negative consequences of drug related behaviors.

Authority: O.C.G.A. § 16-13-32.

Rule 511-2-9-.02 Registration Required.

(1) Any person or entity that operates a Syringe Services Program shall be registered with the Department. Applications for registration shall be filed with the Department as specified in Rule 511-2-9-.03.

(2) Upon receipt of a complete application, the Department shall review the application and take action to approve or deny the registration in accordance with the provisions of O.C.G.A. § 16-13-32 and these rules and regulations.

(3) Once issued, a registration shall be valid for a period of two years or until the biennial registration date established by the Department.

Authority: O.C.G.A. § 16-13-32.

Rule 511-2-9-.03 Application for Registration.

Each application for registration of a Syringe Services Program shall contain:

(1) The legal name of the Program and the name under which it will be doing business.

(2) The name, address, telephone number, and email address of the Administrator of the Program, together with:

(i) A signed, notarized statement attesting that the Administrator accepts full responsibility for ensuring that the Program operates in compliance with the provisions of O.C.G.A. § 16-13-32 and these rules and regulations; and

(ii) All information necessary for the Department to conduct a fingerprint criminal background check of the Administrator. The Applicant shall be responsible for all fees associated with the performance of the background check.

(3) The address and telephone number of each Program Site, including both fixed locations with permanent structures and venues at which services are provided by a mobile unit, as well as the name, address, and telephone number of the legal property owner for each fixed location and the Georgia tag number of each mobile unit.

(4) The scheduled hours of operation for all Program Sites, including both fixed locations and mobile units.

(5) Documentation showing that the Program has provided written notice of its intent to establish and maintain a Syringe Services Program to stakeholders in the community, including the local governing authority and the local law enforcement agencies with jurisdiction over each Program Site. The written notice shall include a copy of the Program's Site security plan.

(6) A copy of the Program's Policies and Procedures Manual.

(7) Such other information as is deemed necessary by the Department.

Authority: O.C.G.A. § 16-13-32.

Rule 511-2-9-.04 Operating Requirements.

(1) Each Syringe Services Program shall:

(a) Accept and dispose of hypodermic needles and syringes at no cost to Consumers and in compliance with the U.S. Occupational Safety and Health Administration's bloodborne pathogen rule, 29 C.F.R. § 1910.1030.

(b) Furnish new hypodermic needles and syringes to Consumers at no cost and in quantities sufficient to minimize the likelihood of reuse. All new hypodermic needles and syringes shall be provided in sealed sterile packaging.

(c) Provide Consumers with direct services or referrals and linkages to care for the following: substance abuse counseling, education, and treatment; training and provision of naloxone to reverse opioid overdoses; screening, prevention, treatment, and care services for HIV, viral hepatitis, sexually transmitted diseases, and tuberculosis; and evidence based interventions to reduce negative consequences of drug related behaviors.

(d) Comply fully with the Program's Policies and Procedures Manual and all applicable federal and state laws and rules.

(e) Accept no remuneration from a Consumer.

(f) Operate only from locations of which the Department has been notified and which must be at least 1,000 feet from any school and any child care learning center licensed by the Georgia Department of Early Care and Learning.

(g) Strictly limit the disclosure of protected health information, including HIV status, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), O.C.G.A. § 24-12-21, and all other provisions of federal and state laws and rules.

(h) Ensure that all Staff are vaccinated against or immune to the hepatitis B virus, unless the individual Staff member has declined the vaccine.

(i) Ensure physical facilities are clean, sanitary, and appropriately maintained.

(j) Be overseen by an Administrator who has been approved by the Department and has accepted the responsibility of ensuring that the Program operates in compliance with O.C.G.A. § 16-13-32 and these rules and regulations.

(2) Each Program shall notify the Department via email or other writing within thirty days of any changes in:

(a) The legal name of the Program or the name under which it does business;

(b) The Program Site(s), including both fixed locations and mobile units and all contact information related thereto;

(c) The Administrator of the Program, including all contact information related thereto;

(d) The Program's operating hours; or

(e) The Program's Policies and Procedures Manual.

(3) Annually by December 1, each Program shall report the following data to the Department, in a format specified by the Department:

(a) Aggregated Consumer demographic information, including age, race, ethnicity, and gender;

(b) The number of new syringes distributed to each Consumer in each transaction;

(c) The number of used syringes returned by each Consumer in each transaction, including the number of syringes disposed of and the disposal method;

(d) The number of referrals and linkages to care made to HIV, viral hepatitis, STD, and/or tuberculosis testing, service, and treatment providers;

(e) The number of Consumers who were tested for HIV, viral hepatitis, STDs, and tuberculosis through the Program;

(f) The number of referrals made to substance abuse treatment providers;

(g) The number of needlestick injuries and splash exposures at the Program, if any, including confirmation that injured individuals received appropriate care following an incident in accordance with the Program's protocol for management of needlestick injuries and splash exposures; and

(h) Such other information as is deemed necessary by the Department.

Authority: O.C.G.A. § 16-13-32.

Rule 511-2-9-.05 Policies and Procedures Manual.

(1) Each Program shall develop a Policies and Procedures Manual for operation of a Syringe Services Program. Such Manual shall include:

(a) A protocol strictly limiting the disclosure of protected health information, including HIV status, in compliance with HIPAA, O.C.G.A. § 24-12-21, and all other provisions of federal and state laws and rules, accompanied by a protocol for handling breaches of privacy.

(b) A plan for the provision of substance abuse and harm reduction counseling, education, and referral services for:

i. Substance abuse disorder treatment;

ii. Training and provision of naloxone to reverse opioid overdoses;

iii. Screening for HIV, viral hepatitis, sexually transmitted diseases, and tuberculosis prevention, treatment, and care services, including immunizations;

iv. Safer injection supplies; and

v. Evidence-based interventions to reduce negative consequences of drug-related behaviors.

(c) A Site biosafety plan, which shall include:

(i) Engineering and work practice controls designed to reduce the likelihood of exposure by Program Staff and Consumers to bloodborne pathogens and other potentially biohazardous materials;

(ii) A protocol for the safe and secure disposal of syringes and related supplies in compliance with federal and state law;

(iii) A protocol for the management of needlestick injuries and splash exposures, which shall include the designation of an exposure manager who must be present during operating hours, a procedure for Staff to immediately report needlesticks and splash exposures, and a process for an injured individual to receive post-exposure prophylaxis or other appropriate medical care;

(iv) A Staff training plan, which shall include education regarding Universal Precautions, safe handling of syringes, confidentiality protocols, bloodborne pathogen infection control, and other subjects deemed necessary by the Department for the safe operation of the Program.

(d) A Site security plan, which shall be provided to all law enforcement agencies with jurisdiction over each Program Site and shall include:

(i) Provisions for reasonable and adequate security of program Sites, equipment, and personnel;

(ii) Operational procedures to protect inventory from loss or theft and ensure the secure storage, distribution, and disposal of syringes;

(iii) Provisions for the regular retrieval of any syringes or other trash discarded within three hundred feet of a fixed or mobile Program Site.

(e) A plan for enlisting community support and addressing community concerns related to the implementation of the Program; and

(f) A data collection protocol for recording the information that must be reported to the Department in accordance with Rule 511-2-9-.04(3)(g).

Authority: O.C.G.A. § 16-13-32.

Rule 511-2-9-.06 Right of Inspection and Copying.

(1) Any duly designated employee of the Department shall have the right to enter upon and into the premises of a Program or Applicant at any time for the purpose of conducting a physical inspection of the Program Site. A satisfactory inspection demonstrating compliance with Rule 511-2-9-.04 shall be required prior to the issuance of an initial registration and upon each biennial renewal.

(2) The Department shall be afforded full access to, and the right to examine and copy, either manually or by photocopy, all manuals, protocols, records, reports, and other documents required to be kept by a Program under these regulations, at no expense to the Department.

Authority: O.C.G.A. § 16-13-32.

Rule 511-2-9-.07 Renewal of Registration.

(a) Each Program may renew its registration biennially by submitting a renewal application and fulfilling all requirements specified by the Department for renewal, including a physical inspection of the Program Site. Renewal applications shall be submitted to the Department not less than 120 days prior to the expiration date of the registration and shall include updated information regarding:

(1) The legal name of the Program and the name under which it does business;

(2) The Program Site(s), including both fixed locations and mobile units and all contact information related thereto;

(3) The Administrator of the Program, including all contact information related thereto;

(4) The Program's operating hours; and

(5) The Program's Policies and Procedures Manual.

(b) A Program registration that is not renewed prior to the expiration date shall be placed in lapsed status. A lapsed registration may be renewed during the six-month period immediately following the expiration date, provided that the Program meets all requirements for renewal.

(c) A Program registration that is not renewed within the six-month late renewal period shall be expired and not eligible for renewal. To regain its registration, the Program shall be required to reapply for registration as a new applicant.

Authority: O.C.G.A. § 16-13-32.

Rule 511-2-9-.08 Granting and Suspension or Revocation of Registration.

(1) The Department shall grant an application for registration only upon a satisfactory showing that both the Program and its Administrator are willing and able to operate in compliance with the Program's Policies and Procedures Manual and all provisions of these rules.

(2) The Department may deny an application for registration or suspend or revoke a registration, after notice and an opportunity for a hearing, upon a finding that the Applicant, Program, or Administrator has:

(a) Failed to meet all requirements for Program registration;

(b) Violated any federal or state law or rule related to Syringe Services Programs, without regard to whether such violation is criminally punishable;

(c) Committed or been convicted of any felony or any crime involving moral turpitude in the courts of this state or any other state or territory or in the courts of the United States; as used in this paragraph, the term "conviction" shall include a finding or verdict of guilty, or a plea of guilty or *nolo contendere*, regardless of whether an appeal has been sought;

(d) Knowingly made misleading, deceptive, untrue, or fraudulent representations related to the operation of a Syringe Services Program or on any document connected therewith, or made a false or deceptive statement to the Department; or

(e) Engaged in any practice harmful to the public which materially affects the ability of the Applicant, Program, or Administrator to operate a Syringe Services Program or threatens the public health, safety, or welfare.

(3) In its sole discretion, the Department may allow a Program an opportunity to correct alleged deficiencies prior to initiating the suspension or revocation of a registration, in accordance with the following procedures:

(a) The Department shall provide written notice to the Administrator, via email and first class U.S. mail to the Administrator's address on file with the Department, of the Program's alleged deficiencies. Notice shall be complete upon mailing.

(b) Within thirty calendar days of the notice, the Program shall develop and submit to the Department a written corrective action plan to address the deficiencies. The corrective action plan shall include:

(i) Steps required to correct the deficiencies; and

(ii) A deadline of no more than ninety calendar days for completion.

(c) If the Department, in its sole discretion, approves the corrective action plan, the Program shall implement the plan. The Department may conduct a Site inspection at any time during the implementation period. If the Department determines, in its sole discretion, that the deficiencies have been corrected, no further action shall be taken.

(d) If the Program fails to submit a sufficient corrective action plan, fails to correct the deficiencies as specified in the corrective action plan, or if the Department determines for any reason that a corrective action program is no longer appropriate, the Department may take action to suspend or revoke the Program's registration.

(4) Procedures for the denial of an application or suspension or revocation of a Program registration.

(a) The Department shall provide written notice to the Program's Administrator, via email and certified mail to the Administrator's address on file with the Department, of the denial of the Program's application or the suspension or revocation of the Program's registration and the grounds therefor. Notice shall be complete upon mailing.

(b) The denial, suspension, or revocation shall become effective twenty days after notice is complete, unless the Program submits a timely request for a hearing; provided, however, that a Program registration may be suspended immediately, prior to a hearing, upon a written finding set forth in the notice that the public health, safety, or welfare imperatively require emergency action. All hearing requests must be delivered to and received by the Director of the Syringe Services Program no later than thirty days after notice is complete.

(c) The Department shall refer a timely request for a hearing to the Office of State Administrative Hearings within thirty days after receipt, unless the Department and the Program agree otherwise. After thirty days from the Department's receipt of the hearing request, the Program may petition the Office of State Administrative Hearings for an order permitting the request to be filed directly with the Office of State Administrative Hearings.

(d) At least one year shall pass from the date of denial of an application before the Department will consider a new application for registration. At least two years shall pass from the date of revocation of a registration before the Department will consider a new application for registration; provided, however, that a Program whose registration was revoked for failure to renew may submit a new application prior to the expiration of the two-year waiting period.

Authority: O.C.G.A. §§ 16-13-32, 31-5-2, 50-13-13, 50-13-41.