INTRODUCTION

Numerous medical organizations and even the federal government itself now recommend that injection drug users employ a new, sterile syringe each time they inject.\(^1\) Unfortunately, the number of sterile syringes required to follow this standard -- approximately 1 billion\(^2\) -- exceeds the available supply by many millions. The continuing shortage of syringes contributes to the spread of HIV, and is thus a major health problem. Many commentators have suggested that the health care system can help increase access to safe injection equipment through prescription, pharmacy sales and other measures such as hospital or clinic-based needle exchange programs.

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This Memorandum assesses the legality, under Connecticut law, of physician prescription and pharmacy sale of injection equipment to patients who are known to be injecting illegal drugs. It assumes that ensuring a patient’s access to sterile injection equipment is clinically effective and conducive to public health, is ethical, and constitutes only one facet of the care the patient is receiving from the physician. These assumptions are justified and discussed in two companion reports: Zita Lazzarini, *Ethical Issues in Prescribing and Dispensing Syringes to Injection Drug Users*, and Josiah Rich, *Syringe Prescription in Rhode Island: A Case Study*. The risk of malpractice liability is discussed in a third companion piece, *Professional Liability in the Prescription and Dispensing of Sterile Injection Equipment to IDU Patients*, by Maxwell Mehlman.

We conclude that physicians may legally prescribe and pharmacists may legally dispense syringes to injection drug users (IDUs) as a health care intervention to prevent a patient acquiring or transmitting HIV.

This Memorandum addresses the following specific questions:

1) May a physician legally prescribe sterile injection equipment to an IDU patient?
2) May a pharmacist legally fill such a prescription?
3) How might Connecticut law be changed or clarified to promote access to sterile injection equipment for IDUs through the health care system?

I. May a Physician Legally Prescribe Sterile Injection Equipment to an IDU Patient?

Answering this question requires a two-step analysis. We determine first whether prescription of sterile injection equipment is consistent with the general law governing medical practice. If so, we then ask whether any other law, such as a drug paraphernalia provision, prohibits prescription of syringes to an IDU patient. We begin with an overview of the regulatory environment.

A. The Regulatory Scheme

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Medical Practice Law

The practice of medicine in Connecticut is governed by chapter 370 of Title 203, with regulations found in sections 19a-9 et seq. and 19a-14 et seq. in the Regulations of Connecticut State Agencies.\(^4\) The Act vests in the Commissioner of Public Health the power to adopt such regulations as are necessary to carry out the purposes of that Act, including standards of practice and standards of care for particular practice settings.\(^5\) Conn. Gen. Stat. Ann. §20-13b. The Connecticut Medical Examining Board has the authority to discipline licensed physicians who violate the accepted standard of care. Conn. Gen. Stat. Ann. §20-13c; Conn. Gen. Stat. Ann. §19a-17(a).

Connecticut medical licensure law is silent on the physician’s general authority to write prescriptions for or dispense drugs and devices. Leaving aside any limitations imposed by other laws, a physician is free to prescribe any drug or device she believes will benefit the patient and the prescription of which is consistent with the accepted standard of care.

Grounds for restriction, suspension or revocation of a physician's license include:

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(4) \text{illegal, incompetent or negligent conduct in the practice of medicine; } \\
(5) \text{possession, use, prescription for use, or distribution of controlled substances or legend drugs, except for therapeutic or other medically proper purposes} \\
(11) \text{violation of any provision of this chapter or any regulation established hereunder.}
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Conn. Gen. Stat. Ann. §20-13c. In addition to restricting, suspending or revoking a license, the Medical Examining Board may:

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(6) \text{Assess a civil penalty of up to ten thousand dollars; or} \\
(7) \text{Summarily take any action specified in this subsection against a practitioner's license or permit upon receipt of proof that such practitioner has been:}
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\(^4\) Osteopathic physicians are governed under Conn. Gen. Stat. Ann. §20-15 et seq., with regulations to be found at §19a-2a-24 et seq. As these are substantially similar to the rules governing allopaths, the osteopathic rules will not be further discussed.

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(A) Found guilty or convicted as a result of an act which constitutes a felony under (i) the laws of this state, (ii) federal law or (iii) the laws of another jurisdiction and which, if committed within this state, would have constituted a felony under the laws of this state; or

(B) Subject to disciplinary action similar to that specified in this subsection by a duly authorized professional agency of any state, the District of Columbia, a United States possession or territory or a foreign jurisdiction. The applicable board or commission, or the department shall promptly notify the practitioner or permittee that his license or permit has been summarily acted upon pursuant to this subsection and shall institute formal proceedings for revocation within ninety days after such notification.


A court will assess a practice alleged to be unprofessional and beneath the standard of acceptable care by considering what the practitioner has done in the particular circumstances, and by comparing his conduct with what reasonably prudent similar health care providers say should have been done. See generally Gibson v. Connecticut Medical Examining Board, 141 Conn. 218, 104 A.2d 890.6

Controlled Substances Law Generally

Every practitioner who prescribes, administers or dispenses any controlled substance within Connecticut must have a certificate of registration issued by the Commissioner of Consumer Protection.7 Conn. Gen. Stat. Ann. §21a-317. Additionally, prescribing powers are

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6 In the case of medical malpractice claims, Connecticut courts have stated:

The standard of care to be exercised by a physician in diagnosis and treatment . . . is well established. A physician is under a duty to his patient to exercise that degree of care, skill and diligence which physicians in the same general neighborhood and in the same general line of practice ordinarily possess and exercise in like cases. Further, the necessity for expert testimony as to this standard is also well established. Usually, proof of the breach of this duty must rest upon the testimony of an expert witness qualified to state what the particular standard of care requires and to express an opinion that the treatment accorded the patient failed to meet this standard.


7 Also, all health care practitioners who utilize controlled substances must do so consistent with the public interest. The following factors shall be considered in determining the public interest:

(a) Maintenance of effective controls against diversion of controlled substances into other
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(a) A physician, in good faith and in the course of the physician's professional practice only, may prescribe, administer and dispense controlled substances . . . for demonstrable physical or mental disorders but not for drug dependence except in accordance with state and federal laws and regulations adopted thereunder.


Although the Controlled Substances Act specifies that a prescription is required before dispensing a substance listed in schedules III through IV, the only other substantive requirements are that schedule V substances may only be dispensed for a medical purpose, and

(f) All prescriptions for controlled substances shall comply fully with any additional requirements of the federal food and drug laws, federal laws and regulations Part 306, U.S. Department of Justice, Bureau of Narcotics and Dangerous Drugs--Federal Register Volume 36 No. 80 et seq., and state laws and regulations adopted under this chapter.


The Controlled Substances Act sets out various other violations and penalties, including:

No person shall sell, prescribe, dispense, compound, process, deliver or administer to another person any restricted substance, except as authorized in this chapter . . .

than duly authorized legitimate medical, scientific, or commercial channels;
(b) Compliance with all applicable state and federal laws and regulations concerning controlled substances;
(c) Any conviction of the practitioner under any state or federal law relating to controlled substances;
(d) Expiration, suspension, revocation, surrender or denial of the practitioner's federal controlled substance registration;
(e) Prescribing, distributing, administering or dispensing of controlled substances in schedules other than those specified in the practitioner's state or federal registration.


(a) Any person who . . . sells, prescribes, dispenses, compounds . . . possesses with the intent to sell or dispense, offers, gives or administers to another person one or more preparations, compounds, mixtures or substances containing . . . heroin, methadone or cocaine . . . except as authorized in this chapter, and who is not, at the time of such action, a drug- dependent person, shall be imprisoned for a minimum term of not less than five years nor more than twenty years; and, a maximum term of life imprisonment. . . .

(b) Any person who . . . sells, prescribes, dispenses, compounds . . . offers, gives or administers to another person any narcotic substance, hallucinogenic substance . . . except as authorized in this chapter, and who is not at the time of such action a drug- dependent person, for a first offense shall be imprisoned not less than five years nor more than twenty years; and for each subsequent offense shall be imprisoned not less than ten years nor more than twenty-five years. . . .

Conn. Gen. Stat. Ann. §21a-278. Finally, the commissioner may suspend, revoke or refuse to

8 Lack of drug dependency is not an element of the offense of sale of narcotics by one who is not drug dependent; rather, drug dependency is an affirmative defense, an exemption from liability under this statute mandating a minimum five-year term, which defendant must prove by a preponderance of the evidence. State v. Jenkins, 41 Conn.App. 604, 679 A.2d 3(1996).

Harsher penalties also apply to:

(a) Any person eighteen years of age or older who violates section 21a-277 or 21a-278, and who is not, at the time of such action, a drug-dependent person, by distributing, selling, prescribing, dispensing, offering, giving or administering any controlled substance to another person who is under eighteen years of age and is at least two years younger than such person who is in violation of section 21a-277 or 21a-278, shall be imprisoned for a term of two years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278.

(b) Any person who violates section 21a-277 or 21a-278 by . . . selling, prescribing, dispensing, compounding . . . offering, giving or administering to another person any controlled substance in or on, or within one thousand five hundred feet of . . . a public or private elementary or secondary school, a public housing project or a licensed child day care center . . . shall be imprisoned for a term of three years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278. . . .

(c) Any person who employs, hires, uses, persuades, induces, entices or coerces a person under eighteen years of age to violate section 21a-277 or 21a-278 shall be imprisoned for
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renew a registration for the following grounds:

(2) conviction of a felony under any state or federal law relating to any controlled substance; (3) failure to maintain effective controls against diversion of controlled substances into other than duly authorized legitimate medical, scientific, or commercial channels; (4) the suspension, revocation, expiration or surrender of the practitioner's federal controlled substance registration . . . (6) the restriction, suspension, revocation or limitation of a professional license or certificate as a result of a proceeding pursuant to the general statutes . . . (8) possession, use, prescription for use or distribution of controlled substances or legend drugs, except for therapeutic or other proper medical or scientific purpose . . .

Conn. Gen. Stat. Ann. §21a-322. Because these provisions refer exclusively to controlled substances, these prescription standards do not explicitly apply to syringes and needles, but are useful by way of analogy.

Syringe Prescription Law

The Controlled Substances Act includes a specific provision restricting the sale of hypodermic needles and syringes:

a term of three years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278.

(a) A licensed manufacturer or licensed wholesaler may sell hypodermic needles and syringes only to the following: (1) To a licensed manufacturer, licensed wholesaler or licensed pharmacy; (2) to a physician, dentist, veterinarian, embalmer, podiatrist or scientific investigator licensed to practice in this state; (3) to a person in charge of a care-giving institution, as defined in subdivision (2) of section 20-571, incorporated college or scientific institution, but only for use by or in such care-giving institution, college or institution for medical or scientific purposes; (4) to a person in charge of a licensed or registered laboratory, but only for use in that laboratory for scientific and medical purposes; (5) to a farmer but only for use on the farmer’s own animals or poultry; (6) to a business authorized in accordance with the regulations adopted under section 21a-66 to purchase hypodermic needles and syringes but only for legitimate industrial or medical use within that business; and (7) to a needle and syringe exchange program established pursuant to section 19a-124.

(b) Except as provided in subsection (a) of this section, no . . . licensed pharmacist shall sell and no person shall buy a hypodermic needle or syringe except upon a prescription of a prescribing practitioner, as defined in subdivision (22) of section 20-571, in a quantity greater than ten. . . . Such a prescription shall be valid for one year from the date thereof and purchases and sales may be made thereunder during such period, provided the seller shall confirm the continued need for such sales with such practitioner at least every six months if sales continue to be made thereunder. Hypodermic needles and syringes in a quantity of ten or less without a prescription may be provided or sold at retail only by the following: (1) By a pharmacy licensed in accordance with section 20-594 and in such pharmacy only by a licensed pharmacist or under his direct supervision; (2) by a needle exchange program established pursuant to section 19a-124; and (3) by a health care facility or a licensed health care practitioner for use by their own patients.

(d) Any person who violates any provision of this section shall be fined not more than five hundred dollars or imprisoned not more than one year or both.


Drug Paraphernalia Law


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9 Additionally, under Conn. Gen. Stat. Ann. §21a-65(c), there are some storage, security, and product destruction guidelines for all locations where hypodermic needles and syringes are kept.
tri-partite definition of "drug paraphernalia." First, it defines drug paraphernalia generally as "equipment, products and materials of any kind which are used, intended for use or designed for introducing into the human body, any controlled substance contrary to the provisions of this chapter." Conn. Gen. Stat. Ann. §21a-240(20). Second, it lists ten types of items as examples of drug paraphernalia. Finally, it offers thirteen factors to be considered when determining whether an item is drug paraphernalia.

The statute once included hypodermic syringes and needles used, intended for use, or designed for use in parenterally injecting controlled substances into the human body in its list of items that can qualify as drug paraphernalia under some circumstances, but only in quantities greater than thirty. Conn. Gen. Stat. Ann. §§21a-240(20). However, the 2006 amendments to the statute redefined drug paraphernalia to exclude equipment and products intended for use in injecting controlled substances. Id. The statutory reference to thirty syringes was also deleted, and these amendments thus indicate that hypodermic syringes and needles no longer qualify as drug paraphernalia regardless of the quantity possessed.

B. Analysis

The first question is whether prescription of sterile injection equipment to IDU's is generally authorized under statutes governing medical practice. The syringe prescription law, Conn. Gen. Stat. Ann. §21a-65(b), prohibits selling or buying hypodermic needles or syringes in quantities greater than ten, without a prescription. This provision by its terms imposes no limits on a physician prescribing a syringe, and is premised on the legality of a physician writing such a prescription. Without any substantive restrictions on prescribing syringes, we must look to the general authority of physicians to prescribe.

Connecticut law nowhere sets out in positive terms the extent or basis of the physician’s general authority to write prescriptions for syringes or devices. This authority is assumed, as an aspect of the professional practice of medicine. The law and regulations governing the prescription of controlled substances and drugs, however, set out the standards that would almost certainly be borrowed by courts in a syringe prescription case. Under these laws, a prescription is valid if it is written (1) in good faith, (2) in the usual course of professional practice, and (3) for a legitimate medical purpose. See Levine, 17 Conn.App. 257, 551 A.2d 1271. All specified criteria must be satisfied for a prescription to be valid, and for the practitioner to fall within the exception. A prescription for sterile injection equipment, issued to a patient who cannot or will not enter drug treatment, for the purpose of preventing the transmission of a serious communicable disease during injection, would seem to be well within the parameters of allowable discretion set by this standard.

No cases in Connecticut have assessed the legality of a syringe prescription, let alone one to an IDU. In cases where a physician is being prosecuted for misprescribing controlled substances, the physician defendant was accused of being virtually a drug pusher. In one such
In determining whether a prescription arises within the usual course of professional practice, courts may consider such matters as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient's risk factors, efforts to provide other harm reducing services, follow up and so on. See generally United States v. Moore, 423 U.S. 122, 142-43, _ 96 S.Ct. 335, 345("The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of "professional practice." As detailed above, he gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher" not as a physician.") Ultimately, what constitutes the usual course of professional practice is "a matter of credibility of the defendant's testimony." Liebowitz, 7 Conn.App. at 415, 509 A.2d at 50. A physician who is providing syringes to a patient who cannot or will not enter drug treatment, and whose injection drug use places him at high risk of contracting or spreading a communicable disease, should have no difficulty satisfying this prong of the prescription standard. It would be difficult to argue that providing sterile injection equipment falls beneath the minimal standards of professional practice set forth in the medical practice act.

On the final prong, there will certainly be some physicians who contend that prescribing injection equipment to an IDU patient is not a legitimate medical practice. Generally, however, courts in other jurisdictions applying this standard do not require unanimity. See, e.g., Glover v. Board of Medical Quality Assurance, 231 Cal.App.3d 203, 282 Cal.Rptr. 137 (1991); Commonwealth v. Salameh, 421 Pa.Super. 320, 324, 617 A.2d 1314, 1316 (1992) (prosecution must prove not simply that some physicians disagree with the practice at issue, but that "'no' responsible segment of the medical profession exists which accepts appellant's methods"). See generally S.E. Stone, The Investigation and Prosecution of Professional Practice Cases under the Controlled Substances Act: Introduction to Professional Practice Case Law. 21 Drug Enforcement 23 (1983). There is ample support for the position that prescribing sterile injection equipment comports with treatment principles accepted by a responsible segment of the medical profession. See Zita Lazzarini, Ethical Issues in Prescribing and Dispensing Syringes to Injection Drug Users, and Josiah Rich, Syringe Prescription in Rhode Island: A Case Study.
Conclusion: A prescription for sterile injection equipment to an IDU patient is consistent with the standard for a valid prescription under the medical practice act and the prescription provision of the Controlled Substances Act.

We turn now to the second question: Do any other laws prohibit physicians from prescribing sterile injection equipment to IDU patients? There are two possibilities.

The first possibility is the Controlled Substances Act's prescription guidelines which state that a physician may prescribe, in good faith and in the course of the professional practice only, "for demonstrable physical or mental disorders but not for drug dependence except in accordance with state and federal laws and regulations." Conn. Gen. Stat. Ann. §21a-252(a). There are only three reported cases discussing this provision, none with a holding on point here. The statute may be raised by opponents of physician prescription as support for the argument that the legislature intended to prevent access to controlled substances for illicit use even when providing those substances for unquestionably legitimate medical purposes. By analogy, this would be offered as support for the proposition that the paraphernalia scheme should be read to bar any prescription or dispensing of needles in large amounts to users, regardless of medical need.

The argument is one by analogy only. Syringes are not classified as controlled substances. Indeed, both the medical practice and controlled substances act to which §21a-252(a) refers do not include devices such as syringes in their definitions of controlled substances and drugs. By confining this provision to controlled substances, the legislature deliberately excluded other devices, such as syringes. Because the literal terms of the statute exclude syringes from coverage, the mere fact that the statute prohibits an arguably analogous act is insufficient to justify interpreting it to actually cover syringe prescription.

Conclusion: Writing a prescription for a syringe does not violate Connecticut law. A physician may legally prescribe injection equipment to an IDU patient.

II. May a Pharmacist Legally Fill a Such a Prescription?

A. The Regulatory Environment

Pharmacy Licensure Law

The practice of pharmacy in Connecticut is governed by the Pharmacy Practice Act, Conn. Gen. Stat. Ann. §20-570 et seq., with regulations found in sections 20-576-1 et seq. in the Regulations of Connecticut State Agencies. The Act, which is controlled by the Department of Consumer Protection, creates a Commission of Pharmacy with the ability to enforce the Act. Conn. Gen. Stat. Ann. §20-572. Additionally, the Commission of Pharmacy may advice and assist the Commissioner of Consumer Protection on promulgating regulations necessary to carry
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The Pharmacy Act authorizes the suspension or revocation of a license if the pharmacist:

(1) Has violated a statute or regulation relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (2) has been convicted of violating any criminal statute relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (3) has been disciplined by, or is the subject of pending disciplinary action or an unresolved complaint before, the duly authorized pharmacy disciplinary agency of any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (4) has been refused a license or registration or renewal of a license or registration by any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction based on grounds that are similar to grounds on which Connecticut could refuse to issue or renew such a license or registration; (5) has illegally possessed, diverted, sold or dispensed drugs or devices . . . (13) has performed or been a party to a fraudulent or deceitful practice or transaction . . . (15) has performed incompetent or negligent work . . .

Conn. Gen. Stat. Ann. §20-579(a). The commission may also assess a civil penalty of up to one thousand dollars for violations of this section.

A pharmacist is authorized to dispense medications ordered by a valid prescription, and is ordinarily expected to do so in the absence of a good reason to refuse. Strauss S. The Pharmacist and the Law. Baltimore MD: Williams & Wilkins, 1980:29-31; Steven W. Huang, The Omnibus Reconciliation Act of 1990: Redefining Pharmacists’ Legal Responsibilities, XXIV Am. J. L & Med. 417 (1998). None of the regulations dealing with the practice of pharmacy are relevant to this Memorandum.

Controlled Substance and Drug Paraphernalia Laws

The controlled substances and paraphernalia provisions discussed in I.A. above are also applicable to pharmacists. The Controlled Substances Act sets out the duties of a dispensing pharmacist, including this one of relevance to this Memorandum.

(a) A pharmacist, in good faith, may sell and dispense controlled substances to any
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person upon a prescription of a physician . . .


Syringe Prescription Law

The syringe prescription law set out in I.A. above applies most directly to pharmacists, because by its terms it regulates the syringe at the point of sale. In addition to requiring a prescription for sale of more than ten syringes, it also regulates the display and disposal of syringes. 11

B. Analysis

We have concluded above that a physician’s prescription for sterile injection equipment, written under the factual conditions assumed for purposes of this Memorandum, is valid under Connecticut law, including the prescription section of the Controlled Substances Act. The syringe prescription provision does not set any additional substantive standards for a syringe prescription, but rather simply requires a prescription as a condition of sale of over ten syringes. Sale of syringes in quantities ten and under have no restrictions whatsoever. Ordinarily, the pharmacist is required to fill a valid prescription. 12 The regulatory exceptions related to prescriptions for controlled substances or prescriptions that threaten the health and safety of the patient are not applicable. The 2006 amendments to the paraphernalia law remove syringes from the definition of drug paraphernalia and so eliminate the paraphernalia law as a barrier to dispensing them to IDUs. Conn. Gen. Stat. Ann. § 21a-240 (20)(A)(ix).

Conclusion: Dispensing syringes to an IDU by prescription does not violate Connecticut law.

III. How Might Connecticut Law Be Changed or Clarified to Promote Access to Sterile

11 (c) At all locations where hypodermic needles and syringes are kept they shall be stored in a manner so as to be available only to authorized personnel and not be openly available to customers or patients. All used, disposable hypodermic needles and used, disposable syringes shall be destroyed. Destruction shall be conducted in a manner which renders such needles and syringes nonrecoverable. Used needles and syringes which have been discarded and are awaiting destruction shall be securely safeguarded or rendered nonreusable. Conn. Gen. Stat. Ann. §21a-65.

12 A pharmacist presumably could refuse to fill a syringe prescription under Conn. Gen. Stat. Ann. §21a-250 if he believed that the prescription was unlawful.
Injection Equipment for IDUs Through the Health Care System?

This Memorandum has concluded that physicians may arguably prescribe and pharmacists may dispense sterile injection equipment to IDUS as a health-care intervention to prevent the transmission of blood-borne pathogens. Nevertheless, several legal measures would add clarity to the legal situation or otherwise protect public health by enhancing access to safe injection equipment.

1. The General Assembly should amend the Controlled Substances Act to legalize the over-the-counter sale of injection equipment without prescription or any numerical limitation.