

COMMONWEALTH OF MASSACHUSETTS  
SUPREME JUDICIAL COURT

BARNSTABLE, SS

NO. SJC-12224

---

AIDS SUPPORT GROUP OF CAPE COD, INC.,  
Plaintiff-Appellant,

v.

TOWN OF BARNSTABLE, BOARD OF HEALTH OF THE TOWN OF  
BARNSTABLE, and THOMAS MCKEAN, in his official Capacity as  
Director of Public Health  
of the Town of Barnstable,  
Defendants-Appellees.

---

REPLY BRIEF OF THE APPELLANT  
AIDS SUPPORT GROUP OF CAPE COD, INC.

---

Andrew Musgrave  
BBO # 678980  
AIDS Action Committee  
of Massachusetts  
75 Amory Street  
Boston, MA 02119  
[amusgrave@aac.org](mailto:amusgrave@aac.org)  
(617) 437-6200

Bennett H. Klein  
BBO # 550702  
GLBTQ Legal Advocates  
& Defenders  
30 Winter Street, Suite 800  
Boston, MA 02108  
[bklein@glad.org](mailto:bklein@glad.org)  
(617) 426-1350

**TABLE OF CONTENTS**

TABLE OF CONTENTS.....i

TABLE OF AUTHORITIES.....ii

REPLY.....1

CONCLUSION.....14

CERTIFICATE OF COMPLIANCE.....15

CERTIFICATE OF SERVICE.....16

ADDENDUM.....following 16

**TABLE OF AUTHORITIES**

**Cases**

Holyoke City Council vs. City of Holyoke,  
Hampden County Superior Court, Civil Action  
No. 12-0837, Order on Defendant’s Motions to  
Reconsider Order on Cross-Motions for Summary  
Judgment, April 20, 2016.....12-13

Holyoke City Council vs. City of Holyoke,  
Hampden County Superior Court, Civil Action  
No. 12-0837, Order on Defendant’s Motion to  
Vacate the Judgement as Moot, to Revise Said  
Order, and for Reconsideration of the Order  
on Cross-Motions for Summary Judgement,  
June 15, 2016.....13

**Statues and Regulations**

G. L. c. 94C, § 27.....passim

G. L. c. 94C, § 27A.....13

G. L. c. 94C, § 32I (d).....10

G. L. c. 111, § 215.....passim

G. L. c. 138, § 34.....4

St. 2006, c. 172.....passim

St. 2006, c. 172, § 3.....4, 8

105 Code of Mass. Regs. § 700.008.....8, 9-10

130 Code of Mass. Regs. § 409.402.....3

130 Code of Mass. Regs. § 409.416.....3

**Other Authorities**

Amendment 77 to H.3944, 189th General Ct. (Ma. 2016)  
(withdrawn),  
[https://malegislature.gov/Bills/189/H3944/  
Amendments/House?pageNumber=4&direction=  
&sortColumn=](https://malegislature.gov/Bills/189/H3944/Amendments/House?pageNumber=4&direction=&sortColumn=).....11

Memorandum to Commissioner Monica Bharel, MD and  
Members of the Public Health Council from Eric  
Sheehan, Interim Director, Bureau of Health Care  
Safety and Quality, dated June 8, 2016.....9

**REPLY**

Under Massachusetts law, it is lawful to possess a hypodermic needle. It is lawful to use one. And it is also lawful to give a hypodermic needle to another person. That is what the staff at AIDS Support Group of Cape Cod's ("ASGCC") Hyannis location was doing when the appellees, Town of Barnstable, et al. (the "Town"), served the cease and desist orders at issue in this case.

All of these activities are lawful because the Legislature in 2006 addressed the public health crisis of HIV and Hepatitis C Virus (HCV) transmission among people who inject drugs by removing hypodermic needles from the definition of drug paraphernalia, and repealing the entire statute that previously had proscribed their possession, delivery, and exchange.<sup>1</sup> In the context of this total repeal, the Legislature has maintained only two precisely specified limits: that "needle exchange programs" that are "implemented" by the Department of Public Health receive local board

---

<sup>1</sup> See St. 2006, c. 172 which repealed G. L. c. 94C, § 27 in its entirety. ASGCC has set out in detail the text and citations for the repealed provisions of G. L. c. 94C, § 27 at pp. 18-22 of its opening brief and will not repeat the specific citations in this reply.

of health approval; and that syringes may be sold only by pharmacists to people over the age of 18. See G. L. c. 111, § 215; G. L. c. 94C, § 27. This Court must adhere to these unambiguous legislative determinations.

The Town does not, and cannot, point to any language in either G. L. c. 111, § 215 or G. L. c. 94C, § 27 that prohibits a person in Massachusetts from possessing a syringe and giving it to another person. The Town, however, rests its entire argument on the claim that Massachusetts law does prohibit one person from giving a syringe to another person; it asserts that "only two outlets are authorized by the 2006 legislation to distribute and possess needles and syringes ... formal needle exchange programs and pharmacies." See Town Brief at 6; 7 (Argument heading). The unavoidable implication of the Town's position is that an individual could not purchase a hypodermic needle and bring (i.e., distribute or "deliver") it to an elderly, housebound neighbor with diabetes. That conclusion cannot stand in the face of the Legislature's sweeping changes to Massachusetts law in 2006.

The Town's unfounded position that the provision of lawfully purchased hypodermic needles can only be undertaken by the Department of Public Health or a pharmacist reveals four errors.<sup>2</sup> First, the Town maintains that an activity is only lawful if the Legislature has affirmatively pronounced that it is permitted.<sup>3</sup> That is simply not how our system of law works. Regardless, the Legislature hardly needed to make an affirmative pronouncement that it is lawful to

---

<sup>2</sup> Before addressing the Town's argument, it should be noted that the Town opened and closed its brief by raising the issue of publicly discarded needles, and falsely asserting the easy availability of hypodermic needles through local pharmacies. These issues are not before the Court and were fully vetted at the preliminary injunction hearing in which the trial judge heard testimony from ten witnesses, including ASGCC's infectious disease expert. See Addendum to Appellant's Brief at 16-17 (noting the "miniscule" risk of harm from publicly discarded needles and observing that the Town and ASGCC are undertaking the proper public health steps to address the issues); at 15 (crediting testimony that pharmacies are not an adequate means of syringe access for people who inject drugs). See also Brief of Amici Curiae Massachusetts Infectious Diseases Society, et al. at 21, 29, 40-43; 130 Code Mass. Regs. §§ 409.402 and 409.416 (syringes are provided by MassHealth through coverage for durable medical supplies that require a prescription and letter of medical necessity).

<sup>3</sup> See, e.g., Town Brief at 6, n.7 ("the Town could find no reference whatsoever in the legislative history indicating that the repeal of the "old § 27" coupled with the passage of the 2006 legislation would allow the unfettered non-sale distribution of needles and syringes by any individual or entity"); 18, 22 (same).

possess and distribute hypodermic needles when it repealed all of the prohibitions of such activity and replaced them with two specific and clear limitations.

Second, the Legislature has demonstrated that it knows how to establish an exclusive limitation on the availability of hypodermic needles when it intends one. In 2006, the Legislature replaced the prior G. L. c. 94C, § 27 with a single paragraph providing, in relevant part, that: "Hypodermic syringes or hypodermic needles for the administration of controlled substances by injection may be sold in the commonwealth, but only to persons who have attained the age of 18 years and only by a pharmacist." St. 2006, c. 172, § 3 (emphasis added). The Legislature did not establish either in G. L. c. 94C, § 27, G. L. c. 111, § 215, or any other statute, a similar exclusivity provision regarding who may deliver, distribute, or exchange hypodermic needles or the age of the recipient. If the Legislature had intended to place any restriction on further distribution of a hypodermic needle after purchase, it would have provided one.<sup>4</sup>

---

<sup>4</sup> See, e.g., G. L. c. 138, § 34 (creating express prohibition on "furnish[ing]" alcohol to a person

Third, the Town uses the phrase "needle exchange program" throughout its brief imprecisely as a generic phrase. The only use of that phrase in any statute, however, is in G. L. c. 111, § 215 which references a "needle exchange program" that is "implement[ed]" by the Department of Public Health. The Legislature has created a clear and unambiguous line: only such state-operated programs require local board of health approval. In contrast, this Court would create a framework fraught with confusion and chaos if it required a determination of when an otherwise lawful activity in which one person possesses and gives a hypodermic needle to another person becomes transformed into an entity subject to the restrictions of G. L. c. 111, § 215. Assume, for example, that Person A goes to the pharmacy, buys 20 syringes, and gives them to other people. That person has not violated Massachusetts law. Person A's friends, Persons B, C and D, realize that handing out clean needles is a good way to prevent the transmission of deadly diseases, and decide to join in. The addition

---

under 21 years of age and stating that "the word 'furnish' shall mean to knowingly or intentionally supply, give, or provide to or allow a person under 21 years of age ... to possess alcoholic beverages").

of three more people to a lawful activity can hardly transform it into a "needle exchange program" under § 215. Then Persons A, B, C and D, decide to take back the dirty needles and dispose of them in biohazard receptacles. There is nothing in Massachusetts law that prohibits that. Can properly disposing of needles be the determinative factor in transforming Person A, B, C and D's activities into a § 215 "needle exchange program"? That can hardly be the case because the Legislature in 2006 specifically removed the prohibition on the "exchange" of needles. If that were the determinative factor, would Persons A, B, C and D no longer be a § 215 program if they ceased taking back the dirty needles and properly disposing of them? The Legislature cannot have intended that result which is so contrary to the public health. Suppose then that Persons A, B, C and D, seeing the life-saving benefits of their activities, decide to rent an office space. The use of a physical structure to undertake an otherwise lawful activity cannot be determinative either.

Further complicating these scenarios, G. L. c. 111, § 215 does not define the features of a "needle exchange program." The Legislature left that

up to the Department of Public Health. Assume that the Department of Public Health decided to change the features of its own § 215 needle exchange programs. Some activities that previously did not resemble Department of Public Health programs might suddenly be swept into § 215's requirements, while other activities might instantaneously be relieved of § 215's requirements.

The Legislature drew a bright line: A "needle exchange program" subject to local board of health approval under § 215 is a "needle exchange program" that is "implement[ed]" by the Department of Public Health. See G. L. c. 111, § 215. It does not matter that the Court may not be able to discern the Legislature's precise reasoning for establishing a requirement for state-operated programs, nor is it for the Court to second-guess the Legislature's choice. Any attempt to determine what other activities might or might not trigger § 215's requirements is unworkable and finds no support in any statutory language.

Fourth, in the absence of any statutory restriction that applies to ASGCC's activities in Hyannis, the Town asks this Court, in effect, to infer

one. This Court has repeatedly stated that it does not infer or add provisions to statutory language that the Legislature has not put there.<sup>5</sup> The Town is plain wrong when it asserts that pharmacists are the "gatekeeper[s]" of the "distribution of hypodermic needles." Town Brief at 10-11. G. L. c. 94C, § 27 speaks only to the sale of needles. The tangential, and even repealed, sources that the Town references hardly provide a basis for the extraordinary step of inferring a restriction where none exists. The Town, for example, points the Court to 105 Code Mass. Regs. 700.008. See Town Brief at 11-13. The operative language of that regulation, however, was repealed by St. 2006, c. 172, § 3. The regulation provides:

(A) License "to sell". No person except a registered physician, dentist, nurse, veterinarian, embalmer, pharmacist, wholesale druggist, or a registered podiatrist certified by the Board of Registration in Podiatry to be competent to use hypodermic needles, shall sell, offer for sale, deliver or have in possession with intent to sell hypodermic syringes, hypodermic needles or any instrument adapted for the administration of controlled substances by injection, unless licensed to do so by the Department.

105 Code Mass. Regs. 700.008 (emphasis added).

---

<sup>5</sup> See ASGCC's Opening Brief at pp. 15-18.

The text of G. L. c. 94C, § 27 (e) as it existed prior to 2006, and repealed by St. 2006, c. 172, provided:

(e) No person except a manufacturer of or dealer in surgical supplies, a manufacturer of or dealer in embalming supplies, a pharmacist or wholesale druggist, which pharmacist or wholesale druggist is licensed under the provisions of chapter one hundred and twelve, shall sell, offer for sale, deliver, or have in possession with intent to sell hypodermic syringes, hypodermic needles or any instrument adapted for the administration of controlled substances by injection, unless licensed so to do by the department.

See Addendum to ASGCC's Opening Brief at 27 (emphasis added). As the regulation that the Town points to simply repeated statutory language that has been repealed, it cannot illuminate the current scope of Massachusetts law with respect to the distribution of hypodermic needles and syringes.<sup>6</sup>

---

<sup>6</sup> The Department of Public Health is in the process of deleting 105 Code Mass. Regs. 700.008 as part of a directive to update and remove outdated regulations. See Memorandum to Commissioner Monica Bharel, MD and Members of the Public Health Council from Eric Sheehan, Interim Director, Bureau of Health Care Safety and Quality, dated June 8, 2016 (Addendum to this Brief at 1, 3). Further, the memorandum makes clear that the purpose of 105 Code Mass. Regs. 700.008 prior to legislative change in 2006 was not, as the Town asserts, to license pharmacists generally to sell hypodermic needles, but to "permit[] pharmacists and prescribers to also obtain a license to sell

Next, the Town points to a sentence in the current drug paraphernalia law which provides that: "This section shall not apply to the sale of hypodermic syringes or hypodermic needles to persons over the age of 18 pursuant to section 27." G. L. c. 94C, § 32I (d); Town Brief at 13-14. This avails the Town of nothing as § 27 applies only to the sale of hypodermic needles and not their distribution. It is hardly a basis to write into § 27 a blanket prohibition on distribution by anyone other than pharmacists or the Department of Public Health.

The Town then points to legislative efforts to repeal G. L. c. 111, § 215, and the 2016 amendment that specified the form of local approval required by § 215 to be approval by a board of health. Town Brief at 19-21. It claims that these legislative actions are an indication "that there are only two approved means of needle and syringe distribution in the Commonwealth," and "a direct, negative legislative response to the argument for unfettered rights of distribution." Town Brief at 6, 21. This assertion, however, cannot overcome the lack of any language in

---

hypodermic needles and syringes without a prescription." Id. at 3.

Massachusetts law restricting delivery, exchange, or distribution by individuals or entities other than the Department of Public Health, the result of the repeal of such restrictions. G. L. c. 111, § 215 does not address, and has never addressed, the legality or illegality of the distribution by individuals or of hypodermic needles. The only statute that made the distribution of needles illegal was G. L. c. 94C, §27, as it existed prior to 2006, and that statute has been repealed. Legislative initiatives to eliminate or reduce barriers to the Department of Public Health's own programs are hardly a basis to infer restrictions on others.<sup>7</sup>

Finally, the Town places great emphasis on the summary judgement decision of the Superior Court in

---

<sup>7</sup> In 2016 there was also proposed legislation that assumed the current legality of the distribution of hypodermic needles by non-Department of Public Health entities and sought to prohibit it. See Amendment 77 to H.3944, 189th General Ct. (Ma. 2016) (withdrawn), <https://malegislature.gov/Bills/189/H3944/Amendments/House?pageNumber=4&direction=&sortColumn=>, (seeking to amend G. L. c. 111, § 215 to provide that "the distribution of hypodermic needles or syringes is otherwise prohibited except as part of a program authorized by the Department of Public Health and approved by the local board of health") (Addendum to this Brief at 5). The history of legislative proposals to § 215 is irrelevant, but, in any event, is at best equivocal.

Holyoke City Council vs. City of Holyoke. See Town Brief at 14-17. The Town misstates the issue and quotes the decision out of context. That case did not raise the issue before the Court here. Rather, that case involved a dispute about the proper municipal authorization for a needle exchange program implemented by the Department of Public Health pursuant to G. L. c. 111, § 215. See Addendum to Town Brief at 45. The trial judge was using the term "needle exchange program" in that context and ruled that G. L. c. 94C, § 27 did not obviate the need for local approval of a Department of Public Health program. Addendum to Town Brief at 52. In two subsequent orders that the Town did not provide to this Court, the trial judge clarified that he was not addressing the issue of the distribution of needles outside of a program implemented by the Department of Public Health as that issue was not before him. See Holyoke City Council vs. City of Holyoke, Hampden County Superior Court, Civil Action No. 12-0837, Order on Defendant's Motion to Reconsider Order on Cross-Motions for Summary Judgment, April 20, 2016 ("The Tapestry program was established pursuant to G. L. c. 111, § 215 ... Notably, the question of whether a

different entity would be duly authorized pursuant to G. L. c. 94C, §§ 27, 27A is not before me.”) (Addendum to this Brief at 6-7); Order on Defendant’s Motion to Vacate the Judgment as Moot, to Revise Said Order, and for Reconsideration of the Order on Cross-Motions for Summary Judgment, June 15, 2016 (repeating the issue in that case, but noting that “[n]either the plain language nor the legislative histories of G. L. c. 111, § 215 and G. L. c. 94C, §§ 27, 27A, nor the case law interpreting those statutes require that an entity compliant with G. L. c. 94C, §§ 27, 27A also comply with the requirements of G. L. c. 111, § 215.”) (Addendum to this Brief at 9-10).

When the Legislature repealed the prohibitions on the “delivery” or “exchange” of hypodermic needles in 2006, G. L. c. 111, § 215 was already in place. If this Court were to interpret St. 2006, c. 172 as limiting the distribution of hypodermic needles solely to the Department of Public Health’s programs under § 215, then the repeal of the prohibitions on “delivery” and “exchange” would have done nothing to increase the availability of hypodermic needles. To the contrary, the sweeping repeal in 2006 indicates the Legislature’s intent to drastically change

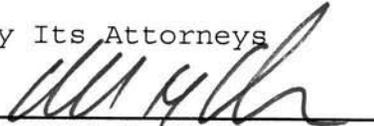
Massachusetts law in the face of the epidemics of HIV and Hepatitis C. The Town's severely restrictive reading of G. L. c. 111, § 215 and G. L. c. 94C, § 27 is contrary to the plain meaning of these statutes, the repeal effectuated in St. 2006, c. 172, and the Legislature's public health goal to make hypodermic needles easily and widely accessible throughout the Commonwealth.

#### **CONCLUSION**

For the foregoing reasons, and for the reasons set forth in ASGCC's opening brief, this Court should enter, or direct the trial court to enter: (1) a declaration that the cease and desist orders dated September 22, 2015 and September 23, 2015 are unlawful, and that Massachusetts law permits, without condition or restriction, the non-sale distribution of hypodermic needles and syringes by any private individual or entity; and (2) an order permanently enjoining enforcement of the cease and desist orders dated September 22, 2015 and September 23, 2015.

Appellant AIDS Support Group  
of Cape Cod

By Its Attorneys

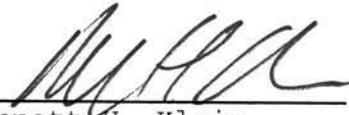
  
Bennett H. Klein  
BBO # 550702  
GLBTQ Legal Advocates &  
Defenders  
30 Winter Street, Suite 800  
Boston, MA 02108  
[bklein@glad.org](mailto:bklein@glad.org)  
(617) 426-1350

Andrew Musgrave  
BBO # 678980  
AIDS Action Committee of  
Massachusetts  
75 Amory Street  
Boston, MA 02119  
[amusgrave@aac.org](mailto:amusgrave@aac.org)  
(617) 437-6200

January 31, 2017

**CERTIFICATE OF COMPLIANCE**

I hereby certify that the foregoing brief complies with the rules of court that pertain to the filing of briefs, including, but not limited to, Mass. R. A. P. 16 (e) (references to the record); Mass. R. A. P. 16 (f) (reproduction of statutes, rules and regulations); Mass. R. A. P. 16 (h) (length of briefs); Mass. R. A. P. 20 (form of briefs, appendices and other papers).

  
Bennett H. Klein

January 31, 2017

CERTIFICATE OF SERVICE

I hereby certify that I, on January 31, 2017, served the foregoing document by email and by mailing two copies, postage prepaid, to Charles S. McLaughlin, Jr. and Ruth J. Weil, Counsel for Defendants-Appellees, Town of Barnstable et al., 367 Main Street, Hyannis, MA 02601.

  
\_\_\_\_\_  
Bennett H. Klein

January 31, 2017

# **ADDENDUM**

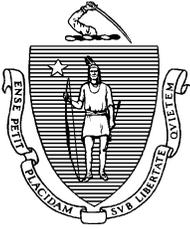
**TABLE OF CONTENTS**

Memorandum to Commissioner Monica Bharel, MD and  
Members of the Public Health Council from Eric  
Sheehan, Interim Director, Bureau of Health Care  
Safety and Quality, dated June 8, 2016.....1

Amendment 77 to H.3944, 189th General Ct. (Ma. 2016)  
(withdrawn),  
[https://malegislature.gov/Bills/189/H3944/  
Amendments/House?pageNumber=4&direction=  
&sortColumn=](https://malegislature.gov/Bills/189/H3944/Amendments/House?pageNumber=4&direction=&sortColumn=).....5

Holyoke City Council vs. City of Holyoke,  
Hampden County Superior Court, Civil Action  
No. 12-0837, Order on Defendant’s Motions to  
Reconsider Order on Cross-Motions for Summary  
Judgment, April 20, 2016.....6

Holyoke City Council vs. City of Holyoke,  
Hampden County Superior Court, Civil Action  
No. 12-0837, Order on Defendant’s Motion to  
Vacate the Judgement as Moot, to Revise Said  
Order, and for Reconsideration of the Order  
on Cross-Motions for Summary Judgement,  
June 15, 2016.....9



The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER  
Governor

KARYN E. POLITO  
Lieutenant Governor

MARYLOU SUDDERS  
Secretary

MONICA BHAREL, MD, MPH  
Commissioner

Tel: 617-624-6000  
[www.mass.gov/dph](http://www.mass.gov/dph)

To: Commissioner Monica Bharel, MD and Members of the Public Health Council

From: Eric Sheehan, Interim Director, Bureau of Health Care Safety and Quality

Date: June 8, 2016

RE: Informational Briefing on Proposed Amendments to 105 CMR 700.000 (*Implementation of M.G.L. c. 94C*)

---

## I. Introduction

The purpose of this memorandum is to provide the Public Health Council (PHC) with information about proposed amendments to 105 CMR 700.000, *Implementation of M.G.L. c. 94C*.

The Bureau of Health Care Safety and Quality's (BHCSQ) Drug Control Program (DCP), within DPH, drafted these amendments to its regulations to update the regulations as part of the regulatory review process, mandated by Executive Order 562, which requires the Department of Public Health (DPH), and all other state agencies, to undertake a review of each and every regulation currently published in the Code of Massachusetts Regulations under its jurisdiction.

The proposed amendments to this regulation will remove outdated definitions and terms and incorporate plain language principles to increase readability and understanding; create consistency with new and evolving areas of law, including mobile integrated health and immunizations; reflect appropriate professional titles for certain advanced practice nurses; remove outdated registration requirements; bolster security requirements to prevent tampering; modernize the regulation of hypodermic needles and human research subjects; and update provisions of the Prescription Monitoring, as they have been amended by Chapter 52 of the Acts of 2016, *An Act relative to Substance Use, Treatment, Education and Prevention*.

## II. Proposed Regulation

### Updated language and references

The proposed amendments delete definitions that are not used in the regulations and update the language throughout.

In the definitions section we propose inserting a definition for “Prescription” which is used throughout the regulations but was not previously defined. The proposed definition is “Prescription means an order for medication which is dispensed to or for an ultimate user. A prescription does not mean an order for medication which is dispensed for immediate administration to the ultimate user.”

### **Mobile Integrated Health Care**

The proposed regulations amend definitions and amend 700.003(A) to reflect the new Mobile Integrated Health (MIH) Care statute. These changes reflect the 2015 statutory language for MIH programs and in the future will allow paramedics and EMTs who work for Department-approved MIH and Community EMS programs to administer controlled substances in accordance with the clinical protocols of Department-approved MIH programs or community EMS programs pursuant to M.G.L. c. 111O. The amendments also reflect that M.G.L. c. 111O permits paramedics employed by MIH or Community EMS programs to provide immunizations as authorized by clinical protocols.

### **Immunizations**

We have updated the section on immunizations to reflect a statutory change that pharmacist interns, as well as pharmacists, can administer the influenza vaccine and other immunizations pursuant to the order of a practitioner. This section also changed the age so that pharmacists are permitted to administer immunizations to any person, 9 years of age or older. Adolescents tend not to access primary care providers at the same frequency as younger children and as a result may not be fully immunized according to the recommended schedule. Permitting pharmacists and pharmacist interns to provide immunization to children from ages nine to 17 will lead to increased access to immunization services and increased immunization rates. At the same time, in order to ensure that children continue to have a relationship with a primary care provider, the regulations also require pharmacists, if they provide childhood immunizations other than the influenza vaccine, to counsel families on the importance of establishing a relationship with a pediatric or family practice for ongoing medical and well-child care. Finally, this section was updated to require pharmacies that provide immunizations to disclose whether they receive vaccines free of charge through the Massachusetts Immunization Program and to notify patients that there may be a difference in cost between immunization services provided at a pharmacy and at a primary care provider’s office.

### **Advance practice nurses and physician assistants**

Throughout the regulation we updated the language to reflect the appropriate professional titles for certain advanced practice nurses: Certified Nurse Practitioners, Certified Registered Nurse Anesthetists, and Psychiatric Clinical Nurse Specialists. In addition, we propose updating 700.004(H) to require advanced practice nurses and physician assistants to include a copy of the guidelines, mutually agreed upon by the advanced practice nurse or physician assistant and their supervising physician, under which they practice, and to notify the Department no later than the next business day after the termination of employment, change in address of where they practice,

or change of supervising physician. These changes will ensure that the Department has necessary information regarding their prescriptive practice.

### **Delete Outdated Registration Requirements**

We propose to delete 105 CMR 700.004(M), which states that a person’s DEA registration number and Massachusetts registration number shall be the same number. This does not reflect practice: these registration numbers are different.

### **Security Requirements**

We propose adding the requirement that registrants report suspected tampering of controlled substances to the Department, as well as theft or loss. Tampering is a form of theft or loss of controlled substances, and this change clarifies that the Department does expect registrants to report suspected tampering as well as other forms of theft or loss.

In addition, we propose updating the reporting requirements, which were outdated and inaccurate. These updates will clarify the Department’s reporting requirements, which will make it easier for registrants to comply.

### **Requirements Regarding Hypodermic Instruments**

We propose deleting 105 CMR 700.008, Requirements Regarding Hypodermic Instruments. Hypodermic needles and syringes can be sold by pharmacists pursuant to a valid prescription. This section permitted pharmacists and prescribers to also obtain a license to sell hypodermic needles and syringes without a prescription. This regulation is outdated because in 2006, M.G.L. c. 94C, §32I was amended to decriminalize the possession of hypodermic needles and c. 94C, § 27 was amended to allow the sale of hypodermic needles and syringes to anyone 18 or older, by a pharmacist; dealer in surgical supplies; or manufacturer of or dealer in embalming supplies. Due to those statutory changes, this regulation is outdated and unnecessary.

### **Research Involving Controlled Substances**

We propose amending 105 CMR 700.009 to address the need for accountability and control of controlled substances and protection of human subjects without unnecessary duplication of existing rules governing research. Much of this section of the regulations mirrored the federal human subject protection rule and is therefore duplicative of rules already imposed on researchers. Among the proposed changes we amended 105 CMR 700.009(A) to clarify that any investigational use on human beings of any drug requires registration with the Department.

The regulations continue to require researchers to provide evidence that they comply with applicable federal laws, that they produce a statement of informed consent for all human subjects, and that they comply with the requirements for the protection of human research subjects by an Institutional Review Committee. We propose eliminating the following subsections: “Protection of Human Subjects,” “Assurance by Institutional Review Committee,”

Institutional Review Committee,” and “Protocol” because these subsections reiterate federal obligations for the protection of human subjects and are unnecessarily duplicative.

### **Prescription Drug Monitoring Program**

We propose the following changes to 105 CMR 700.012, relative to the Prescription Monitoring Program:

- Remove the specific identifiers that pharmacies are required to transmit to the Department because they are fully covered in the PMP Dispensing Guide that is issued by the Department and used by all pharmacies that dispense controlled substances in Massachusetts.
- Insert additional language regarding the requirement that a pharmacy review a customer identifier prior to dispensing controlled substances in Schedules II through V. This language was formerly in 105 CMR 701.000, but it belongs more appropriately in this regulation. This change will provide clarity for pharmacies and pharmacists.
- Remove the reference to the Prescription Monitoring Program Advisory Council, formerly at 105 CMR 700.012(B). This Council has not been established. Its purpose was to assist the Department, at the Department’s discretion, with the development of the online Prescription Monitoring Program. The Online PMP has been developed and operating since 2010 without the assistance of the Council.
- Add language to 105 CMR 700.012(12)(C)(7) to describe the process by which the Department determines that a controlled substance in Schedule VI is an “additional drug” that carries a bona fide potential for abuse and must be reported to the PMP.
- Add language to 105 CMR 700.012(G)(2) to comply with Chapter 52 of the Acts of 2016, requiring that, effective October 15, 2016, a registered individual practitioner must utilize the PMP each time the practitioner prescribes a narcotic drug that is in Schedule II or III, and delete language that is no longer necessary due to this statutory amendment. The deleted language required registered individual practitioners to utilize the PMP each time they prescribed any drug in Schedule II or III that the Department had determined needed additional safeguards.

### **V. Summary**

Staff intends to conduct the public comment hearing and return to the PHC to report on testimony and any recommended changes to the proposed amendments. Following final action by the PHC, the Department will be able to file the final amendment with the Secretary of the Commonwealth.

## **Amendment #77 to H.3944**

### **Mannual Amendment**

Mr. Mannal of Barnstable move that the bill be amended by inserting at the end thereof the following new sections:-

SECTION XX. Section 27 of chapter 94C of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by adding the following paragraph:-

In accordance with section 215 of chapter 111, the distribution of hypodermic needles or syringes is otherwise prohibited except as part of a program authorized by the Department of Public Health and approved by the local board of health of the community in which the hypodermic needle and syringe access program is located.

SECTION XX. Section 32I of said chapter 94C, as so appearing, is hereby amended by striking out, in line 2, the words "sell, or manufacture with intent to" and inserting in place thereof the following words:-

distribute or sell, or manufacture with intent to distribute.

SECTION XX. Said section 32I of said chapter 94C, as so appearing, is hereby further amended by inserting after the figure "27", in line 28, the following words:-

or the distribution of hypodermic needles and syringes pursuant to section 215 of chapter 111.

SECTION XX: Section 215 of chapter 111 of the General Laws as appearing in the 2014 Official Edition, is hereby amended by adding the following paragraph:-

The Department of Public Health is authorized to implement harm reduction health programs, which may provide services including but not limited to: testing and counseling for HIV and Hepatitis C, mental health counseling, community outreach and education, overdose prevention training, hypodermic needles or syringe distribution and disposal programs, and referrals and case management for treatment access, housing, food stamps, and legal services. The Department of Public Health may allocate and expend funds in relation to said harm reduction health programs, provided that hypodermic needle access and disposal programs are authorized by the Department of Public Health and approved by the local board of health of the community in which the program is located. The Department of Public Health shall establish standards for the operation of hypodermic needle and syringe access and disposal programs, including protocols and procedures for safely storing, distributing, collecting, and disposing of used syringes. Nothing in this section shall be construed so as to permit the operation of a hypodermic needle and syringe access and disposal program without the expressed authorization of the Department of Public Health and prior approval of the local board of health in which the hypodermic needle access and disposal program is to be located. Local approval of such a harm reduction program shall not be unreasonably withheld or arbitrarily denied by a board of health without a public hearing on the matter, nor in the absence of reliable and credible evidence that the proposed harm reduction program poses a greater risk to the public health of the community in which it will be located than the foreseeable benefits to the public health of said community.

COMMONWEALTH OF MASSACHUSETTS

HAMPDEN, ss.

SUPERIOR COURT  
CIVIL ACTION  
No. 12-0837

HOLYOKE CITY COUNCIL & others<sup>1</sup>  
Plaintiffs

v.

CITY OF HOLYOKE & others<sup>2</sup>  
Defendants

**ORDER ON**  
**DEFENDANTS' MOTIONS TO RECONSIDER ORDER ON**  
**CROSS-MOTIONS FOR SUMMARY JUDGMENT**

On March 14, 2016, I issued a Memorandum of Decision and Order in which I allowed summary judgment for the plaintiffs on their claim for declaratory relief. The defendants now ask me to reconsider my decision pursuant to Mass.R.Civ.P. 59(e). For the following reasons, the defendants' motions are **DENIED**.

A party seeking reconsideration of a prior ruling must show (1) some changed circumstances such as newly discovered evidence or information, or a development of relevant law, or (2) a particular and demonstrable error in the original decision. *Audubon Hill S. Condo. Ass'n v. Community. Ass'n Underwriters of Am.*, 82 Mass. App. Ct. 461, 470 (2012), citing *Peterson v. Hopson*, 306 Mass. 597, 600 (1940); *Barbosa v. Hopper Feeds, Inc.*, 404 Mass. 610, 622 (1989). Whether to allow the motion is left to the judge's discretion. *Id.*

---

<sup>1</sup> Kevin Jourdain, Daniel Bresnahan, Todd McGee, Joseph McGiverin, James Leahy, and Linda Vacon.

<sup>2</sup> Alex B. Morse, in his official capacity as the Mayor of Holyoke, Robert S. Mausel, Katherine M. Liptak, and Patricia A. Mertes, as Commissioners of Holyoke Board of Health; and Tapestry Health Systems, Inc.

At hearing on the parties' cross-motions for summary judgment, the parties disputed whether G .L. c. 111, § 215 and G. L. c. 4 § 4, govern the parties' actions, as plaintiffs maintain, or whether G. L. c. 94C §§ 27, 27A do so, as defendants maintain. I carefully considered the parties' arguments and wrote a detailed opinion rejecting the defendants' interpretation of the law which governs the parties' dispute. See *Id.* (reconsideration criteria apply with particular force where party has received written, reasoned explanation of a ruling).

As set forth in my ruling, it is the authorization of Tapestry Health System Inc.'s needle exchange program (the "Tapestry program") which was unlawful. The Tapestry program was established pursuant G .L. c. 111, § 215. Indeed, Mayor Morse acknowledged that the Tapestry program was established pursuant to G .L. c. 111, § 215 in his August 14, 2012, letter to then Commonwealth of Massachusetts Department of Public Health Commissioner John Auerbach.<sup>3</sup> The Mayor's letter is, at a minimum, some evidence that the Tapestry program was established pursuant to G .L. c. 111, § 215.

The defendants argue the important public policy behind the 2006 amendments to G. L. c. 94C § 27 *et seq.* to no avail. The parties' dispute has as much to do with municipal separation of powers as it has to do with the legitimacy of needle exchange programs. In the final analysis, it is G .L. c. 111, § 215 and G. L. c. 4 § 4, which govern the parties' actions.

Defendants may not turn the clock back on the defective authorization of the Tapestry program. Notably, the question of whether a different entity would be duly authorized pursuant to G. L. c. 94C §§ 27, 27A is not before me. See Tapestry Health System Inc.'s Memorandum at fn. 3.

---

<sup>3</sup> In his August 14, 2012 letter, Mayor Morse wrote, in part, "Please be advised, in accordance with Massachusetts General Laws c. 111, § 215, I hereby approve the creation of a needle exchange program in the City of Holyoke."

**ORDER**

As the defendants cannot show a clear error and present no newly discovered information, the Defendants' Motions to Reconsider the Court's Order on Cross-Motions for Summary Judgment are **DENIED**.

April 20, 2016

  
\_\_\_\_\_  
Mark D Mason  
Justice of the Superior Court

COMMONWEALTH OF MASSACHUSETTS

HAMPDEN, ss.

SUPERIOR COURT  
CIVIL ACTION NO. 12-0837

HAMPDEN COUNTY  
SUPERIOR COURT  
FILED

HOLYOKE CITY COUNCIL & others<sup>1</sup>

JUN 15 2016

vs.



CLERK OF COURTS

CITY OF HOLYOKE & others<sup>2</sup>

**ORDER ON DEFENDANT’S MOTION TO VACATE THE JUDGMENT AS MOOT,  
TO REVISE SAID ORDER, AND FOR RECONSIDERATION OF THE ORDER  
ON CROSS-MOTIONS FOR SUMMARY JUDGMENT**

On March 14, 2016, I denied the defendants’ cross-motions for summary judgment. The defendant Tapestry Health Systems, Inc. (“Tapestry”), now moves to vacate that judgment as moot, to revise the order, and for reconsideration of the order. For the reasons set forth below, Tapestry’s motion is **DENIED**.

Under Mass. R. Civ. P. 60 (b) (2), a party may seek relief from a final judgment, order, or proceeding due to “newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59 (b) . . . .” *Id.* New developments that occur postjudgment do not constitute newly discovered evidence. See *Ulin v. Polansky*, 83 Mass. App. Ct. 303, 308 (2013) (held wife should have filed new complaint rather than postjudgment motion because disability developed after entry of judgment). See also *Morris v. Brown*, 87 Mass. App. Ct. 1130 n.9 (2015) (Rule 1:28 opinion) (“The motion for relief from judgment was based solely on ‘newly discovered evidence,’ and we agree with the judge that the plaintiff was seeking to rely on postjudgment developments, not newly discovered evidence”).

<sup>1</sup> Kevin Jourdain, Daniel Bresnahan, Todd McGee, Joseph McGiverin, James Leahy, and Linda Vacon.

<sup>2</sup> Alex B. Morse, in his official capacity as the Mayor of Holyoke, Robert S. Mausel, Katherine M. Liptak, and Patricia A. Mertes, as Commissioners of Holyoke Board of Health; and Tapestry Health Systems, Inc.

Whether to allow the motion is at the judge's discretion. *Audubon Hill S. Condo. Ass'n v. Community Ass'n Underwriters of Am., Inc.*, 82 Mass. App. Ct. 461, 470 (2012).

After my denial of the defendants' April 12, 2016, motion to reconsider, Tapestry informed the Department of Public Health that as of July 1, 2016, it would no longer operate a pilot needle exchange program. Tapestry argues that its plans constitute newly discovered evidence. Tapestry's plans, however laudable, constitute a postjudgment development which Tapestry set in motion *because* of the judgment entered in this case. Tapestry's new program did not exist during the course of litigation and, to be accurate, still does not exist.

Tapestry's request that I adjudicate its planned new program to be lawful is not ripe for adjudication. The needle exchange program at issue in the within case was created and existed pursuant to G. L. c. 111, § 215. It was not compliant with G. L. c. 94C, § 27. Defendants represent, on the other hand, that the proposed entity will be in compliance with G. L. c. 94C, §§ 27, 27A. Neither the plain language nor the legislative histories of G. L. c. 111, § 215 and G. L. c. 94C, §§ 27, 27A, nor the case law interpreting those statutes require that an entity compliant with G. L. c. 94C, §§ 27, 27A also comply with the requirements of G. L. c. 111, § 215. Nonetheless, I refer back to my April 20, 2016, order denying the defendants' motion to reconsider wherein I stated, "the question of whether a different entity would be duly authorized pursuant to G. L. c. 94C, §§ 27, 27A is not before me." That remains the case.

**ORDER**

For the foregoing reasons, it is hereby **ORDERED** that the Defendants' Motion to Vacate the Judgment As Moot, to Revise Said Order, and for Reconsideration of the Order on Cross-Motions for Summary Judgment is **DENIED**.

Dated: June 15, 2016

  
\_\_\_\_\_  
Mark D Mason  
Justice of the Superior Court