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1

Section Co-Chairs' Corner

On behalf of the Health Law Section, it is a great pleasure to introduce the latest issue of the Health Law Reporter. The Editors, authors, and peer reviewers of the Reporter are making our journal just what we hoped it would be: the best source for the latest health law developments affecting the Massachusetts health care industry. In addition to our regular features, this issue hits on three of the top law and public policy issues facing health care:

- * Minute Clinics;
- * Health Care Reform; and
- * The Massachusetts Life Sciences Initiative.

The last topic merits additional comment here. With this issue, we are introducing a new column to the Reporter: the **"Life Sciences Corner."** This new column will address issues of particular relevance to attorneys practicing in the life sciences areas - biotechnology, pharma, medical devices, nanotechnology, and research generally. These businesses are a fast-growing segment of the Massachusetts economy, and the overlap with the work of the health care bar is growing with it.

The Health Law Section is responding in kind. We are seeking to offer more opportunities for learning, scholarship, and information exchange for attorneys working in and around the life sciences community. Building on a terrific program three years ago - during which time tremendous strides and legislative changes have been made - on **March 24, 2008**, we will co-sponsor with the BBA's Life Sciences Committee a program on the regulatory issues around stem cells. This co-sponsored event will be the first of a series of annual programs where the Health Law Section and the Life Sciences Committee work together. We welcome our members' comments on our initiatives in the life sciences areas and how we can bring better services to you.

Last month, we held the first of our membership events for 2008 and were fortunate to have **David Spackman**, the Chief of the Non-Profit Organizations/Public Charities Division at the Office of the Attorney General, as our speaker. These social events present an opportunity for our members to meet, to share ideas, and to help shape the future of the Health Law Section. We look forward to seeing you at one of our next membership events.

We hope you enjoy this issue.

- **Larry Vernaglia**

Inside this Issue:

New Massachusetts Law Imposes Records Requirements For All Organizations, Including Those Not Subject to HIPAA
Page 3

"You're Sick. We're Quick!" In-Store Health Care Clinics Come to Massachusetts
Page 6

Chapter 58 Notes: The "Individual Mandate": Up Close and Personal
Page 10

Life Sciences Corner: Massachusetts Advances Stem Cell Research Through Launch of International Stem Cell Registry and Bank
Page 15

Local Health Law Briefs
Page 21

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New Massachusetts Law Imposes Records Requirements For All Organizations, Including Those Not Subject To HIPAA

By Rebecca L. Rausch, Esq.

Enacted on August 2, 2007, and fully effective on February 3, 2008, new chapters of the Massachusetts General Laws require any person or organization with access to records containing personal information about Massachusetts residents to protect those records, regardless of whether the organization is a covered entity for purposes of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the rules and regulations promulgated thereunder. Chapter 93H mandates that security precautions be taken and notice be provided in the event of any unauthorized access to, or use of, personal information or other data that creates a substantial risk of identity theft or fraud. Chapter 93I imposes certain destruction requirements for any records, paper or electronic, containing such personal information.

Although these new laws were a legislative response to recent credit security breaches, such as last year’s TJX incident, the laws are broadly written and apply to a wide range of organizations, including those with access to health records bearing a person’s name and Social Security number. All organizations subject to Chapters 93H and 93I must comply with these new record management requirements or face monetary penalties and potential suit brought by the Massachusetts Attorney General (“AG”). Notably, organizations subject to, and in compliance with, any other law governing data security, such as HIPAA, are deemed to comply with

Chapter 93H, so long as the security breach notifications discussed below are provided.

On December 17, 2007, the Massachusetts Office of Consumer Affairs and Business Regulation (“Consumer Affairs”) issued proposed regulations, 201 CMR 17.00, implementing the security requirements in Chapter 93H. The comment period on these regulations ended on January 25, 2008. At the time of this writing, it is unclear whether the regulations will be modified prior to promulgation in final form.

Identifying “Personal Information”

“Personal information” is defined as a Massachusetts resident’s first name or initial and last name, plus at least one of three additional identifying data: (a) Social Security number; (b) driver’s license number or state-issued identification card number; or (c) financial account number, or credit or debit card number.¹ For purposes of the destruction requirements set forth in Chapter 93I, a biometric indicator may also constitute the additional identifying data component.² Personal information can be in paper or electronic form.³ Thus, a document containing a Massachusetts resident’s full name and address would not constitute personal information, nor would a document containing the resident’s initials and Social Security number, but those two documents maintained together in a single file or electronic record would qualify as personal

information.

Comprehensive Information Security Program

The proposed regulations implementing Chapter 93H prescribe specific security measures for protecting personal information. Every organization that “owns, licenses, stores or maintains personal information about a resident of the Commonwealth shall develop, implement, maintain and monitor a comprehensive, written information security program applicable to any records containing such personal information.”⁴ The safeguards maintained in the comprehensive information security program (“CISP”) must be “reasonably consistent with industry standards” and any otherwise applicable state or federal law, such as HIPAA.⁵

All CISPs must contain at least 11 distinct components, including:

- (1) a designated employee to maintain the CISP;
- (2) methods for identifying and assessing internal and external risks to data security;
- (3) policies for employees who telecommute;
- (4) disciplinary measures for violations of the CISP rules;
- (5) methods of preventing terminated employees from accessing records containing personal information;
- (6) reasonable steps to be taken in obtaining contractual

representations from third party service providers that they have adequate protection for personal information;

- (7) measures to restrict the collection of, and access to, personal information;
- (8) methods for inventorying all records, including paper and electronic records, to identify those records containing personal information;
- (9) procedures for regularly monitoring and auditing employee access to personal information;
- (10) a review, at least annually, of the scope of data security measures; and
- (11) a process for documenting responsive actions taken in connection with any security breach.⁶

Any organization that electronically stores or transmits personal information must include another nine components in its CISP, including:

- (1) user authentication protocols;
- (2) access control measures;
- (3) encryptions of transmitted records containing personal information;
- (4) periodic monitoring of networks and systems for any unauthorized use or access;
- (5) periodic review of audit trails;
- (6) firewalls;
- (7) current system security agent software including antispyware and antivirus components;
- (8) employee education and training; and

(9) a procedure for restricting physical access to computerized personal information records.⁷

An organization that is a covered entity under HIPAA is exempt from these requirements only if the organization maintains a HIPAA-compliant data security policy with provisions concerning responses to a breach, and the organization provides the notices required by Chapter 93H in the event of a breach.⁸ All other organizations will need to comply with the regulatory data security requirements once the regulations are finalized.

Providing Notice of a Security Breach

Chapter 93H mandates prompt reporting of any incident involving any unauthorized access to or use of personal information. The reporting requirements also apply to any “breach of security,” defined by the statute as any unauthorized acquisition or use of other data that “creates a substantial risk of identity theft or fraud”.⁹ Any organization owning or licensing data containing personal information that “knows or has reason to know of a breach of security or . . . that the personal information . . . was acquired or used by an unauthorized person or used for an unauthorized purpose” must issue notice of the breach to: (1) the AG; (2) the Director of Consumer Affairs; and (3) the affected Massachusetts resident(s).¹⁰ Organizations that maintain or store such personal data, rather than directly owning or licensing it, must only provide notice to the data owner/licensee.¹¹ The owner/licensee must then make the three above required notifications.

All organizations, regardless of whether they are HIPAA-compliant

covered entities, must comply with these notice requirements.¹² For covered entities, these notice requirements are a significant change from the HIPAA requirement that an organization merely “mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information in violation of its policies and procedures or the requirements of [the Privacy Rule] by the covered entity or its business associate.”¹³

Destroying Personal Information

Chapter 93I requires all organizations that dispose of records containing personal information to destroy such records, whether paper or electronic, “so that personal information cannot practicably be read or reconstructed.”¹⁴ Paper records containing personal information should be shredded or burned.¹⁵ Electronic records containing personal information must be fully erased,¹⁶ a process that generally requires rewriting over the space on the storage media where the records formerly existed. Stated otherwise, tossing paper into the recycle bin or pressing the “delete” key will no longer suffice.

Organizations may contract with third parties such as data management companies to appropriately destroy records, provided that the third party implements and monitors compliance with the security provisions in Chapter 93H.¹⁷ Contracts with these third parties should now include explicit data safeguard and breach notification requirements.

All organizations, regardless of whether they qualify as covered entities under HIPAA, must comply with Chapter 93I.

Penalties for Failing to Comply

Any organization that violates Chapter 93I faces a civil fine of up to \$100 per affected person, with a total possible fine of \$50,000 for each instance of improper disposal.¹⁸ Failure to comply with either Chapter 93H or 93I may subject the offender to suit by the AG under Chapter 93A.¹⁹ Violations may give rise to triple damages, as well as liability for the AG’s attorney’s fees and legal costs.²⁰

Practical Implications

Any organization that owns, licenses, maintains, or stores data containing personal information about Massachusetts residents must comply with Chapters 93H and 93I. Organizations that do not yet have policies in place addressing data protection, security breaches, and destruction should prepare and implement such policies immediately.

All organizations, regardless of whether those organizations are covered entities under HIPAA, should create or revise data security policies to ensure compliance with the Chapter 93I destruction requirements. There is no deemed compliance status for HIPAA covered entities under Chapter 93I.

For HIPAA covered entities, compliance with HIPAA yields deemed compliance with Chapter 93H, but only insofar as the notice requirements of Chapter 93H are met. Covered entities should review their data security policies and revise those policies as necessary to comply with these notice requirements. As indicated above, these notice requirements extend beyond the general HIPAA duty to mitigate damages stemming from a security breach. Also, covered entities should revise their business associate agreements to include

either implicit or explicit references to Chapters 93H and 93I such that both parties are on notice of these new state law requirements that effectively supplement HIPAA. Further, covered entities should be aware that a security incident now carries a threat of not only a federal investigation or suit, but also a new state cause of action under Chapter 93A.

For organizations not subject to HIPAA, Chapter 93H creates a new realm of responsibilities and liabilities for data management. Routine business functions must be evaluated to identify and correct high security risks. Written security policies must be created or revised as applicable and implemented. Contracts with third parties handling personal information, including data vendors and payroll companies, should be modified to include safeguard and notice requirements.

Finally, all organizations should conduct training sessions with employees, including executives, about their data security policies, with a particular focus on any new or revised security policy components.

and the confidential process or key that is capable of compromising the security, confidentiality, or integrity of personal information, maintained by a person or agency that creates a substantial risk of identity theft or fraud against a resident of the commonwealth.”).

¹⁰ G.L. c. 93H, § 3(b).
¹¹ G.L. c. 93H, § 3(a).
¹² G.L. c. 93H, § 5.
¹³ 45 C.F.R. § 164.530(f); *accord id.* at § 164.308(a)(6)(ii).
¹⁴ G.L. c. 93I, § 2.
¹⁵ *Id.*
¹⁶ *Id.*
¹⁷ *Id.*
¹⁸ *Id.*
¹⁹ *Id.*; G.L. c. 93H, § 6.
²⁰ G.L. c. 93A, §§ 9, 11.

Endnotes

¹ G.L. c. 93H, § 1(a) (2008); G.L. c. 93I, § 1 (2008).
² G.L. c. 93I, § 1.
³ G.L. c. 93H, § 1(a).
⁴ 201 CMR 17.03 (2007) (proposed).
⁵ *Id.*
⁶ *Id.*
⁷ 201 CMR 17.04.
⁸ G.L. c. 93H, § 5.
⁹ G.L. c. 93H, § 1(a) (“ ‘Breach of security’, the unauthorized acquisition or unauthorized use of unencrypted data or, encrypted electronic data

“You’re Sick. We’re Quick!” In-Store Health Care Clinics Come to Massachusetts

By Justin L. DiBiasio, Esq.

On January 9, 2008, the Massachusetts Public Health Council (PHC) approved amendments to 105 CMR 140.000 et seq. allowing for retail-based health care clinics.¹ This action followed an application and waiver request by CVS/Caremark Corporation (CVS) to open the first of many such clinics in its Massachusetts stores.² The clinics were to be operated by industry pioneer MinuteClinic,³ which CVS purchased in July 2006.⁴

Instead of acting on the request, the PHC proposed amendments to its existing clinic licensure regulations under which so-called “Limited Service Clinics” could operate.⁵ Fifty-two individuals and groups participated in the ensuing written comment period and hearings.⁶ This article highlights key concerns raised in the rulemaking process and how they were addressed in the final amendments.

Although new to Massachusetts, there are an estimated 900 retail-based clinics operated by over two dozen companies across America.⁷ MinuteClinic operates 475 clinics in at least 25 states.⁸ Retail-based clinics emphasize accessibility, speed, and cost-efficiency.⁹ They remain open on evenings and weekends, do not require appointments, and treat ailments in about fifteen minutes. Typically, nurse practitioners provide care to visitors under the supervision of off-site physicians available for phone consultation. Treatment is only provided for a pre-identified selection of common conditions, such as sore or strep throat, bronchitis, ear infections, and sinusitis. Visitors pay posted prices a la carte for care. Diagnoses are often made with the aid of computer programs and algorithms, and treatment is standardized. Lengthy or invasive examinations and complex tests are not required. These parameters permit retail-based clinics, as MinuteClinic claims, to provide care at a cost of 30-50% less than primary care practitioners (PCPs).¹⁰

Indications as to the quality of care

provided in retail-based clinics are inconclusive, yet apparently favorable. MinuteClinic, which opened the first such clinic in the Minneapolis-St. Paul metropolitan area in 2000,¹¹ was rated highly for treating sore throats and common colds by a Minnesota nonprofit organization.¹² The PHC cited this report, along with another which concluded that care from appropriately trained nurses was as effective as care from physicians.¹³ MinuteClinic also boasts having JCAHO accreditation and a history of no malpractice claims.¹⁴ Visitor perceptions are likewise positive. Wall Street Journal Online / Harris Interactive Health-Care Polls from 2005 and 2007 show that, respectively, 89% and 90% of adults surveyed were satisfied with the quality of care they received at a retail-based clinic.¹⁵ They also showed decreasing concern as to the qualifications and diagnostic skill of clinic staff.

Nevertheless, quality of care concerns were prevalent during the approval process for the amendments.¹⁶ This led to provisions specifically defining the services that “Limited Services Clinics”

(LSCs) could provide. Permissible services include those that “require only a focused history and physical examination” and qualify as “episodic, urgent care related to an illness or for immunizations.”¹⁷ Certain types of treatment, such as mental health or birth center services, are expressly precluded,¹⁸ along with care for children under the age of two.¹⁹ In addition, LSCs may perform only those services for which it applies and receives Department of Public Health (DPH) approval.²⁰ Such services will be listed on the LSC’s license.²¹

To further address quality of care issues, the amendments require that LSCs establish clinical practice guidelines for diagnosis, treatment, and staffing patterns.²² LSCs must also create a quality evaluation program.²³ Despite concerns about nurse practitioner models of care,²⁴ the PHC did not impose more restrictive requirements for physician supervision at LSCs versus other clinics.²⁵ LSCs must, however, “develop policies and procedures for physician consultation on unclear cases.”²⁶ In addition to quality concerns, there were fears that LSCs would further

fragment health care delivery.²⁷ The final amendments require LSCs to implement methods for coordinating care akin to that which MinuteClinic currently uses.²⁸ LSCs must provide lists of PCPs to visitors who do not have one;²⁹ develop policies to "identify and limit, if necessary," repeat encounters with individual patients;³⁰ and provide medical records to both visitors and their PCPs.³¹ In addition, to assist visitors calling in after-hours, LSCs may leave a message containing a direct, toll-free number to other practitioners.³²

Other provisions linked LSCs with PCPs to ensure that visitors "whose needs exceed the clinic's services" receive proper care.³³ The PHC required LSCs to create policies for referring such patients,³⁴ and assemble lists of nearby PCPs willing to accept those referrals.³⁵ LSCs need not develop formal relationships with other facilities, but those with such relationships may develop mechanisms other than referrals "for assuring continuity of care within the system."³⁶ To increase awareness of their limitations, LSCs must post a statement listing the services they provide and directing visitors to see other practitioners for unlisted issues.³⁷ A LSC must also avoid using "any name that implies that it provides a full range of medical services."³⁸

When addressing comments on requirements for facility structure, the PHC seemed to consider the limited nature and size of retail-based clinics. It permitted LSCs to share toilet facilities with retailers so long as they are "reasonably proximate" to the treatment area.³⁹ Similarly, despite their proximity to retail customers, reception and waiting areas that "provide adequate space" need not be physically separate.⁴⁰ Just like

other clinics, LSCs using electronic medical records may store paper records off-site.⁴¹ Additional requirements imposed on LSCs include placing hand sanitizer dispensers outside of treatment rooms,⁴² and ensuring physical accessibility to the clinic through "well marked corridors or aisles" acceptable for individuals with disabilities.⁴³

Finally, commenters noted possible conflicts of interest unique to LSCs. The PHC was satisfied that existing federal and state fraud and abuse statutes would adequately deter discounts, referral fees, and other inappropriate incentives between a LSC and a host retail location.⁴⁴ Regardless, it required retail-based LSCs to develop policies and procedures for ensuring that their staff does not promote use of the retailer's services.⁴⁵ In addition, misleading advertising is expressly prohibited,⁴⁶ and LSCs located within retailers who sell tobacco must post certain information regarding tobacco usage.⁴⁷

Upon the final amendments' passage, DPH Commissioner and PHC Chair John Auerbach suggested that "[p]roperly regulated, these types of clinics will serve an important function, making care for minor medical care more convenient."⁴⁸ With CVS alone planning to open 100 to 120 in-store clinics in Massachusetts over the next three to five years,⁴⁹ there remains the promise of future debate as to whether the new LSC regulations are adequate and appropriate.⁵⁰

Endnotes

¹ A copy of the final amendments, dated January 18, 2008, along with the initially proposed amendments, can be found at <http://www.mass.gov/dph>.

² Press Release, The Commonwealth

of Massachusetts Executive Office of Health and Human Services, Department of Public Health, Public Health Council Approves Rules For Limited Service Medical Clinics (Jan. 9, 2008), available at <http://www.mass.gov/dph> [hereinafter DPH Press Release]. Pursuant to 105 CMR 140.099, clinics may request a waiver of one or more of the requirements listed in 105 CMR 140.000 et seq. CVS's particular waiver request was not immediately available.

³ DPH Press Release, *supra* note 2; Liz Kowalczyk, *CVS Seeks to Open Clinics in its Stores*, BOSTON GLOBE, May 2, 2007, available at http://www.boston.com/business/globe/articles/2007/05/02/cvs_seeks_to_open_clinics_in_its_stores/?page=1.

⁴ Pallavi Gogoi, *Drugstore Clinics Are Bursting with Health*, BUSINESSWEEK, July 17, 2006, available at http://www.businessweek.com/investor/content/jul2006/pi20060717_240148.htm.

⁵ 105 CMR 140.1001 ("Limited Service Clinics").

⁶ DPH Press Release, *supra* note 2. Public comment and hearings commenced after being called for by five medical and provider groups. Liz Kowalczyk, *Provider Groups Object to MinuteClinics in CVS Stores*, BOSTON GLOBE, JUNE 14, 2007, available at http://www.boston.com/yourlife/health/blog/2007/06/provider_groups_1.html.

⁷ Convenient Care Association, <http://www.convenientcareassociation.org/aboutcca.htm> (last visited Jan. 20, 2008).

⁸ Stephen Smith, *In-Store Healthcare Wins State Approval*, BOSTON GLOBE, Jan. 10, 2008, available at http://www.boston.com/news/local/articles/2008/01/10/in_store_healthcare_wins_state_approval; Stephen Smith, *Upbeat Diagnosis*

- for Clinics, BOSTON GLOBE, Jan. 22, 2008, available at http://www.boston.com/business/healthcare/articles/2008/01/22/upbeat_diagnosis_for_clinics.
- ⁹ MinuteClinic, Inc., Comments to Department of Public Health Regarding Proposed Amendments to 105 CMR 100, Licensure of Clinics (Sept. 5, 2007), at 4, available at <http://www.mass.gov/dph> [hereinafter MinuteClinic Sept. 9, 2007 Comments]; Richard Bohmer, *The Rise of In-Store Clinics - Threat or Opportunity?*, 356 New England Journal of Medicine 765, 766-767 (2007) [hereinafter *The Rise of In-Store Clinics*]; Mary Kate Scott, *Health Care in the Express Lane: The Emergence of Retail Clinics*, California HealthCare Foundation (July 2006), at 6, 9-11, 14-15, available at <http://www.chcf.org/documents/policy/althCareInTheExpressLaneRetailClinics.pdf> [hereinafter *Health Care in the Express Lane*].
- ¹⁰ MinuteClinic Sept. 5, 2007 Comments, *supra* note 9, at 7 (citing a 2005 HealthPartners Minnesota cost study, a 2005 Mercer / Black and Decker study, and findings by Blue Cross and Blue Shield of Minnesota); see also *Health Care in the Express Lane*, *supra* note 9, at 9 (describing a one-year analysis of claims by HealthPartners, which showed that MinuteClinic's episodes of care are about 15% cheaper than those at a physician's office or urgent care center).
- ¹¹ *Health Care in the Express Lane*, *supra* note 9, at 8-9.
- ¹² Memorandum from the Bureau of Health Care Safety and Quality to Commissioner John Auerbach and Members of the Public Health Council (Dec. 12, 2007), at 3, available at <http://www.mass.gov/dph> [hereinafter PHC Dec. 12, 2007 memorandum].
- ¹³ *Id.* at 2-3.
- ¹⁴ MinuteClinic, Inc., Comments to Department of Public Health Regarding Proposed Amendments to 105 CMR 100, Licensure of Clinics (Sept. 28, 2007), at 3, available at <http://www.mass.gov/dph> [hereinafter MinuteClinic Sept. 28, 2007 comments].
- ¹⁵ The Wall Street Journal Online / Harris Interactive Health-Care Poll, *Most Adults Satisfied with Care at Retail-Based Health Clinics* (April 11, 2007), at 1, available at http://www.harrisinteractive.com/news/newsletters/wshealthnews/HI_WSJ_HealthCarePoll_2007_v06_i06.pdf; The Wall Street Journal Online / Harris Interactive Health-Care Poll, *Many Agree on Potential Benefits of Onsite Clinics in Major Retail Stores That Can Provide Basic Medical Services, Yet Large Numbers Are Also Skeptical* (Oct. 26, 2005), at 1, available at http://www.harrisinteractive.com/news/newsletters/wshealthnews/WSJOnline_HI_HealthCarePoll2005vol4_iss21.pdf.
- ¹⁶ PHC Dec. 12, 2007 memorandum, *supra* note 12, at 2; Massachusetts Medical Society, Testimony Before Department of Public Health on Proposed Amendments to 105 CMR 140 et seq. (Sept. 5, 2007), available at <http://www.massmed.org> [hereinafter MMS Sept. 5, 2007 testimony]; see also *The Rise of In-Store Clinics*, *supra* note 9, at 767 (quality of care concerns "have thus far remained theoretical").
- ¹⁷ See 105 CMR 140.020 for a complete definition of "Limited Services."
- ¹⁸ *Id.*
- ¹⁹ 105 CMR 140.1001(A)(4).
- ²⁰ 105 CMR 140.1001(A)(1).
- ²¹ 105 CMR 140.103(F).
- ²² 105 CMR 140.1001(B)-(C).
- ²³ 105 CMR 140.370.
- ²⁴ MMS Sept. 5, 2007 testimony, *supra* note 16.
- ²⁵ 105 CMR 140.313; PHC Dec. 12, 2007 memorandum, *supra* note 12, at 2-3.
- ²⁶ 105 CMR 140.1001(D).
- ²⁷ PHC Dec. 12, 2007 memorandum, *supra* note 12, at 2. Retail-based clinics have, for example, faced criticism for unfairly cherry picking less sick patients. *The Rise of In-Store Clinics*, *supra* note 9, at 767-768. MinuteClinic, however, claimed that its presence in Minnesota has not caused a demonstrable negative impact to other practitioners or providers. MinuteClinic Sept. 5, 2007 comments, *supra* note 9, at 6-7. Further, an American Medical Association report indicated that retail-based clinics and PCPs effectively communicate, and that the clinics "seem to have integrated well in serving the needs of Minnesota residents." American Medication Association, Report 7 of the Council on Medical Service (A-06), available at <http://www.ama-assn.org/ama1/pub/upload/mm/372/a-06cmsreport7.pdf> (last visited January 24, 2008).
- ²⁸ See MinuteClinic Sept. 5, 2007 comments, *supra* note 9, at 5, 6-7.
- ²⁹ 105 CMR 140.1001(E).
- ³⁰ 105 CMR 140.1001(F).
- ³¹ 105 CMR 140.1001(G). See also MinuteClinic Sept. 28, 2007 comments, *supra* note 14, at 1.
- ³² 105 CMR 140.304.
- ³³ 105 CMR 140.1001(D).
- ³⁴ *Id.*
- ³⁵ 105 CMR 140.1001(E).

- ³⁶ 105 CMR 140.1001(F)(2). physically present some or all of the time; requiring supervising physicians to be located in-state; and issuing licenses to clinics at the corporate level that cover multiple sites. *Id.*
- ³⁷ 105 CMR 140.1001(I)(1).
- ³⁸ 105 CMR 140.1001(J).
- ³⁹ 105 CMR 140.205(E). The PHC claimed this would impose more stringent requirements on LSCs performing uranalysis as opposed to those that do not. Memorandum from the Bureau of Health Care Safety and Quality to Commissioner John Auerbach and Members of the Public Health Council (Jan. 9, 2008), at 4 [hereinafter PHC Jan. 9, 2008 memorandum]. Similarly, LSCs may store supplies in a janitor's closet "or other designated space" located within the retailer so long as it is "suitably located." 105 CMR 140.206.
- ⁴⁰ See 105 CMR 140.202-203 (concerning areas for reception, waiting, offices, consultation, examination, treatment, and dressing).
- ⁴¹ 105 CMR 140.302; PHC Dec. 12, 2007 memorandum, *supra* note 12, at 5.
- ⁴² 105 CMR 140.1002(D).
- ⁴³ 105 CMR 140.209(B).
- ⁴⁴ PHC Jan. 9, 2008 memorandum, *supra* note 39, at 2-3.
- ⁴⁵ 105 CMR 140.1001(H).
- ⁴⁶ 105 CMR 140.1001(I)(2).
- ⁴⁷ 105 CMR 140.1001(L).
- ⁴⁸ DPH Press Release, *supra* note 2.
- ⁴⁹ Smith, *In-Store Healthcare Wins State Approval*, *supra* note 8.
- ⁵⁰ Licensure regulations for retail-based clinics vary from state to state. *Health Care in the Express Lane*, *supra* note 9, at 12. Examples of differing provisions in other states include requiring supervising physicians to be

Chapter 58 Notes: The “Individual Mandate”: Up Close and Personal

By Barbara Anthony, Esq., Georgia Maheras, Esq., and Matt Selig, Esq.

Introduction

Massachusetts’ 2006 health care reform law (Chapter 58 of the Acts of 2006, “AN ACT PROVIDING ACCESS TO AFFORDABLE, QUALITY, ACCOUNTABLE HEALTH CARE”, referred to herein as the “Act”) has helped approximately 300,000 formerly uninsured consumers enroll in health care plans, with the overwhelming majority of these consumers enrolling in subsidized state insurance products.¹ While the reform law has improved access to health insurance, many consumers, particularly those who remain uninsured,² face significant challenges meeting the legal requirements imposed by the law’s “individual mandate.” There will be some consumers who need a knowledgeable health care attorney to assist them in meeting their responsibilities under the law and in making prudent decisions in terms of the choice they face between paying premiums or penalties. This article endeavors to supply an overview of the State’s enforcement of the individual mandate and practice tips for representing clients with potential exposure to the mandate’s tax penalties.³

Non-Compliance and Tax Penalties

Under the Act, most adults over age 18 with access to affordable health insurance,⁴ defined by the State, are required to purchase such insurance.⁵ Those individuals who do not comply with the individual mandate lose their 2007 tax year credit, which is worth \$219. For tax year 2008, the penalty for

non-compliance with the individual mandate will increase significantly.⁶ Counsel advising clients should be aware that for some clients, there is more at stake than the monetary penalty. In addition to the penalties discussed above, individuals with incomes below 400% of the Federal Poverty Level (FPL) can be denied eligibility for the Health Safety Net⁷ (formerly the Free Care Pool), based on their failure to comply with the individual mandate.

Affordability and Premiums

The Act grants the State’s Connector Authority (Connector) the power to develop criteria to define what ‘affordable health insurance’⁸ is for various income levels and related premium tables. See Tables 1 and 2. If the premiums in Table 2 are greater than the levels deemed affordable in Table 1, the individuals or families will be exempt from the requirement to purchase health insurance.

The following hypothetical provides an example of how to read these tables: a 46-year-old single client, earning \$38,000 a year, and living in Suffolk County, would be deemed to be able to afford \$200 per month in insurance premiums. However, according to Table 2, the cheapest insurance available to this person costs \$235 per month. Because the premium exceeds the amount the person is deemed to be able to afford, the person is exempt from the mandate.

Department of Revenue Schedule HC: Exemptions and Penalties

Every Massachusetts taxpayer must complete Department of Revenue Schedule HC.⁹ This is a new form developed especially to ensure compliance by taxpayers with the individual mandate to purchase health insurance. This is the form where taxpayers declare whether or not they have health insurance. If, according to the Schedule HC, a taxpayer did not have health insurance on December 31, 2007, that taxpayer may be subject to the penalty of losing her exemption which is worth about \$219. Full discussion of how to complete this form is beyond the scope of this article. Rather, this article discusses only the filing of an appeal for an exemption from the mandate.

Filing an Appeal with the Tax Return

Anyone who did not have health insurance on December 31, 2007, can file an appeal for an exemption from the mandate to purchase health insurance. The first step in this appeal process is determining whether the client had affordable insurance. Taxpayers may submit an appeal to the Department of Revenue (“DOR”) by filing Schedule HC-A, Health Care Appeals, with their Schedule HC and claiming that a hardship prevented the purchase of affordable insurance.

Filing an appeal is a three-step process where: 1) the taxpayer fills in the appropriate “oval(s)” under Question 2 that reflect his or her

Table 1: Affordability

Individual or married filing separately		
a. Federal adjusted gross income		b. Monthly premium
From	To	
\$ 0	\$15,315	\$ 0
\$15,316	\$20,420	\$ 35
\$20,421	\$25,525	\$ 70
\$25,526	\$30,630	\$105
\$30,631	\$35,000	\$150
\$35,001	\$40,000	\$200
\$40,001	\$50,000	\$300
\$50,001	Any individual with an annual income over \$50,000 is deemed to be able to afford health insurance.	

Married filing jointly (no dependents)		
a. Federal adjusted gross income		b. Monthly premium
From	To	
\$ 0	\$20,535	\$ 0
\$20,536	\$27,380	\$ 70
\$27,381	\$34,225	\$140
\$34,226	\$41,070	\$210
\$41,071	\$50,000	\$270
\$50,001	\$60,000	\$360
\$60,001	\$80,000	\$500
\$80,001	Any couple with an annual income over \$80,000 is deemed to be able to afford health insurance.	

Head of household or married filing jointly (1 or more dependents)		
a. Federal adjusted gross income		b. Monthly premium
From	To	
\$ 0	\$ 25,755	\$ 0
\$25,756	\$ 34,340	\$ 70
\$34,341	\$ 42,925	\$140
\$42,926	\$ 51,510	\$210
\$51,511	\$ 70,000	\$320
\$70,001	\$ 90,000	\$500
\$90,001	\$110,000	\$720
\$110,001	Any family with an annual income over \$110,000 is deemed to be able to afford health insurance.	

Table 2: Premiums

Region 1. Berkshire, Franklin and Hampshire Counties			
Age	Individual*	Married couple (no dependents)	Family**
0-26	\$150	\$300	\$ 720
27-29	\$210	\$420	\$ 720
30-34	\$225	\$450	\$ 800
35-39	\$240	\$480	\$ 820
40-44	\$260	\$520	\$ 830
45-49	\$285	\$570	\$ 830
50-54	\$370	\$740	\$ 900
55-59	\$380	\$760	\$1,030
60+	\$380	\$760	\$1,240

Region 2. Bristol, Essex, Hampden, Middlesex, Norfolk, Suffolk and Worcester Counties			
Age	Individual*	Married couple (no dependents)	Family**
0-26	\$150	\$300	\$ 570
27-29	\$185	\$370	\$ 570
30-34	\$185	\$370	\$ 760
35-39	\$185	\$370	\$ 750
40-44	\$235	\$470	\$ 750
45-49	\$235	\$470	\$ 780
50-54	\$280	\$560	\$ 880
55-59	\$370	\$740	\$1,020
60+	\$370	\$740	\$1,130

Region 3. Barnstable, Dukes, Nantucket and Plymouth Counties			
Age	Individual*	Married couple (no dependents)	Family**
0-26	\$150	\$300	\$ 750
27-29	\$210	\$420	\$ 750
30-34	\$220	\$440	\$ 800
35-39	\$260	\$520	\$ 850
40-44	\$300	\$600	\$ 820
45-49	\$355	\$710	\$ 820
50-54	\$410	\$820	\$ 890
55-59	\$410	\$820	\$1,020
60+	\$410	\$820	\$1,230

*Includes married filing separately.
 **Head of household or married couple with dependent(s).

hardship(s) (the taxpayer may fill in as many ovals as are applicable) and mails in his or her tax return to the DOR; 2) the DOR sends a follow-up letter and forms to the taxpayer, seeking documentation to support the reasons for the appeal (this documentation must be submitted to the DOR within 30 calendar days of receipt of the DOR's letter); and 3) the DOR forwards the

information to the Connector, which will review the submission and decide the appeal.

Although all documentation is sent to the DOR, the client must explicitly authorize the DOR to share his or her income information with the Connector; this is done by filling in the appropriate "oval" on line 1 at the top Schedule HC-A (which is

page 3 of Schedule HC). Failure to do so will result in dismissal of the appeal. It is also critical that clients fill in the "oval" at the very bottom of page 2 of Schedule HC under the Heading "Appeals." The language after the "oval" states in bold: "Fill in oval if filing Schedule HC-A (page 3 of Schedule HC)." If this oval is not filled in, the taxpayer's appeal may be dismissed on its face.

Connector Review of Appeal

While most appeals will be decided on the papers, the Connector may require the appellant to participate in a fair hearing. Counsel may recommend that their clients request a hearing from the Connector, unless the appeal can be decided favorably on the papers. Requesting an appeal should be done when the taxpayer returns all documentation to support his or her appeal.¹⁰ This must be done within 30 days of the taxpayer's receipt of the letter from the DOR requesting such information. There is no particular form for taxpayers to use when requesting a hearing, although when the DOR writes to request additional documentation to support the appeal, there will be a form asking the taxpayer if he or she wishes to waive a hearing. Therefore, the taxpayer or counsel should write a letter to the DOR and Connector stating that a hearing is requested, unless the appeal is being granted on the papers filed.

Grounds for Hardship Appeal During 2007

There are seven grounds enumerated on Schedule HC for granting a hardship appeal:

1. Homelessness, rent or mortgage arrearage, eviction or foreclosure notice;
2. Shut-off, shut-off notice or refusal by a utility to provide essential utilities;
3. Non-cosmetic medical or dental expenses totaling more than 7.5% of adjusted gross income;
4. The expense of purchasing health insurance would cause serious deprivation of food, shelter, clothing or other

necessities;

5. Fire, flood or other unexpected event causing substantial household damage;
6. A significant increase in essential expenses due to domestic violence, death, major or extended illness, including parents and other family members; or
7. Other grounds – the application of the affordability tables in schedule HC is inequitable, the appellant has been unable to obtain government-subsidized insurance despite being income eligible, or other circumstances that caused the appellant to be unable to purchase insurance.

How Will Appeals be Handled and Decided?

The first six grounds are fairly straightforward. Therefore, an appellant should provide documentary evidence that clearly supports the reasons claimed for the appeal. Number 7, "Other Grounds," is a catch-all category where the appellant can make the argument that his or her disposable income is such that the 'affordable' insurance is not affordable to him or her. Using this "catch-all" will likely require a showing of income and expenses and all other circumstances that support granting an exception to the state mandate.

There is limited information available about the appeals conducted to date. About half of the appeals heard by the Connector were approved.¹¹ Of those appeals that were denied, the appellant's qualification for a different state-subsidized program appeared to be the deciding factor. At this

time, it does not appear that the Connector is going to release copies of its appellate decisions or the rationales behind them, although counsel could request such information under a M.G.L. Ch. 66 public records request.

A Case Experience

Health Law Advocates ("HLA") has represented a client seeking a premium reduction based on the receipt of a utility shut-off notice. HLA's client avoided a shut-off notice by appealing to her town, which paid utilities for residents struggling to heat their homes during the winter months. HLA argued that without the town's assistance, the client could not have paid her utility bill and would have received a shut-off notice. A hearing officer found that although the client made a compelling case, her case did not meet the "letter of the regulation."

The client, a woman in her late fifties, worked at a food pantry. In a good year, her annual gross income was \$28,000. From that income, she supported herself and helped her grown children with their student loans. Her primary asset was an old car, and she lived in subsidized housing. As part of her appeal, the client submitted complete financial statements¹² showing her income and expenses. She demonstrated that she relied on credit card advances to pay her monthly bills and had no additional funds for health insurance premiums. Despite her minimal net income, our client's adjusted gross income qualified her for state-subsidized health insurance, which means she cannot qualify for an automatic exemption based on income. Her only option was to plead an exception under financial hardship. Without such an exemption, our client would

pay the \$219 tax penalty and be ineligible for the Health Safety Net after April 1, 2008.¹³

At the hearing, the hearing officer¹⁴ questioned our client.¹⁵ There was no opportunity for any opening statement by counsel. After the hearing officer's examination, a Connector attorney questioned the client about her income and expenses. Connector counsel noted the client paid for cable television while claiming health insurance premiums were unaffordable, the inference being that paying for cable was a luxury. The hearing officer added that had our client not pursued the funds from the health department, she might have been able to explore other possible avenues of relief before receiving a shut-off notice. After this questioning, appellant's counsel was permitted to question her and to make a closing statement.

Based on this very limited experience, we conclude that the Connector is likely to interpret strictly the language of the exceptions above. We also believe that the Connector will scrutinize a client's expenditures and make judgments regarding the essential nature of such expenditures if the client is claiming that he or she cannot afford health insurance premiums. This is the same kind of financial information a taxpayer should submit when he or she is basing an appeal on number 7 above. Although financial data on income and expenses is not required by the appeal provisions, it seems prudent to support any appeal involving unaffordability claims with supporting financial data.

Practice Tips for Counsel at the Vanguard of this New Appeals Process:

- Submit forms and documentation to DOR within 30 calendar days of receipt of the DOR's request.
- Authorize the DOR to share information with the Connector on Schedule HC-A of their tax form.
- Request an administrative hearing be granted to consider the request.
- Conduct mock witness examinations with your client to prepare for the hearing.
- Advise clients that as of April 1, 2008, they will be ineligible for Health Safety Net – Primary coverage if health insurance is deemed "affordable" for them.
- If your uninsured client is below 300% of the Federal Poverty Level, contact the Connector at 1-877-MA-ENROLL (1-877-623-6765) and consult the Connector's regulations at 956 C.M.R. § 3.00 et seq. to determine if your client is eligible to enroll in the Commonwealth Care program, which provides state-subsidies for private insurance.
- If your client is eligible for the Commonwealth Care program and is charged a premium, review the Connector's regulations at 956 C.M.R. § 3.11(5) for guidance on applying for a waiver or reduction of the premium due to extreme financial hardship.
- Build a record at the hearing: a Mass. Gen. L. Ch. 30A appeal to the Superior Court can be taken from a denial of a hardship appeal.

Conclusion

Implementation of the 2006 health care reform law is undoubtedly a work in progress. State agencies charged with implementing the law have faced a monumental task in breathing life into this sweeping legislation. The process has included numerous regulatory revisions and troubleshooting episodes by state attorneys and other key government officials and more are sure to follow. As a result, lawyers representing consumers on health reform-related matters are wading into uncharted territory and have to face the risks that poses, while seizing opportunities to develop advocacy strategies before the Connector.

Endnotes:

¹ A Healthy Blog, Connector Board Report: New Year's Resolutions, Jan. 11, 2008, at 5:37 p.m. (<http://blog/hcfama.org>).

² A number that is estimated to be between 150,000 and 355,000. DHCFP report *Health Care in Massachusetts: Key Indicators January 2008*, p. 25.

³ Attorneys can assist low-income consumers on health reform matters by joining Health Law Advocates' Pro Bono Legal Network. For more information, contact HLA Staff Attorney Matt Selig at 617-275-2986.

⁴ Access to affordable health insurance is based upon the affordability guidelines established by the Connector Authority, as discussed later in this article. Any individual who has the ability to sign up for health insurance that is deemed affordable is considered to have access to this insurance. This affordable insurance can be through the Connector's Commonwealth Care or Commonwealth Choice plan offerings, employer-sponsored insurance, or small-group insurance offerings.

The merger of the small group and individual group insurance markets under Chapter 58 of the Acts of 2006 lowered the cost many health insurance plans for those individuals who do not have access to employer-sponsored insurance. 956 CMR 4.00 discusses access to Employer-Sponsored health insurance and 956 CMR 6.00 discusses affordability in general.

⁵ There are two new State programs designed to help individuals acquire health insurance: Commonwealth Care and Commonwealth Choice. Individuals with incomes below 300% of FPL qualify for state-subsidized insurance in the Commonwealth Care program. Individuals with incomes above 300% of FPL can purchase Commonwealth Choice health plans, which provide a number of benefit packages and ranges in premiums. Individuals above 300% of FPL are of course free to purchase any insurance product offered by the private market, subject to some State requirements on minimum creditable coverage.

⁶ The proposed tax penalties for the 2008 tax year are as follows (see chart below):

- Individuals with incomes up to 150% of FPL are not subject to any penalty for failure to purchase health insurance, as those at this income level are not required to pay an enrollee premium for Commonwealth Care health

insurance. For the 2007 tax year, these individuals may still be liable for the \$219 loss of their personal exemption unless they demonstrate a hardship through the appeals process.

- Penalties for individuals with incomes from 150% to 300% of FPL will be half of the lowest-priced Commonwealth Care enrollee premiums for which an individual would have qualified, depending on his or her income.
- Penalties for individuals with incomes above 300% of FPL will be:
 - Half of the lowest priced Commonwealth Choice Young Adult Plan premium (without prescription drug coverage) for individuals through age 26.
 - Half of the lowest priced Commonwealth Choice Bronze premium (without prescription drug coverage) for individuals age 27 and over.
- Penalty rates are based on the Commonwealth Health Insurance Connector's plan prices as of 1/08.
- Penalties for married couples without health insurance (with or without children) will equal the sum of individual penalties for each spouse.

⁷ The Health Safety Net replaced the Free Care Pool on October 1, 2007. It is a fund established to help pay for emergency services received by low-income residents of Massachusetts. Emergency services provided by Community Health Centers and most hospitals are covered by the Health Safety Net. See 114.6 CMR 13.00.

⁸ MASS. GEN. LAWS ch. 176Q, s. 3 (2006).

⁹ This form is available online at <http://www.mass.gov/Ador/docs/dor/health%20care/HC.pdf>.

¹⁰ 956 CMR 6.00 et seq.

¹¹ 92 out of 177 requests for waivers were approved as of December 5, 2007. Connector Board Hearing 12/5/2007.

¹² These financial statements were created by Health Law Advocates and show basic income and expenses over the course of each month.

¹³ 114.6 CMR 13.04 (4) (b) (1).

¹⁴ All of the Connector hearing officers are trained attorneys.

¹⁵ While this is the format that our hearing followed, these administrative hearings are somewhat informal and the exact format may change depending on the circumstances or the hearing officer. The general hearing process is outlined in 801 CMR 1.00.

Penalties for 2008					
Individual Income Category*	150-200% FPL	200-250% FPL	250-300% FPL	Above 300% FPL Age 18-26	Above 300% FPL Age 27+
Penalty	\$17.50/month \$210/year	\$35/month \$420/year	\$52.50/month \$630/year	\$56/month \$672/year	\$76/month \$912/year

Life Sciences Corner: Massachusetts Advances Stem Cell Research Through Launch of International Stem Cell Registry and Bank

By Susan Stayn, Esq.

Introduction:

A recent business report asks, “Is 2008 the year of the stem cell?”¹ The article reports on novel clinical trials that stem cell companies are planning, including the first experimental trials that would test human embryonic stem cell-based products in people with spinal cord injuries (California-based Geron) and retinal degenerative disease (California-based Advanced Cell Technology, with facilities in Massachusetts). Both companies have been in discussions with the Food and Drug Administration, and, if approved, Geron’s first human trial using a human embryonic stem cell-based product reportedly could begin in a few months.²

This announcement is one example of the progress that scientists have made in the ten years since human embryonic stem cells were first derived. While potential treatments and cures are still expected to be many years away, scientists in laboratories around the world have succeeded in deriving hundreds of human embryonic stem cell lines (with varying qualities and properties). Because these cell lines give scientists an opportunity to better understand human development, disease development, and potential therapeutic tools and products, the cell lines are of great interest for biomedical research conducted in universities, hospitals, research institutes, and industry.

Federal and State Policies:

As the stem cell research field advances globally, U.S. researchers continue to grapple with federal funding restrictions that curtail and complicate the daily conduct of this research. Current federal policy bars the use of federal funds both to derive new human embryonic stem cells from embryos, and to conduct research on already-derived cell lines, except on designated cell lines created before August 9, 2001 (the date of President Bush’s policy announcement).³

As a result, researchers in the U.S. may use only 21 human embryonic stem cell lines with federal support. These “presidentially approved” lines are listed on the National Institutes of Health (NIH) Registry, and most are maintained at the National Stem Cell Bank at the WiCell Research Institute (WiCell) in Wisconsin. Researchers who wish to use and analyze the cell lines created around the world since 2001, or wish to make their own (for example, to study a particular disease or to ensure donated materials are from a racially diverse population), need major financial support from state, private, or other non-federal government sources to ensure they have non-federally funded space, equipment, personnel, and supplies to conduct such work.

Against the backdrop of these federal restrictions, Massachusetts is one of eight states that has committed substantial public funds to support human embryonic stem cell research.⁴ In 2006,

the Massachusetts Legislature appropriated \$10 million to establish the Massachusetts Life Sciences Center (MLSC) and \$1 million to a stem cell biology initiative at the University of Massachusetts. In the fall of 2007, the MLSC awarded approximately \$8.2 million to create a new international human embryonic stem cell research registry and bank at the University of Massachusetts.⁵ Most recently, in February 2008, the MLSC announced a Matching Grants Program that will award an initial \$12 million to support new investigators’ research, faculty retention and recruitment, and industry-sponsored research at academic and non-profit research institutions.⁶ Governor Patrick proposed more comprehensive legislation to enhance the life sciences in Massachusetts, and a broad life sciences initiative announced by Speaker DiMasi passed the House in late February.⁷

Ethical Guidelines and “Provenance”:

In recognition of the sensitivity of human embryonic stem cell research,⁸ national and international committees of experts have developed ethical guidelines that, while not binding, guide many research entities’ oversight of this research. These recommendations – known as the National Academy of Sciences (NAS) Guidelines and the International Society for Stem Cell Research (ISSCR) Guidelines – address many issues, including institutional oversight, informed consent, and nonpayment of

individuals who donate research materials.⁹

Importantly, the NSC and ISSCR guidelines recognize that researchers routinely import cell lines for study from other research entities and jurisdictions. As an ethical matter, the guidelines recommend that before human embryonic stem cell lines are imported or used, the researcher's institution verify the "provenance" of the cell lines. Provenance generally means adequate assurance that those who created the lines (i) obtained informed consent from donors of embryos, eggs/sperm, and other cells, and did not pay donors more than ethical or legal standards permit; (ii) an institutional review board or similar body oversaw the research; and (iii) legal requirements were met in the state or country in which the lines were created. Some states, such as California and Connecticut, mandate that institutions verify provenance of human embryonic stem cell lines, and many research entities in other states voluntarily follow this ethical recommendation.

Provenance can be challenging for a single research entity to determine on its own. This is particularly true when foreign jurisdictions are involved. For example, consent materials are in a foreign language, and oversight may not be conducted through an institutional review board. Currently there is duplication of effort in provenance inquiries among universities, hospitals, and other research entities.

A comprehensive, international stem cell registry that collects information about individual cell lines has the potential to facilitate sharing of cell lines, in accordance with ethical standards, by including provenance-related information. Internationally, some registry initiatives are newly in place or underway: for example,

the European Commission formally launched a new human embryonic stem cell research registry ("hescReg") at a Berlin symposium in January, and it is working in partnership with the U.K. Stem Cell Bank, which maintains and distributes human embryonic stem cell lines; and the ISSCR also has been planning an international registry.

Intellectual Property and Materials Transfer:

In addition to federal and state laws and funding policies, other countries' laws, and ethical guidelines, counsel who work in this field need to consider intellectual property issues and material transfer terms. The intellectual property issues need analysis in light of evolving patent case law, as well as a formal challenge to core patents in the field.

In 2006, certain non-profit groups petitioned for re-examination of three broad human embryonic stem cell patents held by the Wisconsin Alumni Research Foundation (WARF), stemming from the first derivation of human embryonic stem cells by University of Wisconsin researcher Jamie Thomson in 1998. The patents relate to the method used to create the stem cells and the stem cells themselves. In March 2007, the U.S. Patent and Trademark Office (USPTO) issued a preliminary ruling in favor of the groups seeking to invalidate the patents. WARF sought to amend the scope of its patent claims. At the end of February, USPTO arrived at a "non-final office decision" supporting one of the patents, and the process continues.¹⁰ Many academic and commercial research entities are following the matter with great interest to see how it ultimately resolves and what that means for their practices.

Massachusetts' International Stem Cell Registry and Bank:

In this year of key stem cell research developments across the country and abroad, the director of the new Massachusetts human embryonic stem cell research registry and bank describes in an interview below this new initiative, its significance, and the opportunities this Massachusetts-based resource will offer. Its director, Gary Stein, Ph.D., is professor and chairman of the Department of Cell Biology at University of Massachusetts Medical School, and Deputy Director of the University of Massachusetts Cancer Center. His research has focused on cell development, including core issues of how cells divide and specialize into different kinds of cells; what factors and "architecture" within a cell control gene expression; and how cell-based approaches ultimately may be used as new modalities for therapy.

Interview with Gary Stein, Ph.D.

How did the international human embryonic stem cell research registry (Registry) and bank (Bank) become a top priority for Massachusetts policymakers?

The Bank and the Registry were put into place out of necessity. First of all, this is an area that is growing in terms of the knowledge base, and growing in terms of understanding the applications. There is really a need to be able to have all the information known about how you grow the cells, properties of the cells, applications of these cells, what in fact has been done with them in the published literature, and provenance information related to these cell lines. That is what the Registry is charged to do.

The Registry is going to cover all of the NIH cell lines. It is also going to cover the lines that have been developed outside of the present

[federal funding] moratorium. That information will be available to the entire international scientific community. So it will be the most comprehensive database. It's going to provide explanations where a controversy exists. So it will help somebody navigate through the amount of information that is out there. And as the literature grows and the applications become more extensive, that information is going to be added to the Registry. So as the field expands, the importance of the Registry and the complexity increase significantly.

The NIH has a registry, which is nothing more than a catalogue, and this Registry is going to provide explanations, which are very important to an investigator. It is important to bring stem cell research to Massachusetts, to retain stem cell investigators in Massachusetts, and to serve as an asset to biotech and pharma in Massachusetts. So we see it as important to both academia and to support the economy as well. A lot of jobs are tied to stem cell research and stem cell applications; regenerative medicine is a crucial area; there are many, many spin-offs on it. So the Registry is an authoritative, documented source of information that is going to be current and expand as the field expands.

The Bank is a facility where both NIH-approved lines and those that are developed outside the [federal funding] moratorium can be brought in, and it can be verified that they are in fact what they are supposed to be, and have the properties that they are supposed to have. The lines are expanded out, they're frozen, they go through some very stringent quality control, and then they're going to be provided to investigators both in academia and the private sector, as a series of frozen vials with the specifications

associated with it.

How does one launch such a complex initiative – the creation of a new human embryonic stem cell research Registry that intends to be international in scope?

What we did – largely to develop the strategies for the acquisition and integration of information, and also to develop the configuration of the site – was that we looked at the two NIH lines that are most extensively studied – one is male, one is female – and then acquired all of the information that is currently out there about those two. Then we went to the Harvard Stem Cell Institute, and we took the cell line that is most widely distributed, and we looked at it similarly. Now we're going ahead and expanding, to bring in information about the other NIH lines and some of the other lines that the Harvard Stem Cell Institute has [derived with private support after 2001], and then we're going to go beyond that and continue to expand.

The fact that we started off with the three lines that are the most extensively studied lines means that that was the most complex task to pursue. There's less information about the others; consequently, we'll be accruing information at a much more rapid rate. So that's where we started off, and that's where we are currently.

What information will you track in the Registry? Is this information that researchers already have, or would additional funding support be required for researchers to populate required fields?

The need [for a Registry] arises because there are probably many, many, many explanations on how to grow these cells; there are multiple statements about some of the properties of these cells, all of which are not in total agreement; and this

is all going to be in the Registry so an investigator can look at this and see where there's agreement and where there are open-ended questions. It is very difficult to cover the entire literature and to interpret where there is agreement and where there are things that have to be resolved: that is what the Registry is going to have for investigators in a very user-friendly way.

Will the Registry facilitate the ability of universities, hospitals, and other research entities to determine provenance of the cell lines?

We're going to try to obtain the maximal amount of information and will indicate in the Registry what documentation we have. If, in fact, we cannot access the information, it will be so indicated. It will be very transparent. If we have been assured that the documentation exists by an IRB, but we don't have a copy of it, that will be indicated, that it's on file at a particular institution.

What is the governance of the Registry? Is there a board or steering committee that oversees it?

There is a steering committee. We work with our ESCRO [Embryonic Stem Cell Research Oversight committee]. So there is already significant oversight.

In addition, the Registry is staffed by two faculty members, and this is their full-time activity. These are people who are knowledgeable about human embryonic stem cells and their applications, and the issues of quality control, the particular markers that characterize these cells, and the growth properties, as well as the issues related to provenance, applications, consent, and so on.

Will the Registry include any individually identifiable health information about donors of materials, or indicate if the researchers who derived the lines have access to such information?

We certainly will indicate if that information can be sought out. Whether we're going to have the actual identity of the patient in the bank, I don't really know. Our objective is to maximize the amount of information we can obtain. To answer the question accurately, we're going to have to go through the lines we have, and we are not going to have similar information about every one of them.

What is the expected timeline for the Registry and Bank?

The Registry is in place already; we are already down the road on that. For the Bank, we are now hiring the folks who will be operating it, and that, we anticipate, will be in place by April or May.

Are there any minimum ethical or regulatory standards for inclusion of a human embryonic stem cell line in the Registry or the Bank?

With respect to the Registry, we will make a concerted effort to acquire the information and to make certain that what we are entering and providing to investigators is, in fact, accurate. And we will explain how it's verified, so it's not just a question of "here it is."

The Bank is a very different story: there are ethical considerations. Standards are being developed. We anticipate there will be a requirement for evidence of documentation that the lines were developed under conditions established by institutional and ethical guidelines with informed consent. There will be stringent oversight.

How will the Bank operate?

We are developing the Bank so that we can handle the NIH-approved lines and the lines that are developed outside of the [federal funding] moratorium. That's being done by setting up laboratories and facilities in parallel, so they are identical but physically separate.

Which human embryonic stem cell lines do you expect to bank? What is the process for collecting additional lines?

The Harvard lines, definitely, the NIH lines, probably.

We will take the initiative to request lines to put into the Bank, and we will accept deposits from folks, and there again, these lines would have to meet a set of criteria. That's where we would want to make certain that all of the appropriate approvals are in place, that we have a clear idea of what the characteristics of those lines are, and that will go through approval of our ESCRO and our Oversight Committee.

If the Bank would include NIH-approved lines, how would that intersect with the National Stem Cell Bank at WiCell, which currently distributes those lines? Will cell lines be available in both places?

We're developing the Bank to have the capabilities to be able to do that. There is a question of licensing agreement, and that is what we are exploring. The Bank is being developed with the capability of being able to handle NIH and non-NIH lines.

Have you been in dialogue with any other human embryonic stem cell registries and banks, such as the NIH Registry, National Stem Cell Bank at WiCell, and initiatives abroad?

Yes, they've been largely informal, but we've had discussions with

folks in the U.K. and with people at NIH. We have had discussions with people at WiCell, and we visited WiCell and they visited us. So this is not at all being done in a silo-type of a manner. What is our view on cooperation? We want the goal to be maximally collaborative. I say that unequivocally, without any reservation.

What is the scope of the Bank and Registry? Is the focus exclusively on human embryonic stem cell lines, or would other types of pluripotent stem cell lines, such as those created through reprogramming adult cells, be included?

What you're looking at is a rapidly evolving field. The focus is going to be on human embryonic stem cells. This becomes somewhat semantic, because if you can reprogram a lineage-committed cell to de-specialize, de-differentiate and re-acquire all the properties of a primitive cell, then it sort of is a human embryonic stem cell. We initially are going to try to put into the Registry the most complete compendium of information about the NIH and the non-NIH human embryonic stem cell lines. Other lines will be added if in fact they exhibit properties of stem cells and their applications are going to be the same as human embryonic stem cells, but you have to have some starting point.

Will the Bank have the capacity to store both research-grade and clinical-grade cell lines (i.e., higher quality cell lines that will have capacity for use in clinical trials and beyond)?

We certainly will have the capacity to. We haven't made a final decision, but currently what's out there are research-grade. The question is whether it is being built as a GMP [Good Manufacturing Practices]

facility; it currently is not. We have capabilities to have a GMP facility, but that is not in the current plan. It will depend upon the applications developed. Our objective is to meet the needs first of the Massachusetts academic, biotech, and pharma community, and then go beyond that. What the requirements are depend upon the applications that are developed, and that is going to be evolving. It's a neat opportunity.

What significant issues relating to material transfer agreements (MTAs) and intellectual property do the Bank and Registry need to consider?

That is something that we are currently working through with our material transfer people. And [these discussions] include the dean and the chancellor; we have the engagement of the people in the leadership roles, it is not being delegated.

The issue of what types of licensing is required, what types of agreement have to be established, is open-ended, and what has been taken for granted is currently being challenged, so that is what we're trying to navigate through right now. I think that clarifying those issues is going to be very crucial. That's what we're up against, but so is every other bank out there.

In referring to current challenges, do you mean the challenges to the WARF patents?

Exactly. To what extent do we require establishing an agreement with WiCell for what we're distributing? And, to what extent do those that we distribute to have to have in place licensing agreements?

This is what needs to be clarified, and that's what we are currently trying to understand. Our legal people and our tech transfer people

are doing that. The Bank is being developed, the physical renovations are being completed right now, and we're hiring people. We do not have cells in the Bank at the moment, so we have to establish what are the limitations and what are the requirements.

If local researchers have Massachusetts funding for research that results in the creation of human embryonic stem cell lines, is there any materials-sharing requirement – for example, as a condition of receiving state funding, the researchers have to deposit the lines and information in this Registry and Bank?

I am not aware of the answer to that. Data-sharing is generally based on the provider of the funds. NIH has requirements for data-sharing; some private foundations do, and others don't.

Do you expect the Bank to partner with industry or other parties to address complex technical issues related to maintaining and characterizing cell lines, ensuring quality control, and carrying out other responsibilities of the bank?

Yes, and that will become important, because one of our objectives, and one of the Governor's objectives in setting up this Bank and Registry, is to support economic growth in Massachusetts that is linked to human embryonic stem cells. So, the answer is we will make every effort.

What do you see as the major challenges for the Bank?

I can tell you what our objectives are. It is not simply to be able to have the maximal number of criteria for quality control and to make certain that is as stringent as possible. We are identifying additional markers so we can enhance our capability for

quality control. We're also going to have an education component to the bank, where we will provide hands-on training as well as education. So we're going to have a training group as well as a group that is actually handling the receipt, the quality control, and the distribution of the cell lines.

Is there anything else that you think those in the broad life sciences community would be interested to know about this new initiative in Massachusetts?

To me, it is extremely important to maximize the amount of well-documented information about human embryonic stem cell lines and their applications. That is our objective, and we're developing the strategies to be able to do it. I think it is extremely important and I'm saying this from experience, because our research laboratory – which is totally separate from the Bank or Registry – uses human embryonic stem cells, and we published several papers this last year on human embryonic stem cells, so I'm speaking from experience. Working in the field gives me direct insight into what the requirements are. I understand that it's a big black box, and we're going to try to make it as informative and as accessible as possible.

Endnotes

¹ S. Solovitch, "Out Front on Stem Cell," *Silicon Valley/San Jose Business Journal*, Feb. 8, 2008, p.1. See also A. Smith, "Human Stem Cell Tests Could Be Near," *CCN Money.com*, Feb. 12, 2008 (available at <http://money.cnn.com/2008/02/11/news/companies/geron/index.htm?postversion=2008021115>).

² Solovitch, *supra* n.1.

- ³ Bush address to nation on stem cell research, Aug. 9, 2001, *available at* <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>. In addition, since 1996, the Dickey-Wicker amendment to Department of Health and Human Services appropriations bills has prohibited the use of federal funds for research that destroys an embryo or knowingly subjects it to risk of injury.
- ⁴ The other seven states, with approximate funding totals, are California (\$3 billion/10 years), Connecticut (\$100 million/10 years), Illinois (\$15-35 million), Maryland (\$38 million/2 years), New Jersey (\$15 million in research grants, \$270 million in facilities support), New York (\$600 million/11 years), and Wisconsin (\$5 million). See S. Stayn, "A Guide to State Laws on hESC Research and a Call for Interstate Dialogue," BNA Medical Research Law & Policy Report, Nov. 1, 2006, at 718; J. Fossett, "Federalism by Necessity: State and Private Support for Human Embryonic Stem Cell Research," Rockefeller Institute Policy Brief, Aug. 9, 2007. For additional information on supportive state programs, see www.iascr.org (website of the Interstate Alliance on Stem Cell Research).
- ⁵ L. Eckelbecker, "Banking on stem cells," Worcester Telegram & Gazette, Oct. 28, 2007.
- ⁶ For more information, see http://www.masslifesciences.com/match_grant.html.
- ⁷ See, respectively, H.B. 4234 (filed July 19, 2007), and H.B. 4539 (filed Feb. 14, 2008 amended to H.B. 4554 and approved by the House on Feb. 28, 2008).
- ⁸ Human embryonic stem cells usually have been derived from pre-implantation embryos, which originally were created for fertility purposes and were donated to research by patients/couples with informed consent. The field is evolving quickly, and other methods for deriving human embryonic or embryonic-like stem cells have been reported and are the subject of ongoing study. See, e.g., G. Kolata, "Scientists Bypass Need for Embryo to Get Stem Cells," NYT (Nov. 21, 2007) (reporting on Takahashi and Thomson teams' reprogramming studies).
- ⁹ For further information and specific principles, see NAS Guidelines (published in Apr. 2005, amended in 2007), *available at* http://www.nap.edu/catalog.php?record_id=11278, and ISSCR Guidelines (published in Dec. 2006), *available at* <http://www.isscr.org/guidelines/index.htm>.
- ¹⁰ For additional information, see Plomer, Taymor, and Scott, "Challenges to Human Embryonic Stem Cell Patents," Cell Stem Cell, Vol. 2 No. 1, Jan. 10, 2008, at 13-17. [*Editors' Note:* As this issue went to press, the USPTO upheld the validity of the two other patents that had been challenged.]

Local Health Law Briefs

By Julia R. Hesse, Esq.

Alan v. Boston Redevelopment Authority, 450 Mass. 242 (Dec. 13, 2007)

On December 13, 2007, the Massachusetts Supreme Judicial Court (the "SJC") ruled in favor of a group of city residents who brought an action against the Boston Redevelopment Authority, University Associates Limited Partnership (the developer), the Trustees of Boston University, and Boston Medical Center Corporation to challenge the final environmental impact report for the Biosafety Level 4 Laboratory planned in the South End (the "Biolab"). The SJC upheld an August 2006 lower court ruling which had ordered further scrutiny of the environmental impact of the BioLab on the surrounding neighborhoods. If approved, the BioLab will house some of the world's deadliest pathogens, including the Ebola virus, smallpox, anthrax, and botulism.

Massachusetts statutes require environmental impact reports ("EIR") to include an assessment of "issues which by the nature and location of the project are likely to cause damage to the environment." The EIR for the Biolab was originally reviewed and approved by the Secretary of the Executive Office of Environmental Affairs (EOEA) in November 2004. The SJC ruled that while the review of the EIR is not an adjudicatory proceeding, the process by which such information is gathered, identified, and applied to the statutory standards under the Massachusetts Environmental Policy Act ("MEPA") must be logical, and not arbitrary or capricious.

The SJC found that, despite the fact that the Secretary of EOEA has "considerable discretion" over the scope of an EIR, MEPA is intended to provide "meaningful opportunities for public review of the potential environmental impacts" of projects under review. The SJC determined that, while the likelihood of an accident or catastrophic event taking place at the Biolab may be remote, the EIR must focus on whether such an event would be "likely to cause damage to the environment." As a result, the SJC found that the inadequate discussion of "worst case" scenarios related to potential release of "highly contagious and virulent pathogens" in the EIR denied the state a meaningful opportunity to review the environmental impact of the project, and as a result, its approval was arbitrary and capricious. The SJC also found that the Secretary of EOEA's certification of the EIR was arbitrary and capricious, because the developer failed to address alternative physical locations for the facility. As a result of the ruling, the developer is now required to complete a new EIR of the BioLab. Construction on the Biolab is reportedly ongoing, and Boston University Medical Center is preparing an additional EIR.

Coombes v. Florio, 450 Mass. 182 (Dec. 10, 2007)

In *Coombes v. Florio*, the Massachusetts Supreme Judicial Court (the "SJC") ruled that a physician may be responsible for third parties who are injured by the physician's failure to warn patients about the possible side effects of treatment. The SJC's

decision reversed the judgment of a Massachusetts Superior Court and extended a physician's liability for failure to warn to now include all "foreseeable" third parties, when in the past it included only the patient. Justice Roderick Ireland wrote for the majority, stating that "a physician owes a duty of reasonable care to everyone foreseeably put at risk by his failure to warn about the side effects of his treatment of a patient."

In the case, Lyn-Ann Coombes' ten-year-old son was killed in March 2002 when Dr. Florio's patient, 75-year-old David Sacca, lost consciousness while driving and his automobile left the road and hit Coombes, who was standing on the sidewalk with a friend. Coombes died of his injuries. At the time of the accident, Sacca had prescriptions from Dr. Florio for Oxycodone, Zaroxolyn, Prednisone, Flomax, potassium, Paxil, Oxazepam, and Furosemide. Potential side effects of the drugs collectively include drowsiness, dizziness, lightheadedness, fainting, altered consciousness, and sedation. The plaintiff's expert in the case opined that the sedating effects of the drugs could be more severe in older patients, and that the standard of care for a primary care physician includes warning elderly or chronically ill patients about the potential side effects of these drugs and their effect on a patient's ability to drive. Sacca's last visit to Dr. Florio before the accident was on January 4, 2002, and at that visit, Dr. Florio did not discuss potential side effects and gave no warning about driving.

The SJC was divided in its opinion, but the majority concluded that a physician owes a duty of reasonable care to everyone foreseeably put at risk by his failure to warn of the side effects of his treatment of a patient. A concurring opinion from Justice Greaney (concurring in part, and dissenting in part) disagreed that the duty should be so broadly construed, but concluded that, in this case,

ruling in favor of the physician, under the summary judgment standard, was inappropriate because the physician should have warned the patient not to drive a motor vehicle at all. Two other members of the SJC dissented, with Chief Justice Marshall stating in her dissent that the majority's opinion "impedes not only the work of doctors," but it also "impedes the work of our Courts,"

and concluding that "the trial judge is left the unenviable task of divining from the vague generalizations of the concurring opinions the outer limits of a novel duty of physicians to third party non-patients."

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