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## Section Co-Chairs' Corner

On behalf of the Health Law Section of the Boston Bar Association, we want to thank you for your interest in this issue of the Boston Health Law Reporter. Through its work on publications like the Reporter as well as its various programs and events, the Health Law Section strives to provide important and timely information to its members.

This issue of the Reporter contains impressive and varied articles on mental health law and civil commitment by Fran O'Connor, the gift ban regulations from an industry and consumer perspective by Bill Mandell and Georgia Maheras respectively, and the impact of privacy and security provisions in the stimulus package on Massachusetts providers by Mark Rogers. In addition, this issue of the Reporter includes an informative piece on the Health IT Council as well as our regular Washington Word column discussing health care implications of the stimulus package by Kalah Auchincloss and Health Law Briefs by Meghan Cosgrove. We hope you find these pieces informative.

In addition to the direct support of its membership through undertakings like the Boston Health Law Reporter, the Section works to serve the larger community in recognition of the supportive role that lawyers can play in it. Along these lines, the Health Law Section recently hosted a membership event at which several area organizations presented an overview on how lawyers could become involved in pro bono cases. The event featured representatives from Greater Boston Legal Services, Health Law Advocates, the Medical Legal Partnership for Children, the Lawyers Clearinghouse, and the Volunteer Lawyers Project. Through the ongoing work of its Social Action Committee, the Section also makes available to the public through the BBA web site its Children's Mental Health Guide. The Section will continue to explore opportunities to further the public interest through similar events and efforts.

So, if you find yourself mulling the future during some downtime over the summer, we encourage you to consider becoming initially or further involved in the Health Law Section and its work. We have a number of committees that would benefit from your participation on them. For more information, please contact the Boston Bar Association at <http://www.bostonbar.org/cnct/index.htm> (tel. 617-778-2040) or call Dave or myself as the current Co-Chairs of the Section.

We hope to see you at an upcoming event!

**Matt Herndon and Dave Szabo**

### Inside this Issue:

Washington Word - Stimulating Medical Research and the Healthcare Industry: The American Recovery and Reinvestment Act of 2009

Page 3

Highlights of the HIPAA Privacy and Security Rule Changes under the American Recovery and Reinvestment Act

Page 7

The Massachusetts Health Information Technology Council and e-Health Institute: An Overview

Page 11

The Final DPH Pharmaceutical and Medical Device Manufacturer Conduct Regulations: The Industry Perspective

Page 15

New Massachusetts Regulations are a Positive Step Toward Improving Industry-Provider Transparency and Reducing Drug Costs for All Residents

Page 18

Mental Health Law and Civil Commitment: Litigation and the Need for Further Reform

Page 22

Local Health Law Briefs

Page 27

Editors

Page 31

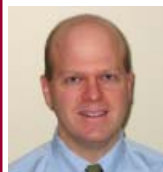
Authors

Page 32

Section Leadership

Page 34

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# Washington Word - Stimulating Medical Research and the Healthcare Industry: The American Recovery and Reinvestment Act of 2009

By: Kalah Auchincloss, Esq.

## Introduction

President Barack Obama signed H.R. 1, the American Recovery and Reinvestment Act of 2009<sup>1</sup> (“ARRA” or “Recovery Act”) into law on February 17, 2009. The bill represents the largest investment in public works since the Great Depression and is an effort to revitalize an economy in crisis by infusing \$787 billion into state coffers, small businesses, and struggling families.

The President has repeatedly stated his priorities for rebuilding America: repair the healthcare system, reform our energy policies, and invest in education and job creation. As he stated in a speech to Congress on February 24, 2009, eight days after enacting ARRA:

“Now is the time to act boldly and wisely – to not only revive this economy, but to build a new foundation for lasting prosperity. Now is the time to jumpstart job creation, restart lending, and invest in areas like energy, healthcare, and education that will grow our economy, even as we make hard choices to bring our deficit down.”<sup>2</sup>

The Recovery Act is the first step in implementing the Administration’s agenda. ARRA funds investments in renewable energy technology and energy efficiency programs, provides money to local school districts and public colleges and universities to improve our education

framework, and takes initial steps to fix our ailing healthcare system.<sup>3</sup>

In fact, one of the most important (and largest) components of the Recovery Act is the more than \$150 billion allocated to health-related programs. As we wait for Congress to hammer out legislation that we hope will dramatically reform healthcare, ARRA provides interim funding to expand coverage and create healthcare jobs: the Recovery Act is a down payment on health reform.

Much of the healthcare spending from the Recovery Act will be parceled out to states in the form of enhanced Medicaid matches or used to subsidize expansion of insurance coverage for low-income and unemployed individuals. For example, the legislation subsidizes 65% of unemployed individuals’ COBRA healthcare continuation coverage premiums. Additional funding is allocated for healthcare infrastructure, including health information technology and prevention and wellness programs.<sup>4</sup> Appropriations allocated for the National Institutes of Health (NIH) and comparative effectiveness research (CER) are equally critical, and offer exciting opportunities for medical researchers. Given the importance of the life sciences industry to the Massachusetts economy, practitioners in the Commonwealth should be aware of the opportunities available under the Recovery Act.

## National Institutes of Health

The National Institutes of Health received \$10.4 billion in the Recovery Act, an unprecedented flow of cash for the agency, which had an annual budget of less than \$30 billion in Fiscal Year (“FY”) 2008, and just over \$30 billion in FY09.<sup>5</sup> Senator Arlen Specter (D-PA), a long-time friend of medical research, championed the amendment to the Recovery Act in the Senate which increased NIH funding from \$3.5 billion to its current \$10.4 billion.<sup>6</sup>

Of the \$10.4 billion, the largest chunk—\$8.2 billion—is transferred to the Office of the Director, of which \$7.4 billion is designated for the individual Institutes for grants for scientific research. The remaining \$800 million will stay with the Office of the Director to support additional research-related activities, including Challenge Grants and Grand Opportunity grants (discussed below). \$400 million will be transferred from the Agency for Healthcare Research and Quality (“AHRQ”) for comparative effectiveness research.

In addition to supporting scientific research, \$1 billion of the NIH funding is allocated for competitive awards for construction and renovation of extramural research facilities; \$500 million is earmarked for renovation of NIH facilities (through the National Center for Research Resources); and \$300 million is for

the purchase of equipment (also through the National Center for Research Resources).

The challenge for NIH in obligating ARRA funding for scientific research is the reality that such funds are only available for FY09 and FY10. The Recovery Act is a short-term infusion of capital into the economy to mitigate job loss, jump-start job creation, and stabilize the economy—hence the two-year limitation on availability of funds. For medical research, this could present a problem. It can take years to see meaningful scientific results from an experiment; thus many NIH grantees are typically assured funding for multiple years to allow investigators time to complete, or make significant advances, in their research. Two-year grants may be insufficient for this purpose, and could leave investigators grappling for funding midway through a project that has not yet produced results, but which could, down the road, provide a medical breakthrough.

To address this issue while remaining consistent with ARRA's requirements, Dr. Raynard Kington, Acting Director of the NIH, has indicated that the Institutes will strive to fund projects that are expected to have a significant scientific impact within two years, and has impressed upon the community that grantees should not expect Recovery Act funding beyond FY10.<sup>7</sup>

Much of the \$8.2 billion for research will be allocated to Research Project Grants (known as "R01 grants"), the most common grant application at NIH. NIH expects to fund R01s, which have already been received and reviewed by the Institutes and found to be meritorious, but it may award grants to new R01s if appropriate. The Institutes

also hope to accelerate ongoing projects by funding supplemental grants, especially by providing support for infrastructure or the purchase of equipment.<sup>8</sup>

At least \$200 million will be used to fund "NIH Challenge Grants". Challenge Grants are two-year grants of \$500,000 per year in 15 identified "challenge areas", including stem cells, biomarker discovery, clinical research, and health disparities. The NIH has published a list of challenge grant topics, and actively sought applications for such grants, which were due on April 27, 2009.<sup>9</sup>

Finally, with ARRA funds, the NIH has created a new program, the Research and Research Infrastructure "Grand Opportunities" grants, to "address large, specific biomedical and biobehavioral research endeavors" over the course of two years.<sup>10</sup>

While R01 and supplemental grant funding will be a boon to scientists and will support widespread scientific research, Challenge Grants and Grand Opportunities funding may represent the best opportunity for medical researchers, universities, and the life sciences industry to receive awards for new projects, if such projects are reasonably expected to have a scientific impact within two years.

Despite the challenges involved with obligating \$10.4 billion in two years, this money offers incredible opportunities to realize scientific advances and medical breakthroughs. During the initiative to double the NIH budget from 1998-2003 (from approximately \$13.6 billion to \$27 billion)<sup>11</sup>, we saw the completion of the Human Genome Project (sequencing the entire human genome)—a discovery that

has begun to foster advances in medical care, including the development of many diagnostic tools to identify an individual's genetic risk for developing certain diseases, or to predict, based on genetic profiling, a patient's response to certain drugs. The additional appropriations for NIH over the next two years could lead to similarly significant discoveries.

In addition, there is no doubt that the NIH funding will help revitalize the economy. A study done by Families USA analyzing the economic impact of potential increases in NIH funding found that in FY07, NIH grants and contracts created and supported more than 350,000 jobs that generated wages in excess of \$18 billion in the 50 states. The average wage associated with the jobs created was \$52,000.<sup>12</sup> According to the same report, FY07 NIH funding led to 30,864 new jobs in Massachusetts, with total wages from those jobs reaching \$1.815 billion. Not surprisingly, NIH funding has in the past created more jobs and more economic benefit in Massachusetts than in any other state except California. Furthermore, Families USA estimated that if the sum of all NIH awards to the states were to increase by 6.6%, the national economic benefit would add up to \$3.1 billion worth of new business activity, 9,185 additional jobs, and \$1.1 billion in new wages.<sup>13</sup> The \$10.4 billion from the Recovery Act, which represents a 33% increase in the NIH budget, could presumably have up to five times that impact.

As Acting Director of NIH, Dr. Raynard S. Kington stated on the NIH website, "NIH is well positioned to fund the best science in pursuit of improving the length and the quality of the lives of our citizens, while at the same time stimulating the

economy.”<sup>14</sup> Medical researchers in all capacities at all institutions will benefit from this funding, particularly in Massachusetts.

### **Comparative Effectiveness Research (CER)**

In addition to providing funding for medical research through the NIH, the Recovery Act provides the Department of Health and Human Services (HHS) with \$1.1 billion to “conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition.”<sup>15</sup>

Comparative effectiveness has become a hot-button topic in Washington. Some think it will provide the solution to curbing out-of-control healthcare spending by enabling insurers to factor cost into decisions on whether to provide coverage for certain services. Others fear that insurers or public health care programs such as Medicare and Medicaid will use CER as evidence to deny medically necessary care, resulting in poor quality care and patient suffering. Still others down-play the cost component, and view CER as an invaluable tool to facilitate the practice of evidence-based medicine and to provide the best quality care to patients.<sup>16</sup> To placate some stakeholders, the Recovery Act includes specific language which states that:

“Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer. None of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.”<sup>17</sup>

Regardless of one’s views on the merits of CER, the Recovery Act has made such research inevitable (both now and as part of healthcare reform) by providing funding and infrastructure to engage in CER. As a result, the discussion in Washington has reached a fever pitch. Under ARRA, \$300 million for CER is allocated to AHRQ, \$400 million to the NIH, and \$400 million to the Secretary of HHS, to disperse at her discretion. The Recovery Act also establishes a Federal Coordinating Council for CER (the “Council”) and requires the Institute of Medicine (IOM), with input from public stakeholders, to submit a report to relevant Congressional committees by June 30, 2009, recommending funding for specific CER initiatives.<sup>18</sup> The IOM has already convened a public meeting to gather input on research priorities. Additionally it has solicited thoughts from a broad array of stakeholders through a questionnaire on its website.<sup>19</sup> The Council is similarly engaging in a process to allow public input on CER priorities.<sup>20</sup>

The Council and the IOM report will largely determine the direction of Recovery Act spending on CER. Although the Council has been appointed, the IOM report is not due until June, suggesting that spending decisions and grant opportunities will be delayed until mid-summer.

However, through its Challenge Grant program, discussed above, the NIH has already published numerous grant opportunities for comparative effectiveness research. Of the more than 200 NIH Challenge Grants, approximately 69 are related to CER.<sup>21</sup> As noted earlier, applications for these grants were due on April 27, putting NIH ahead of AHRQ and the Council in investing in CER.

Moreover, at least a few of these explicitly include cost-effectiveness components, sparking some unease. For example, one grant, under the heading “Prevention of Chronic Diseases in Disparity Populations,” proposes “research to examine and inform the clinical and cost effectiveness of prevention efforts, including medical devices, behavioral interventions, care management approaches,...pharmaceuticals, surgery, and other interventions for the prevention of chronic disease.”<sup>22</sup>

As NIH Challenge Grants are awarded and the Council and HHS begin to allocate their CER funds, the structure and form of CER research will begin to take shape, perhaps resolving some of the debates surrounding CER. Other controversial decisions will be left to Congress to settle in health reform discussions, or to HHS to grapple with in the future. Regardless, CER funding, both from the NIH and eventually from AHRQ and HHS, provides excellent opportunities for medical researchers.

### **Conclusion**

The Recovery Act represents an extraordinary investment in the American economy and a down payment on Administration priorities, including healthcare reform. By expanding health coverage and services for low-income and unemployed individuals and investing in new infrastructure to improve healthcare quality, such as health information technology and prevention and wellness, ARRA is a precursor to Congressional health reform in the coming months.

For life sciences researchers, investments in the NIH and CER offer extraordinary opportunities to engage in cutting-edge science, to discover medical breakthroughs,

and to revitalize the economy by creating new healthcare jobs.

- 1 American Recovery and Reinvestment Act, H.R. 1 and Pub. L. No. 111-3 (Feb. 17, 2009) [hereinafter ARRA or “the Recovery Act”].
- 2 Remarks of President Barack Obama—Address to Joint Session of Congress, Feb. 24, 2009, available at [http://www.whitehouse.gov/the\\_press\\_office/remarks-of-president-barack-obama-address-to-joint-session-of-congress/](http://www.whitehouse.gov/the_press_office/remarks-of-president-barack-obama-address-to-joint-session-of-congress/) (last accessed Apr. 4, 2009).
- 3 ARRA is also consistent with the President’s initiatives to improve transparency and seek public input. The President has established a website dedicated to ARRA spending at <http://www.recovery.gov>; requires weekly reports from all agencies receiving ARRA funding to be available on the website; and has directed the agencies to require heightened reporting obligations from recipients of ARRA funding. See Office of Management and Budget, Memorandum for the Heads of Departments and Agencies Preparing for Implementation of the Pending Recovery Legislation, Feb. 9, 2009, available at <http://www.recovery.gov/files/recoverylegislationmemo.pdf> (last accessed Apr. 4, 2009); OMB, Memorandum for the Heads of Departments and Agencies on Initial Implementing Guidance for the American Recovery and Reinvestment Act of 2009, Feb. 18, 2009, available at <http://www.recovery.gov/files/Initial%20Recovery%20Act%20Implementing%20Guidance.pdf> (last accessed Apr. 4, 2009); OMB, Memorandum for the Heads of Departments and Agencies on Ensuring Responsible Spending of Recovery Act Funds, Mar. 20, 2009 available at [http://www.whitehouse.gov/the\\_press\\_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-20-09/](http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-20-09/) (last accessed Apr. 4, 2009); OMB, Memorandum for the Heads of Departments and Agencies on Updated Implementing Guidance for the American Recovery and Reinvestment of 2009, Apr. 3, 2009, available at <http://www.recovery.gov/sites/default/files/m09-15.pdf> (last accessed Apr. 4, 2009).
- 4 For additional information on ARRA healthcare spending, see House Committee on Appropriations, Summary of ARRA, Feb. 12, 2009, available at <http://appropriations.house.gov/pdf/Press-Summary02-12-09.pdf> (last accessed Apr. 4, 2009).
- 5 FY08 Appropriations for the Departments of Labor and Health and Human Services, Pub. L. No. 110-161 Div. G, Title II (Dec. 26, 2007); FY09 Appropriations for the Departments of Labor and Health and Human Services, Pub. L. No. 111-8, Div. F, Title II (Mar. 11, 2009).
- 6 S.AMDT 178 to H.R. 1, as proposed by Senators Harkin (D-IA), Durbin (D-IL), and Specter (R-PA), agreed to by voice vote, Feb. 3, 2009. Senator Specter changed his party affiliation from Republican to Democrat on April 28, 2009.
- 7 [http://www.nih.gov/about/director/02252009statement\\_arra.htm](http://www.nih.gov/about/director/02252009statement_arra.htm) (last accessed Apr. 9, 2009).
- 8 *Id.*
- 9 [http://grants.nih.gov/grants/funding/challenge\\_award/](http://grants.nih.gov/grants/funding/challenge_award/) (last accessed Apr. 4, 2009).
- 10 <http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-004.html> (last accessed Apr. 9, 2009).
- 11 <http://www.nih.gov/about/almanac/appropriations/index.htm> and <http://www.nih.gov/about/almanac/appropriations/part2.htm> (last accessed Apr. 6, 2009).
- 12 In Your Own Backyard, How NIH Funding Helps Your State’s Economy, Families USA, Jun. 2008, available at <http://www.familiesusa.org/issues/global-health/publications/backyard-key-findings.html> (last accessed Apr. 4, 2009).
- 13 *Id.*
- 14 [http://www.nih.gov/about/director/02252009statement\\_arra.htm](http://www.nih.gov/about/director/02252009statement_arra.htm) (last accessed Apr. 4, 2009).
- 15 H.R. Rep. No. 111-16 at 453, 111th Cong., 1st Sess. (Feb. 12, 2009).
- 16 John Reichard, The Two Sides of the Comparative Effectiveness Coin, CQ HealthBeat, Mar. 19, 2009.
- 17 ARRA Div. A, Title VIII, § 804.
- 18 *Id.*; ARRA Div. A, Title VIII.
- 19 <http://www.iom.edu/CMS/64305.aspx> (last accessed Apr. 4, 2009).
- 20 HHS Press Release—Federal Coordinating Council on Comparative Effectiveness Research, Apr. 7, 2009, available at <http://www.hhs.gov/news/press/2009pres/04/20090407a.html> (last accessed Apr. 7, 2009).
- 21 See NIH Challenge Grants at [http://grants.nih.gov/grants/funding/challenge\\_award/](http://grants.nih.gov/grants/funding/challenge_award/) (last accessed Apr. 9, 2009).
- 22 *Id.* (emphasis added).

# Highlights of the HIPAA Privacy and Security Rule Changes under the American Recovery and Reinvestment Act

By: **Mark C. Rogers, Esq.**

After seemingly endless debate, the federal economic stimulus package is now a reality. The American Recovery and Reinvestment Act of 2009 (the “Act”) was passed by Congress on February 13, 2009, and signed into law by President Obama on February 17<sup>th</sup>. Health care is a significant focus of the Act. In particular, Title XIII of the Act – Health Information Technology for Economic and Clinical Health Act – sets forth substantial changes to the HIPAA Privacy and Security Rules.<sup>1</sup> These changes mean that providers or “covered entities”<sup>2</sup> will need to amend their existing HIPAA Privacy and Security policies and procedures in order to be in compliance with the Act. This article provides an overview of the Act’s significant amendments to the HIPAA Privacy and Security Rules and how these amendments will affect Massachusetts providers.

## **Business Associates**

The Act requires business associates to comply with the administrative, physical, and technical safeguards of the HIPAA Security Rule. As a result, business associates will be required to develop written policies and procedures pertaining to the security of electronic protected health information (“PHI”). Furthermore, the Act prohibits business associates from using or disclosing PHI that is not in compliance with each of the required terms of a business associate

agreement. The Act provides that business associates who violate the HIPAA security standards or the terms of their business associate agreement will now be subject to the same civil and criminal penalties as the covered entities.

Covered entities will likely need to amend their business associate agreements to require their business associates to comply with the administrative, physical, and technical safeguards of the HIPAA Security Rule and to require that they adopt appropriate written policies and procedures. The U.S. Department of Health and Human Services (“HHS”) is expected to issue regulations specifically addressing what new provisions need to be incorporated into business associate agreements.

## **Accounting of Disclosures**

Covered entities that utilize or maintain electronic health records (“EHRs”) are required under the Act to provide individuals with an accounting of disclosures for disclosures of PHI through an electronic health record (EHR) that relate to treatment, payment, or health care operations. Previously, covered entities were exempt from providing individuals with an accounting of disclosures for such disclosures of PHI. In addition, the Act provides that for disclosures by business associates, the covered entity may provide the accounting or it may direct the individual to the business associate, who must comply

with the accounting of disclosure requirements.

A covered entity may impose reasonable fees on an individual for the production of an accounting of disclosures. However, the fees may not be greater than the covered entity’s labor costs in responding to the request.

The Secretary of HHS (the “Secretary”) is required to adopt standards that will detail what information must be included in accounting of disclosures for treatment, payment, and health care operations. The effective date of this provision of the Act depends upon when a covered entity acquires an EHR. If a covered entity acquired an EHR prior to January 1, 2009, it will not be required to begin making accountings until January 14, 2014. If a covered entity acquires an EHR after January 1, 2009, the effective date for these new accountings will be January 1, 2011. The Secretary may extend these effective dates until 2016 and 2013, respectively.

## **Privacy and Security Breach Notifications**

Prior to the Act, HIPAA did not require a covered entity or business associate to notify an individual about a privacy or security breach related to his/her PHI. The Act now requires a covered entity or business associate to notify individuals whose “unsecured protected health information” has been or is reasonably believed to have

been accessed, acquired, or disclosed as a result of a privacy or security breach. The Act defines “unsecured protected health information” to mean PHI that is not secured through the use of a technology or methodology specified by guidance issued by the Secretary.

On April 17, 2009, the HHS issued the aforementioned guidance specifying the technologies and methodologies that render PHI unusable, unreadable, or indecipherable to unauthorized individuals for purposes of the breach notification requirements under the Act.<sup>3</sup> According to the guidance, PHI is rendered unusable, unreadable, or indecipherable to unauthorized individuals only if it is (i) encrypted by “the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key”; or (ii) the media on which the PHI is stored or recorded has been destroyed.<sup>4</sup>

The Act requires notification to the affected individuals within sixty (60) calendar days of the discovery of the breach. Furthermore, if a breach involves more than 500 residents of a state, a covered entity must provide notice to prominent media outlets serving the state, as well as immediate notice to the Secretary. If a breach includes fewer than 500 individuals, the covered entity must notify the Secretary – but may do so as an annual submission. Pursuant to the Act, all breach notifications must contain the following: (i) a description of the incident, including the date of the breach and the date of the discovery of the breach (if known); (ii) a description of the type of PHI involved in the breach; (iii) guidance on what individuals should do to protect themselves from potential

harm resulting from the breach; (iv) a description of what the covered entity is doing in response to the breach, including how it is mitigating future harm and what it is doing to protect against further breaches; and (v) instructions for how individuals can contact the covered entity to obtain additional information (this should include a toll-free phone number, an email address, website or postal address).<sup>5</sup>

Massachusetts already has a “Security Breach Law” (G.L. c. 93H), which requires covered entities to provide notice to affected Massachusetts residents whose personal information has been subject to a security breach. The Massachusetts law provides that notice must be made “as soon as practicable and without unreasonable delay.”<sup>6</sup> Although the Massachusetts Security Breach Law states that a “person”<sup>7</sup> is not relieved from the duty to comply with the requirements of any applicable general or special federal law regarding the protection and privacy of personal information, it provides that a person who maintains procedures for responding to a breach of security pursuant to federal law is deemed to be in compliance with the Massachusetts Security Breach Law, if the person notifies: (1) Massachusetts residents of a security breach in accordance with the maintained or required procedures; and (2) the Massachusetts Attorney General’s Office and the Massachusetts Office of Consumer Affairs and Business Regulation.<sup>8</sup>

### **Requests for Privacy Restrictions**

HIPAA currently provides that a covered entity has the discretion to not agree to comply with an individual’s request to restrict the disclosure of his/her PHI that re-

lates to treatment, payment and health care operations. The Act amends the HIPAA provision to require covered entities to comply with requests from an individual to restrict the disclosure of his/her PHI that relates to treatment, payment and health care operations if: (i) the restriction relates to disclosure to a health plan for purposes of carrying out payment or health care operations; (ii) the restriction does not relate to disclosure to a health plan for the purpose of carrying out treatment; and (iii) the PHI pertains solely to a health care item or service for which the health care provider involved has already been paid out-of-pocket in full.<sup>9</sup>

### **Marketing and Fundraising Communications**

Currently, a covered entity can only issue a marketing communication to an individual with that individual’s prior written authorization, unless such communication meets one of the following exceptions to the definition of marketing under the HIPAA Privacy Rule: (i) a communication made by a covered entity about the entity’s own health related products or services; (ii) a communication for treatment purposes; or (iii) communications for case management or care coordination of the individual or to recommend alternative treatments, therapies, health care providers, or settings of care. A communication that meets one of the above exceptions does not require an authorization from the individual, as the authorization is most likely considered to be for treatment or healthcare operations purposes under the HIPAA Privacy Rule.

The Act provides that a marketing communication is not considered

a healthcare operation unless it meets one of the exceptions to the definition of marketing **and** the covered entity does not receive direct or indirect remuneration for making the communication. If a covered entity does receive direct or indirect remuneration, the communication will not be considered marketing if the communication is for treatment purposes or if: (i) the communication is about a current drug or biologic the recipient is taking and any payment is reasonable as defined by the Secretary; (ii) the communication is made by a covered entity based on a valid HIPAA authorization from the individual; or (iii) the communication is made by a business associate of a covered entity in accordance with a business associate agreement.

The Act requires that any fundraising communications from a covered entity shall state in a “clear and conspicuous manner” that the recipient has the right to opt-out of receiving further fundraising communications.<sup>10</sup> An opt-out by an individual shall be treated as a revocation of authorization under the HIPAA Privacy Rule.

The Act’s restrictions on marketing and fundraising communications pertain to such communications made after February 17, 2010.

### **Electronic Health Record Access**

The Act provides that if a covered entity uses or maintains an EHR with respect to PHI, an individual shall have the right to obtain a copy of his/her PHI in electronic format. This provision of the Act may require covered entities to review their EHR system for necessary technical upgrades.

### **Minimum Necessary**

The Secretary is required to issue guidance within 18 months of the passage of the Act on what the term “minimum necessary” encompasses in terms of the disclosure, use and request of PHI under the HIPAA Privacy Rule.

### **Sale of PHI**

The Act prohibits a covered entity or business associate from directly or indirectly receiving remuneration in exchange for PHI without a valid authorization from the individual that includes a specific authorization as to what PHI may be sold. The prohibition does not apply to the sale of PHI related to:

- Public health activities;
- Research, and the price charged reflects the costs of preparation and transmittal of the data;
- Treatment of the individual;
- Sale, transfer, merger or consolidation of all or part of the covered entity;
- Business associate functions pursuant to a business associate agreement; and
- Providing an individual with a copy of his/her PHI.

The prohibition also does not apply to any activity deemed necessary and appropriate by the Secretary. In accordance with the Act, the Secretary must promulgate regulations pertaining to the prohibition on the sale of PHI.

### **Increased HIPAA Enforcement**

Pursuant to the Act, the Secretary is required to impose a civil penalty for a violation due to willful neglect

and to conduct a formal investigation of any complaint if a preliminary investigation indicates willful neglect. Furthermore, within three (3) years of the enactment of the Act, the Secretary must issue regulations providing a methodology for sharing civil monetary penalties or monetary settlements with individuals harmed by violations. Obviously there is great concern about this provision from the provider perspective as this sharing of monetary settlements and penalties could incentivize individuals to file HIPAA complaints.

### **New Penalties**

The Act significantly increases the civil monetary penalties for violations of both HIPAA and the Act. Currently, HIPAA provides for a \$100 penalty for each violation with a cap of \$25,000 for multiple violations in a given calendar year. The Act amends this to increase the penalty to \$1,000 for each violation “due to reasonable cause and not willful neglect.” with a cap of \$100,000 each calendar year.<sup>11</sup> The Act also provides that if a violation was due to willful neglect, but was corrected, the penalty shall be \$10,000 for each violation with a \$250,000 annual cap.<sup>12</sup> Finally, the Act states that if a violation was due to willful neglect and was not corrected, the penalty shall be \$50,000 for each violation with a \$1,500,000 annual cap.<sup>13</sup>

### **Conclusion**

The Act represents significant changes to the HIPAA Privacy and Security Rules. Massachusetts providers need to review and revise their current privacy and security policies/procedures to ensure compliance with the Act.

- 1 45 C.F.R. Parts 160, 162, 164 and 165.
- 2 A "covered entity" is (1) a health plan; (2) a health care clearinghouse; or (3) a health care provider who transmits any health information in electronic form in connection with a covered transaction. See 45 C.F.R. § 160.103.
- 3 See "Guidance Specifying the Technologies and methodologies That Render Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals for Purposes of the Breach Notification Requirements under Section 13402 of Title XIII (Health Information Technology for Economic and Clinical Health Act) of the American Recovery and Reinvestment Act of 2009; Request for Information".
- 4 See *id.*
- 5 Title XIII of the American recovery and Reinvestment Act of 2009.
- 6 G.L. c. 93H, § 3.
- 7 A "natural person, corporation, association, partnership or other legal entity." G.L. c. 93H, § 1.
- 8 G.L. c. 93H, § 5.
- 9 See *id.*
- 10 Title XIII of the American Recovery and Reinvestment Act of 2009.
- 11 See *id.*
- 12 See *id.*
- 13 See *id.*

# The Massachusetts Health Information Technology Council and e-Health Institute: An Overview

By: Dave Szabo, Esq.

President Barack Obama has made the adoption of health information technology (HIT) a major component of both his economic stimulus package and health care reform efforts. However, just as Massachusetts health care reform has provided a template for national efforts, the Massachusetts General Court was well ahead of Congress in promoting HIT. This article will describe the major elements of state law enacted in 2008 to promote HIT adoption, and recent activities to promote HIT adoption at the state level.

Chapter 305 of the Acts of 2008, officially named “An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care,” is also known as the “Cost Containment Bill” (the “Act”). The Act was enacted to follow up on the near-universal coverage plan enacted in Chapter 58 of the laws of 2006. The Act is wide-ranging, and includes provisions relating to health care transparency, administrative efficiency, cost control, and primary care. Equally important, however, are provisions in the Act relating to HIT. These included:

- Mandating that all hospitals and community health centers adopt computerized physician order entry systems by 2012 as a condition of licensure;
- Mandating that all hospitals and community health centers adopt electronic health

records by 2015 as a condition of licensure;

- Mandating that the Board of Registration in Medicine promulgate regulations on physician competency in the use of computerized physician order entry, e-prescribing, electronic health records and other forms of HIT by 2015 as a condition of licensure;
- Amending hospital licensing laws to expressly authorize electronic medical records and reduce the record retention period from 30 years to 20 years; and
- Mandating full implementation of electronic health records systems and the statewide interoperable electronic health records network by January 1, 2015.

The Act created two new organizations charged with executing the implementation of electronic health records systems and the interoperable health records network. First, the statute establishes the Massachusetts e-Health Institute (the “Institute”) within the Massachusetts Technology Park Corporation (better known as the Massachusetts Technology Collaborative) (the “Collaborative”). The Collaborative, a quasi-public entity, operates as a state-chartered corporation under Chapter 40J of the General Laws, and is a quasi-public entity. As mandated by Chapter 305, the Institute’s mission is to “advance the dissemination of health information technol-

ogy across the Commonwealth, including the deployment of electronic health records systems in all health care provider settings that are networked through a statewide health information exchange.”

The Act also creates the Massachusetts Health Information Technology Council (“the Council”). The Council is charged with the duty to advise the Institute on the dissemination of health information technology across Commonwealth, including the deployment of electronic health records systems in all health care provider settings that are networked through a statewide health information exchange. The Council consists of a combination of ex-officio members drawn from state government, including the Secretary of Health and Human Services, the Director of MassHealth, the Secretary of Administration and Finance, and the Executive Director of the Cost and Quality Council, along with five other persons appointed by the Governor.

Two Council seats currently are not filled. The statute calls for the Executive Director of the Health Care Quality and Cost Council to serve on the Council, but this post currently is vacant. One of the appointed members of the Council, Dr. Howard Koh, recently resigned when nominated to be Assistant Secretary of the United States Department of Health and Human Services.

The statute creates an unusual relationship between the Council and the Institute. Clearly, the Institute is the organization primarily charged with implementing the legislature's directives, but the Council is not merely advisory – it has an important supervisory role, and must approve key aspects of the Institute's work. As a result, the Institute's staff must serve on two boards: the Collaborative's own board of directors, and the Council.

The Institute will be led by an executive director, who will report to the director of the Collaborative. The Institute's director is charged with preparing and annually updating a statewide electronic health records plan. Each annual plan shall contain a budget for the Institute. The Institute's director must submit the annual plan, updates, and associated budgets to the Council for its approval. Each such plan and the associated budget also will be subject to approval of the Board of the Collaborative, following action on it by the Council.

The statute also authorizes the Institute, through the Technology Collaborative, to contract with one or more "implementing organizations" that will do the work of assisting providers with electronic health record implementation and the development of an interoperable health exchange network. Contracts with implementing organizations will be subject to procurement by the Technology Collaborative, and must be affirmatively approved by the Council. By law, the Institute must develop community-based implementation plans that assess a municipality's or region's readiness to implement and use electronic health record systems and an interoperable electronic health records network within the referral

market for a defined patient population.

The activities of the Institute and Council are funded by the E-Health Institute Fund, which is a fund within the Technology Collaborative dedicated to this purpose. The fund can be credited with appropriations, proceeds of bonds issued by the Commonwealth, other monies authorized by the legislature, federal grants or loans, private gifts, grants or donations, and investment income. The statute directs the Institute's director to seek private gifts, grants and donations to the Fund. The E-Health Institute Fund will be administered by the executive director without the need for further appropriation by the legislature, provided, that any expenditures from the fund for grants or for contracts with implementing organizations must be approved by the Council.

Amounts credited to the Fund will be available for expenditure by the Massachusetts Technology Collaborative to support the dissemination and development of health information technology in the Commonwealth. The Fiscal Year ("FY") 2008 state budget appropriated \$15 million to the Institute for the implementation of electronic health records and a health exchange network – a significant amount to be sure, but far short of the hundreds of millions of dollars that would need to be spent to realize the vision spelled out in the Act. Because the monies have been appropriated by the legislature into the Fund, the balance can carry over from one state fiscal year to the next, and does not revert to the Commonwealth's general fund.

The Council and the Institute are accountable to the Legislature. The law requires the Institute, in

consultation with the Council, to submit a report to the Joint Committee on Health Care Financing and the Senate and House Committees on Ways and Means on the status of HIT in the Commonwealth on or before July 31, 2012. The report must include the status of: (i) the implementation and use of electronic health records systems, such as rate of provider participation; (ii) the statewide interoperable electronic health records network and its capacity to exchange health information between and among components of the health system, with special focus on ambulatory care providers; (iii) the security and privacy of HIT developed and disseminated through activities of the Council; and (iv) the impact of HIT on health care quality, health outcomes of patients, and health care costs. This is a significant undertaking in both implementation and performance measurement.

Significantly, the Act also sets specific privacy and information security requirements, which must be incorporated into the annual plan and which must be observed from every implementing organization and grantee that received monies from the Fund. These requirements include:

- 1) establishing a mechanism to allow patients to opt-in to the health information network and to opt-out at any time;
- 2) maintaining identifiable health information in physically and technologically secure environments by means including, but not limited to: prohibiting the storage or transfer of unencrypted and non-password protected identifiable health information on portable data storage devices; requiring data encryption, unique alpha-numerical identifiers and pass-

- word protection; and other methods to prevent unauthorized access to identifiable health information;
- 3) providing individuals the option of, upon request, obtaining a list of individuals and entities that have accessed their identifiable health information; and
  - 4) developing and distributing to authorized users of the health information network and to prospective network participants, written guidelines addressing privacy, confidentiality and security of health information and inform individuals of what information about them is available, who may access their information, and the purposes for which their information may be accessed.

Additionally, Section 4 of the Act creates a distinct data breach notification requirement that applies only to the statewide health information network, the Institute's technology grantees, and implementing organizations that contract with the Institute. In the event of a security breach, the network operator, grantee, or contractor, as applicable, must report the conditions of such unauthorized access or disclosure as required by the Massachusetts e-Health Institute; and must provide notice, as defined in Section 1 of Chapter 93H of the General Laws, as soon as practicable, but not later than ten (10) business days after such unauthorized access or disclosure, to any person whose patient health information may have been compromised as a result of such unauthorized access or disclosure, and shall report the conditions of such unauthorized access or disclosure. It should be noted that the Act's data breach notification requirements are in addition to, and different than, those imposed by

Chapter 93H regarding breaches of "Personal Information" and those imposed by the HIPAA amendments contained in the American Recovery and Reinvestment Act ("the ARRA"). The ten-day notification requirement may be difficult to comply with, especially if investigation of the data breach requires technical or forensic investigation.

Chapter 93H provides that entities that have adopted data breach notification procedures in compliance with federal rules or guidelines may comply with those procedures in lieu of compliance with all of the requirements of Chapter 93H, so long as they provide prompt notice of the data breach to the Attorney General and the Director of Consumer Affairs and Business Regulation. It is unclear, however, whether compliance with the data breach notification provisions recently enacted by Congress as part of the HIPAA amendments will supplement, or supersede, the distinct notification requirements set forth in the Act.

The Council and Institute have begun their work. The Institute proposed, and the Council approved, a budget for funding the Institute's staff and for developing the Institute's initial plan. A Request For Proposals has been released for professional consultation services, and soon the Institute will recruit an Executive Director who will report to the Collaborative and the Council. The Council has held public hearings around the Commonwealth to solicit public input on its activities and suggestions for the content of the statewide plan. The Institute is now in the process of drafting its first plan, and once the plan is approved, an RFP for implementing organizations will be released.

The advent of the ARRA has been both a help and a hindrance to the Council's and Institute's work. The positive aspects are obvious. Under ARRA, federal funds will be made available to providers who install certified electronic health records and demonstrate "meaningful use" of HIT by deadlines specified in the federal law. Just as important, ARRA also authorizes the Secretary of Health and Human Services to make a variety of investments in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States.

ARRA authorizes and directs the Office of the National Coordinator of Health Information Technology ("the National Coordinator") to develop a strategic plan for nationwide HIT adoption, and provides the Secretary with several funding vehicles to achieve the plan's objectives. One of these funding vehicles is a Health Information Technology Implementation Extension Program. The extension program will include funding for, among other things, the creation and support of regional HIT extension centers. These regional HIT extension centers, which must be affiliated with non-profit organizations, are intended to enhance and promote the adoption of HIT. The regional centers are directed to prioritize their risk for non-profit hospitals, critical access hospitals, entities that serve unreserved populations, and primary care medical practices. The regional centers will be recognized and funded by the Secretary based on criteria and processes that have not yet been fully defined. The Council and Institute will need to coordinate their work with regional extension centers as they are approved and funded by the federal government.

ARRA also sets up a program of state grants for various purposes. These include planning grants and implementation grants, both of which can be awarded directly to states or to “qualified state-designated entities”. A qualified state designated entity is defined as a multi-stakeholder, non-profit organization that has been designated by a state to receive grants for planning, implementation or both. Planning and implementation grants are subject to matching requirements, which initially will start at 10% and increase to 33% over time. As of the date of this article, the exact terms on which such grants will be awarded have not been determined.

ARRA also permits the National Coordinator to award competitive grants to states and Indian tribes to support loans to health care providers to be used by providers to purchase certified electronic health records, to enhance the use of HIT, to train personnel, and to improve the secure electronic exchange of health information. The statute permits states to use the grants directly for loans, or to guarantee local loans, to provide security for state bonds, or for similar specified purposes. Loan-related grants are subject to a 20% state matching requirement. The combination of a loan program and reimbursement incentives should provide an economic stimulus for the adoption of electronic health record systems by health care providers.

It is possible that either the Commonwealth or the Institute could seek federal planning grants, implementation grants, or loan related grants from the federal government in order to leverage the Commonwealth’s investment in the Institute and to finance the implementation of the statewide plan

mandated by the Act. Thus, the Institute might be a recipient of some of the federal stimulus monies for expenditure through the e-Health Institute Fund, while at the same time, private non-profit organizations, including regional extension centers designated by the federal government, could obtain their own funds that would complement the implementation of the state plan.

ARRA also presents significant challenges. The federal Medicare and Medicaid bonus payments for providers that implement certified electronic medical records will be available on a faster schedule than the planning deadlines contained in the Act. The Institute and the Council will be greatly challenged to align their plans with the market forces that these bonus payments will create, especially in providing timely useful assistance to physicians to enable them to earn their “bonus” payments from Medicare or Medicaid. Further, while federal aid, such as aid for planning grants and loan grants, is crucial in this time of constrained state budgets, many of the terms of the availability of federal aid are yet to be defined. The promise of substantial federal funding combined with the absence of clear federal guidelines can create stasis, instead of stimulus.

Dr. JudyAnn Bigby, the Secretary of the Massachusetts Executive Office of Health and Human Services, has made it clear that the state plan must be aligned with federal funding requirements in order to take appropriate advantage of federal funding opportunities, especially those that are subject to matching. Unfortunately, this has led to a delay in the development of the first state plan, but Secretary Bigby has directed the Institute to advance its efforts as quickly as possible, with

the goal of developing the first plan in the Fall of 2009.

Accordingly, the Council must develop its first annual plan with one eye on developments in Washington, and the other focused on the needs of the local health care community. With sustained and thoughtful effort, the Council and the Institute can craft a state plan that meets the ambitious goals set by the Legislature, takes advantage of federal assistance, and ultimately improves the quality and effectiveness of our health care delivery system.

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# The Final DPH Pharmaceutical and Medical Device Manufacturer Conduct Regulations: The Industry Perspective

By: William Mandell, Esq.

On March 11, 2009, the Massachusetts Department of Public Health (DPH) issued its final regulations, 105 CMR 970.000 (the “Final Regulations”), implementing Massachusetts General Law, Chapter 111N. Chapter 111N, which sets forth the most comprehensive state law to date regulating pharmaceutical and medical device marketing to physicians and other prescribers, was enacted under Chapter 305 of the Acts of 2008 (An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care).

The Final Regulations present a mixed bag to industry and thus will lead to a variety of responses and reactions from industry once they become effective on July 1, 2009. While industry welcomes the efforts of DPH to safeguard trade secrets and proprietary information, there remain significant concerns that the scope of Chapter 111N and the Final Regulations will have a detrimental overall impact on the viability of the biotechnology industry in the Commonwealth.

## Overview of the New Law

Massachusetts is now the sixth state to enact its own law regulating financial relationships between industry and medicine, and it is the first state to do so in such a comprehensive fashion.

While Chapter 111N and the Final Regulations have become known as the “Gift Ban” law, this short-

hand reference is a misnomer. In fact, the Massachusetts law does not prohibit all forms of gifts and meals.

As confirmed in DPH’s second set of FAQs issued on May 22, 2009, and available on its website,<sup>1</sup> Chapter 111N does not ban educational items that are consistent with the PhRMA and AdvaMed Codes of Conduct.<sup>2</sup> The 2009 versions of these voluntary trade association codes, while prohibiting recreational items and even minimal non-educational items such as notepads, pens and mugs with company logos, do permit pharmaceutical and medical device companies to offer items designed primarily for the education of patients or healthcare professionals, if the items are not worth more than \$100 and have no value outside of a professional’s practice (e.g., a text book would be OK, but a DVD player would not). Furthermore, meals can be provided if modest, accompanied by an educational or training presentation and provided at a hospital, medical office or medical-device training site, but Massachusetts goes beyond the PhRMA and AdvaMed Codes of Conduct to prohibit the direct provision of meals by pharmaceutical and medical device companies in restaurants unless such a restaurant is within a hospital.

The Final Regulations require both pharmaceutical and medical device manufacturers and distributors to: (i) adopt and comply with a compliance program and Mar-

keting Code of Conduct (which in many respects is more stringent than the standards set forth in the 2009 versions of the PhRMA Code and AdvaMed Code); (ii) annually submit compliance plan information and certifications to DPH; and (iii) beginning on July 1, 2010, annually disclose to DPH – for posting on a public website – the value, nature, purpose, and recipient of any sales and marketing activity payment, or other benefit, with a value of at least \$50 to physicians, prescribers, hospitals, nursing homes, pharmacists, and other prescribers.

Pharmaceutical manufacturers and distributors are further required to (i) comply with limitations and requirements on the use of non-patient identified prescriber data, including an “opt-out” for physician and other prescribers on having their prescriber data used for marketing purposes, and (ii) obligate all contracted speakers and consultants who serve on a formulary or clinical guideline committees to disclose their company relationship to the committee.

## Industry Reaction to the Final Regulations

The variety of industry perspectives on the DPH’s implementation of Chapter 111N are reflected in the myriad views expressed through the extensive written comments submitted to DPH between the proposed version of 105 CMR 970.000, issued in December 2008 (the “Proposed Regulations”), and

the promulgations of the Final Regulations. Although many company advocates and trade associations were highly critical of the proposed regulations, a significant percentage of these comments focused on requirements and limitations already mandated by the statute itself. DPH has worked toward addressing many of industry's ongoing questions and concerns about the elements of the Massachusetts-mandated Code of Conduct and scope of the reporting obligations by issuing two sets of FAQs.<sup>3</sup>

Local research institutions and biotech interest groups were satisfied to see that the Final Regulations excluded company funding of clinical trials and genuine research from the public disclosure requirement. DPH further confirmed that certain post-FDA approval research would not be subject to public reporting if a market research company funded by a pharmaceutical or medical device company pays physicians to participate in the market research study, provided that the physician is not paid directly by the funding company and is not aware of the company involved.

DPH has also made it clear that the Massachusetts law does not prohibit continued commercial funding for CME, as well as other non-CME conferences and meetings. This is an important aspect of the law, given the major ongoing efforts by many advocacy groups to eliminate even indirect funding of CME by pharmaceutical and medical device companies.<sup>4</sup> Company underwriting of CME events is permitted as long as certain safeguards are followed, such as adherence to the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Commercial Support (even if ACCME accreditation is not secured), and the separation of

CME grant-making functions from company sales and marketing departments. However, company underwriting of CME events, as well as other conferences and meetings, cannot include payment for meals directly to any health care practitioner (except as part of reimbursement for speakers and event organizers), although the Final Regulations allow "a CME provider or conference or meeting organizer" to apply company financial support for the event or meeting to provide meals for all participants.<sup>5</sup>

Furthermore, both Chapter 111N and the Final Regulations prohibit the provision of meals by companies outside of a medical office or hospital/device training setting. This off-site meal prohibition is absolute, even if the meal is offered with an informational presentation.<sup>6</sup> Thus, Massachusetts now outlaws the very common practice of hosting informational presentations that include meals at restaurants and hotels — activities that are permitted even in the more stringent 2009 updated versions of the PhRMA and AdvaMed Codes.

It is also important to note that DPH and the Massachusetts Attorney General's Office view Chapter 111N and the Final Regulations to apply to any financial relationships between pharmaceutical and medical device manufacturers and distributors that market their products in Massachusetts or to Massachusetts prescribers outside of Massachusetts, and any Massachusetts licensed prescribers, regardless of the location of the relationships. Thus, the Massachusetts-mandated Code of Conduct restrictions and disclosure requirements must be understood and followed by companies in their efforts with meetings, contracts, and relationships that take place

outside of Massachusetts if they are with Massachusetts-licensed physicians and other prescribers.<sup>7</sup>

### The Future of the Law

Even though DPH has worked hard to consider the concerns of industry in issuing the Final Regulations and providing additional agency guidance, Chapter 111N and the Final Regulations could still have a deleterious impact on the local economy, including loss of biotech activities and the patronage of convention centers, hotels, and restaurants.

DPH was sensitive to this latter concern, and added a provision to the Final Regulations stating that there is no prohibition on the "use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific, educational or professional meetings or conferences."<sup>8</sup> Notwithstanding DPH's efforts to protect the Massachusetts convention and event business, and the fact that the Massachusetts law applies equally to conventions and meeting both inside and outside Massachusetts, there may thus be a perception and reality disconnect that could still hurt the local economy of the state.

DPH and the Legislature will need to consider in the required reevaluation of the law (which DPH has announced it plans to conduct on or about July 2010) whether the statute and its Final Regulations have had the unintended consequence of harming the state's economy in excess of the intended savings to the cost of health care in the Commonwealth. It is hard to imagine that the legislative leaders who brought Chapter 111N into existence intended to support a law that could save certain costs

within the health care system while causing substantially more lost dollars to the local economy. Whether that scenario plays out is yet to be seen.

The Massachusetts law also is understood by industry to be part of the growing national trend toward more mandatory, as well as voluntary, reform of industry's relationships with medicine. In addition to the more restrictive PhRMA and AdvaMed Codes that are going into effect this year, several other states are likely to pass laws similar to Chapter 111N. The federal government is also proposing to become involved in this area, with Senators Charles Grassley and Herbert Kohl promoting a bipartisan bill (entitled the Physician Payment Sunshine Act of 2009) that would create a national public reporting system of industry-physician payments.<sup>9</sup> Finally, a growing number of academic medical centers are adopting very stringent conflict of interest and disclosure policies; and, professional societies are starting to tighten their policies on the permissible scope of accepting financial support for CME and other activities. As of mid-2009 the Institute for Medicine, Association of American Medical Colleges, American Medical Association, as well as the ACCME, have established more stringent standards, or are all in the process of modifying their positions, on permissible industry relationships and managing conflicts.

## Conclusion

The Massachusetts efforts to regulate financial relationships between industry and medicine are just part of an ongoing evolution toward tougher legal and ethical standards intended to protect the integrity of medicine and lower health care costs.

The largest pharmaceutical and medical device manufacturers with in-house compliance officers and legal counsel are generally well aware of Chapter 111N and the Final Regulations and are already in the process of devising strategies to comply. Compliance with the Massachusetts mandatory Code of Conduct and reporting requirements will be more challenging for the smaller biotech start-ups and medical device distributors.

While it is inevitable that drug and device companies, physicians, and other regulated parties will be subject to a growing number of internal and external laws, rules, and policies establishing conflicting limits and reporting obligations, there is one absolute that can be stated:

The best approach to addressing financial conflicts for physicians maintains the primacy of the physician's role in medicine and research and allows physicians to pursue their professional calling and commitment with integrity; placing the best interest of each patient and of medicine as a whole ahead of any financial self-interest.<sup>10</sup>

- 7 DPH Guide to 105 CMR 970.000: Pharmaceutical And Medical Device Manufacturer Conduct [http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/pharmaceutical\\_medical\\_device\\_conduct\\_fa\\_090311.pdf](http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/pharmaceutical_medical_device_conduct_fa_090311.pdf).
- 8 105 CMR 970.007 4.c.
- 9 Physician Payments Sunshine Act of 2009 (S.301) (<http://thomas.loc.gov/cgi-bin/query/z?c111:S.301>).
- 10 Steve Schachter, William Mandell, Scott Harshbarger & Randall Grometstein, *Managing Relationships with Industry: A Physician's Compliance Manual* 246 (2008).

- 1 See [http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/pharmaceutical\\_medical\\_device\\_conduct\\_fa\\_090311.pdf](http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/pharmaceutical_medical_device_conduct_fa_090311.pdf).
- 2 Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, revised in July, 2008 and effective January 1, 2009; Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals, revised in December, 2008 and effective July 1, 2009.
- 3 See [http://www.mass.gov/pagelD=eohhs2modulechunk&L=4&LO=Home&L1=Government&L2=Departments+and+Divisions&L3=Department+of+Public+Health&sid=Eeohhs2&b=terminalcontent&f=dph\\_quality\\_healthcare\\_p\\_ph\\_mdm\\_conduct\\_code&csid=Eeohhs2](http://www.mass.gov/pagelD=eohhs2modulechunk&L=4&LO=Home&L1=Government&L2=Departments+and+Divisions&L3=Department+of+Public+Health&sid=Eeohhs2&b=terminalcontent&f=dph_quality_healthcare_p_ph_mdm_conduct_code&csid=Eeohhs2).
4. See e.g., David J. Rothman, ph.D., et. al., *Professional Medical Associations and Their Relationships with Industry*, JAMA, April 1, 2009.
- 5 105 CMR 970.007 1.c.
- 6 105 CMR 970.006.

# New Massachusetts Regulations are a Positive Step Toward Improving Industry-Provider Transparency and Reducing Drug Costs for All Residents

By: Georgia J. Maheras, Esq.<sup>1</sup>

In 2008, the Massachusetts Legislature passed Chapter 305 of the Acts of 2008, an omnibus bill designed to reduce health care costs and increase health care quality and transparency in the Commonwealth. One key element of Chapter 305 was the creation of Chapter 111N of the General Laws, which sought to address concerns regarding the transparency of physician interactions with pharmaceutical and medical device manufacturers (“industry”) by establishing an industry marketing Code of Conduct and a requirement for public disclosure of industry-physician payments.<sup>2</sup> The code of conduct and the disclosure provisions will be implemented on July 1, 2009, pursuant to new regulations issued by the Department of Public Health (DPH).

The high and rising cost of prescription drugs threatens patient access to needed medications, and industry marketing to health care providers is one of the major contributors to these high costs. The pharmaceutical industry spends approximately \$57.5 billion dollars annually on marketing, over \$20.4 billion of which is spent in “detailing” to physicians.<sup>3</sup> Detailing is the practice of sending industry sales representatives into providers’ offices to provide information about brand-name, new to market, and often higher-priced, drugs.<sup>4</sup> The cost of prescription drugs is borne by uninsured and underinsured consumers who must pay for the drugs

out-of-pocket, as well as by insured consumers whose premiums and out-of-pocket costs are increasing. These costs put consumers at risk for medical debt and bankruptcy, as each day patients are forced to choose between taking their medication and paying for food, housing and other necessities.

## Background

Prescription drug marketing, like all marketing, is intended to increase product sales for the company. Prescription drug marketing is slightly different, however, in that the person who pays for the product—the consumer—is not usually the person selecting the product. Instead physicians, nurse practitioners, and physician assistants prescribe a drug for the consumer who then purchases it. Given this relationship between prescriber and consumer, much of the prescription drug company marketing is focused on prescribers instead of consumers.<sup>5</sup> In addition to the \$20.4 billion spent annually on detailing, \$15.9 billion is spent on drug samples given to prescribers, and the remainder spent on continuing medical education, medical journal advertisements, consulting arrangements and other industry/provider arrangements.<sup>6</sup> Detailing also often includes the provision of items of value to physicians: A 2007 survey published in the *New England Journal of Medicine* found that a staggering 94% of physicians receive meals, drug samples,

honoraria, speaker’s bureau payments or other payments or benefits from pharmaceutical companies.<sup>7</sup> Social scientists have found that “the more contact doctors have with pharmaceutical sales representative, the more likely they are to prescribe drugs unnecessarily and inappropriately.”<sup>8</sup> Unnecessary prescribing drives up costs for the consumer and the health care system as well as lowers quality of care.

A reduction in the cost of marketing results in two possible types of drug savings. The first is by a reduction in the marketing budget expenditures by the company. The second is by reducing the influence that marketing has on prescribing patterns. Marketing is intended to increase the sales of specific products, predominately higher-priced drugs.<sup>9</sup> The overall result will be lower costs to the consumer because generic medications can be as much as 14 to 18 times cheaper than their brand-name therapeutic equivalent.<sup>10</sup>

## Industry Code of Conduct

Chapter 111N, and its accompanying regulations (105 CMR 970.000) prohibit certain gifts made by the industry to providers, with the aim of eliminating financial conflicts of interest that may inappropriately influence prescribing decisions. Pharmaceutical marketing predominately promotes prescribing of more expensive drugs in place

of equally safe and effective lower cost drugs, which may be either other brand name drugs or generic drugs. Numerous studies reviewed in the *Journal of the American Medical Association* show that physician prescribing is highly responsive to marketing.<sup>11</sup> The provision of pharmaceutical gifts to providers also threatens quality of care. Gifts and financial incentives from pharmaceutical companies create conflicts of interest that interfere with the ability of health care providers to make prescribing decisions based only on the needs of their patient.<sup>12</sup>

The creation of the Massachusetts Code of Conduct is in line with other state and institutional efforts nationwide to reduce the inappropriate influence of pharmaceutical gifts. Several states (Minnesota, Vermont, Maine, and West Virginia) as well as the District of Columbia have taken legislative action in this regard.<sup>13</sup> In Massachusetts, Boston University School of Medicine/Boston Medical Center, UMass Memorial Health Care, and Partners HealthCare have each instituted their own conflict-of-interest policies that ban clinicians from accepting personal gifts and all meals from pharmaceutical companies.<sup>14</sup> Most recently, the American Psychiatric Association ended industry-sponsored seminars and is phasing out industry-sponsored meals at its annual meeting.<sup>15</sup>

The Code of Conduct promulgated by DPH largely mirrors the Pharmaceutical Research and Manufacturers of America (PhRMA) Voluntary Code, and relies on both the PhRMA Code and the Advanced Medical Technology Association (AdvaMed) Code as its base.<sup>16</sup> The regulations do not completely ban gifts to providers. For example, companies may continue to provide

“occasional and modest” meals to providers in their offices. Such meals, however modest, add to the cost of prescription drugs and continue to improperly influence providers. Another area of concern has been the influence of industry funding for Continuing Medical Education (CME). The DPH regulations adopt the guidelines promulgated by the Accreditation Council for Continuing Medical Education (ACCME) for CME accreditation, which require the provider of the CME to adhere to specific guidelines and forbid industry funders from influencing the content of CME programs.<sup>17</sup> The Institute of Medicine has noted that enforcement of the ACCME guidelines is a challenge due to the high quantity of CME that is funded by industry, but the new DPH Code of Conduct now authorizes DPH or the Attorney General to enforce violations of these requirements.<sup>18</sup>

Another specific allowance in the Code of Conduct is for the provision of drug samples to providers “solely and exclusively for use by the health care practitioner’s patients.”<sup>19</sup> Drug samples are a key component of a manufacturer’s marketing efforts, and studies have shown that poor and uninsured individuals are less likely than those who are insured or wealthy to receive drug samples.<sup>20</sup> The use of drug samples as a marketing tool undermines the altruistic nature of giving samples to the poor and uninsured, which can be seen as laudable. Given the unique challenge that drug samples provide, DPH is engaging in a study on the best way to ensure drug samples get to the poor and uninsured. Some individual providers and academic medical centers are implementing their own policies regarding drug samples that reduce potential conflicts of interest.<sup>21</sup>

## **Disclosure of payments made to providers**

Chapter 111N and the accompanying regulations require manufacturers to report many types of gifts and payments valued at \$50 or more made to health care practitioners. The regulations do not require disclosure of every interaction between Industry and providers.<sup>22</sup> The overwhelming majority of research payments made to providers are expressly excluded from the disclosure requirement.<sup>23</sup> The regulations do, however, require disclosure of any research payment made with the primary intent of influencing sales –including so-called “seeding trials,” which are marketing strategies disguised as research.<sup>24</sup>

However, in light of the diverse tactics such as sham seeding trials, or sham advisory boards used by prescription drug companies to give money to doctors, anything less than full disclosure of all payments—including research payments—made by Industry to clinicians puts the Commonwealth and consumers at a disadvantage. MedPAC, the federal Medicare Payment Advisory Commission, recently raised such concerns to Congress, noting that “clinical research funded by manufacturers is not always objective and publicly available.”<sup>25</sup> Some industry leaders, notably GlaxoSmithKline, Merck, and Eli Lilly, have begun voluntarily disclosing certain high-value payments they make to providers.<sup>26</sup> The public has a right to know if the doctors who treat them are receiving money or other influential benefits from the companies whose drugs they prescribe. Full disclosure will allow the Commonwealth to evaluate whether industry is adhering to the Code of Conduct and to understand how

payments to providers continue to impact prescribing decisions.

While some critics believe that the disclosure requirement will inhibit research in Massachusetts and potentially reveal trade secrets, companies already report detailed information about their clinical trials on ClinicalTrials.gov, a website run by the National Institutes of Health (NIH).<sup>27</sup> Minnesota already collects and publishes this information,<sup>28</sup> and certain companies, such as Eli Lilly, GlaxoSmithKline, and Merck, are making this information available voluntarily on public websites. Additionally, academic medical institutions including the Cleveland Clinic, Stanford University, and the University of Pennsylvania, are also making this information publicly available. Disclosure of financial conflicts of interest does not threaten the status of Massachusetts as a global leader in medical research.<sup>29</sup>

## Conclusion

In promulgating the PhRMA Code of Conduct and the Advamed Code, industry has essentially asked consumers to allow it to police itself. Unfortunately, industry practice has demonstrated that industry does not always comply with its own voluntary codes of conduct.<sup>30</sup> Recent investigations by both the New York Times<sup>31</sup> and Senator Charles Grassley<sup>32</sup> have indicated that industry has the intent to employ their large marketing budgets to influence the prescribing practices of health care practitioners. Further, the voluntary guidelines lack adequate procedures to ensure industry compliance.<sup>33</sup> As Senator Grassley has stated, “[p]eople are less apt to violate a federal law than a code of ethics of its own profession.”<sup>34</sup> The Massachusetts Legislature insisted on

developing a law with enforcement procedures, through DPH and the Attorney General’s Office, to ensure that the state would have a means to ensure industry compliance with the code of conduct and disclosure requirements.

The residents of Massachusetts deserve the most affordable, highest quality treatment for their health care needs. Chapter 111N will make drugs more affordable to all and reduce the industry barriers between patients and providers.

- 1 The author wishes to acknowledge the assistance of Allan Coukell, Director of the Pew Prescription Project and Wells Wilkinson, Esq., Director of Prescription Access Litigation.
- 2 Chapter 111N also established an evidence-based prescribing program that offers prescribers a source of unbiased information about drugs to counteract the effects of pharmaceutical detailing. M.G.L. c. 111N §4.
- 3 Gagnon, Marc-Andre and Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, PLoS Medicine (Jan. 2008), available at <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050001>.
- 4 Approximately one percent of detailing is for generic drugs. The remainder is for brand-name products. Kesselheim, Dr. Aaron S., on file with author. May 11, 2009. Dr. Kesselheim is an Instructor in Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women’s Hospital.
- 5 There is a significant amount of money spent on Direct-to-Consumer (DTC) advertising, however it accounts for less than 10 % of the marketing expenses. See Brennan, Troyen, et al., *Health Industry Practices that Create Conflicts of Interest*, 295 JAMA 429-433 (2006).
- 6 Gagnon, *supra* note 3.
- 7 Campbell, E.G. et al., *A National Survey of Physician-Industry Relationships*, 356 New Eng. J. Med. 1742-1750 (Apr. 26, 2007).
- 8 Wall, L. Lewis and Douglas Brown, *The High Cost of a Free Lunch*. 110 *Obstet Gynecol* 169-73 (2007); Zipkin, D.A. and M. A. Steinman, *Interactions between pharmaceutical representatives and doctors in training*, 20 J. Gen. Internal Med. 777-786 (2005).
- 9 See, e.g., *National study by PeopleMetrics Rx confirms the importance of emotional connection between pharmaceutical sales reps and physicians*. Business Wire, Aug. 11, 2008, available at <http://www.reuters.com/article/pressRelease/idUS168653+11-Aug-2008+BW20080811>.
- 10 Consumer Union of U.S. Inc., *Consumer Reports Health Best Drugs For Less* (2009). (For instance, brand name heartburn treatment Nexium at \$215 per month costs 14-18 times the over-the-counter version of generic Prilosec for \$12-15/month.)

- 11 Wazana, Ashley. *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?* 283 JAMA, 373-380 (2000).
- 12 Dana, Jason and George Loewenstein. *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252-255 (2003).
- 13 As of May 2009, Connecticut, Texas, Oregon, and Minnesota all had legislative activity to create or strengthen existing gift ban and disclosure requirements. Vermont passed more stringent gift ban and disclosure requirements in April of 2009. At the federal level, the Physician Payments Sunshine Act, S. 301, 111th Cong., (2009) was filed in January 2009.
- 14 See, e.g., Partners Commission on Interactions with Industry, available at [http://www.partners.org/documents/CommissionReport\\_PartnersHealthCare2009.pdf](http://www.partners.org/documents/CommissionReport_PartnersHealthCare2009.pdf).
- 15 The Spine Surgeons of America has also recently implemented a conflicts of interest policy, available at <http://www.spine.org/Pages/PracticePolicy/EthicsProfConduct/Default.aspx> (accessed May 1, 2009).
- 16 Pharmaceutical Research and Manufacturers of America, *PhRMA Code on Interactions with Healthcare Professionals*, Revised January 2009, available at [http://www.phrma.org/code\\_on\\_interactions\\_with\\_healthcare\\_professionals/](http://www.phrma.org/code_on_interactions_with_healthcare_professionals/). See also, the Advamed Code of Conduct available at <http://www.advamed.org/MemberPortal/About/code/default.htm>.
- 17 ACCME Standards for Commercial Support are available at [http://www.acme.org/dir\\_docs/doc\\_upload/68b2902a-fb73-44d1-872580a1504e520c\\_uploaddocument.pdf](http://www.acme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-872580a1504e520c_uploaddocument.pdf).
- 18 Committee on Conflict of Interest in Medical Research, Education, and Practice, Institute of Medicine *supra* note 4.
- 19 105 CMR 970.008 (2)(e)(2009).
- 20 Cutrona, Sarah L. and Steffie Woolhandler et al. *Free drug samples in the United States: Characteristics of pediatric recipients and safety concerns*. 122 *Pediatrics*. 736-742 (2008) Tong, Kevin L. and Chia-Yen. Lien, *Do Pharmaceutical Representatives Misuse Their Drug Samples*. 41 *Canadian Family Physician*, 1363-1366 (1995).
- 21 Boston Medical Center, Partners HealthCare and UMass Memorial Medical Center all have existing or proposed policies under which drug samples are processed through a central pharmacy instead of in individual provider’s offices. The Partners HealthCare policy is available at [http://www.partners.org/documents/CommissionReport\\_PartnersHealthCare2009.pdf](http://www.partners.org/documents/CommissionReport_PartnersHealthCare2009.pdf).
- 22 Massachusetts State Senator Mark Montigny filed a technical corrections bill in the 2009-2010 legislative session to address this issue. See S. 547, 186th Leg. (Mass. 2009) available at <http://www.mass.gov/legis/bills/senate/186/st00pdf/st00547.pdf>.
- 23 105 CMR 970.004 (2009).
- 24 Hill, K.P. et al., *The ADVANTAGE Seeding Trial: A Review of Internal Documents*, 149 *Annals Int. Med.* 251-258 (2008).
- 25 Medicare Payment Advisory Commission, *Report to the Congress: Promoting Greater Efficiency in Medicare* (2007) available at [http://www.medpac.gov/documents/jun07\\_entirereport.pdf](http://www.medpac.gov/documents/jun07_entirereport.pdf); see also Wright et al., *Reporting of 6-month vs 12-month data in a clinical trial of celecoxib*, 286 JAMA 2398-2400 (2001).
- 26 See e.g., <http://www.gsk.com/responsibility/public-disclosure-of-clinical-research.htm>; <http://www.merck.com/corporate-responsibility/business-ethics-transparency/ethics-financial-support-third-parties/approach.html>; <http://newsroom.lilly.com/releasedetail.cfm?ReleaseID=336444>.

- 27 See <http://clinicaltrials.gov/> (The NIH provides approximately \$6 billion of funding annually to the Commonwealth, and disclosure of this information is reportable to NIH as part of the contract for funding. However, the NIH website lacks information about potential financial conflicts of interest).
- 28 See MINN. STAT. §§ 151.461, 151.47 (2006).
- 29 Recent newspaper articles indicate that Massachusetts' biotechnology industry is growing with companies making long-term commitments to expand their infrastructure and staffing capacity. See, e.g., Todd Wallack, *Biotech Notes Steady Growth in Massachusetts*, The Boston Globe, April 15, 2009, at B5.
- 30 Chimonas, Susan et al., *Physicians and drug representatives: exploring the dynamics of the relationship*. 22 J. Gen. Internal Med. 184, 189 (2007).
- 31 See, e.g., Gardiner Harris, *Crackdown on Doctors Who Take Kickbacks*, N. Y. Times, Mar. 4, 2009, at A14.
- 32 Weiland, M. *Senate Aging Panel Hears Support for Physician Payment Disclosure Proposal*. BNA's Health Care Daily Report 13, no. 39 (Feb. 28, 2008).
- 33 Chimonas, *supra* note 30, at 184-190.
- 34 Ceci Connolly, *With More Oversight on the Horizon, Drugmakers Work to Polish Image*, Wash. Post, Jan. 8, 2009, at A01.

# Mental Health Law and Civil Commitment: Litigation and the Need for Further Reform

By: Francis J. O'Connor, Esq.

## I. Introduction

It has been nearly nine years since there have been any significant changes to mental health laws governing civil commitments in the Commonwealth of Massachusetts. Those changes instituted procedural rather than substantive amendments to the civil commitment process. Following the trend of prior reforms, emphasis remained on patients' due process rights in the context of expanding enumerated patients' rights and more stringent filing requirements.<sup>1</sup> Existing patient rights in the civil commitment process seemed strengthened with reduced periods for filings designed to speed up the process and improve outcomes for patients. Since then there has been some progress and there have been some pitfalls. Additionally, there is still a need for substantive reform in the practice of mental health law and civil commitments, particularly as it relates to the non-dangerous patient. This article briefly summarizes the modern history of civil commitment in the Commonwealth of Massachusetts, the most recent reforms, and the continuing practical shortcomings in existing mental health law litigation and the treatment of non-dangerous patients facing commitment.

## II. History Of Modern Mental Health Law And Civil Commitments

Chapter 123 of the General Laws of Massachusetts was intended to make mental health laws and regulations adaptable to changing conditions and to advances in methods

of care and treatment of the mentally ill.<sup>2</sup> Modern mental health law has rapidly advanced since the late 1960's and early 1970's. Prior to that time, the prevailing point of view toward mentally ill patients was vividly captured by the holding in *Inhabitants of Amherst v. Inhabitants of Shelburne*, where the Supreme Judicial Court ("SJC") stated, "[a] commitment of a lunatic to a hospital by a judge need not be in open court, nor be recorded."<sup>3</sup> Mental illness, in general, was something that was repressed and not discussed in public. The stigma of psychiatric hospitalization to the individual patient, and derisive terms such as "lunatic", "insane asylum" and "demonic possession" were commonly used and accepted regarding the mentally ill. This view broadly pertained to all mentally ill patients, even those considered not dangerous. The focus of modern mental health law has centered on the patient's rights to due process rather than treatment. This focus has evolved from the government's strict *parens patriae* approach – where the state, acting in its role as parent for those in need, serves as the decision-maker for the patient from commitment through treatment – to the more relaxed approach of individual liberty. The development of due process regarding modern civil commitment provides for the patient, where possible, to decide for him or herself the need for admission to a mental health facility and treatment.

The law has increasingly recognized due process rights of mental health patients who have been admitted involuntarily to a mental health facility.<sup>5</sup> This increased emphasis

on civil rights arose in response to mental health confinement horror stories which were discovered to exist as recently as several decades ago.<sup>6</sup> Further, coinciding with the civil rights movement as well as advances in modern medicine helped place more of an emphasis on due process. Significant changes in mental health law have evolved as a result, including the landmark decision by the United States Supreme Court in *O'Connor v. Donaldson*.<sup>7</sup> *O'Connor* established a dangerousness standard for commitment of the mentally ill.<sup>8</sup> Massachusetts, in the decision in *Thompson v. Commonwealth*, adopted the standard in *O'Connor*.<sup>9</sup> In *Thompson*, the SJC made it clear that the dangerousness standard elucidated in *O'Connor* would apply to Massachusetts civil commitment proceedings, stating that the Commonwealth cannot constitutionally confine a non-dangerous individual who is capable of surviving safely in freedom by himself or with the help of willing and responsible family members or friends.<sup>10</sup> The SJC recently affirmed the primacy of due process in its recent decision in *Newton-Wellesley Hospital v. Magrini*.<sup>11</sup> There, the SJC further extended procedural protections to patients by stating a broader interpretation of a patient's right to an emergency hearing under the commitment statute, pointing out that attempts by the hospital to circumvent the statutory scheme were precisely what the statute was intended to prohibit.<sup>12</sup>

## III. The Most Recent Statutory Changes

In 1998, the Massachusetts Department of Mental Health (DMH)

promulgated regulations creating a patient's bill of rights detailing a number of specific obligations a facility had to offer and apprise a patient of, adding due process protections.<sup>13</sup> In 2000, Acting Governor Swift signed into law an amendment to G.L. c. 123, § 12 which significantly reduced the amount of time a psychiatric facility could hold a patient without the necessity of petitioning for intervention/action by the courts.<sup>14</sup> Governor Mitt Romney signed a further amendment in 2004 modifying the timeframes slightly but not significantly altering the impact of the 2000 legislation.<sup>15</sup>

Prior to the two most recent amendments, a psychiatric facility could hold a patient under Section 12 for a period of up to ten (10) days before having to file a petition for civil commitment with the District Court.<sup>16</sup> This period was reduced to four (4) days by the 2000 amendment and then three (3) days in 2004.<sup>17</sup> Prior to the amendments a hearing had to be scheduled within fourteen (14) days of a petition being filed.<sup>18</sup> The 2000 amendment lowered this period to four (4) days and then extended it to five (5) days under the 2004 amendment.<sup>19</sup> Both in theory and in practice, the state of the law before the amendments allowed facilities and psychiatrists sufficient time to evaluate mentally ill patients to determine the degree of their mental illness and what risks and/or dangers a patient posed to himself, herself or others. The net effect of the amendments reduced the timeframe for an evaluation from up to twenty-four (24) days down to eight (8). The twenty-four (24) day period most often times resulted in a patient's discharge prior to hearing, particularly in those instances where patients were compliant

with treatment recommendations and/or a more appropriate setting/placement became available. In practice the more stringent requirement of filing a petition for commitment within three (3) days has resulted in the filing of more commitments and placed a strenuous burden on facilities and psychiatrists which in some respects, although captioned in favor of patient's civil rights, has been detrimental to the facilities' ability to treat the patient's illness.<sup>20</sup>

No one argued vehemently against shortening the existing timeframe for filing as proposed by the 2000 amendment. However, the significance in the reduction increased the pressure on psychiatrists and psychiatric facilities, already overburdened and underfunded, to assess the mental illness and dangerousness of a patient with little or no additional information beyond the patient's presentation. Practitioners were more accustomed to using the longer period of time allotted before passage of the amendment to gather historical and medical information on the patient or to simply observe the patient in the Mental Health Unit in order to make a more practical assessment or proper diagnosis of the patient's mental illness, the patient's substantial likelihood of harm to himself, herself or others, and the appropriate treatment.

The result of the changes in the law with respect to psychiatric admissions was an increase in the number of petitions filed and the number of petitions actually heard by the courts.<sup>21</sup> While the intent of the amendments – placing more emphasis on the patients by affording him or her more rights – was correct with universal concurrence, the impact of the amendments made it more dif-

ficult for the patient to receive effective care and treatment for his or her mental illness. By mandating use of a criminal standard for a civil commitment process of a mentally ill patient, the illnesses of the patient is secondary to the procedural aspects of filing a petition for civil commitment based upon a shorter timeframe. The three (3) day filing timeframe heightens the inherent sense of distrust of involuntarily confined, mentally ill patients by fostering a more adversarial process between the patient and caregivers.

The barrier to treatment is profound when the psychiatrist in the psychiatric facility, already perceived as the enemy, is now confirmed as the same upon the filing of the petition. Further exacerbating the adversarial nature of the psychiatrist-patient relationship is the requirement that a psychiatrist inform the patient that any information he or she shares with the psychiatrist may be used in a commitment hearing against the patient.<sup>22</sup> The ability of the psychiatrist to develop a relationship with his or her patient and to garner the patient's trust has been hindered by the process. Once the petition is filed, counsel is appointed for the patient, and the facility and the patient are now adversaries in litigation, with conflicting goals. The expressed goal of patient's counsel is to obtain a patient's release under any circumstances, whether in the patient's best interests or not.<sup>23</sup> The opposing side consists of the psychiatrist in the psychiatric facility, with the help of counsel, seeking to treat a patient in what it perceives to be in the patient's best interests. In the middle is the court trying to navigate through the adversarial process and in much less time.

#### IV. Civil Commitment Practice

Where medicine has made significant advances in the care and treatment of the mentally ill, the law has not progressed as swiftly particularly as it relates to litigation. This lag has effectively counteracted medical advances by treating civil commitments in some ways as analogous to criminal proceedings. There is general agreement that a patient involuntarily confined to a mental health facility should be afforded civil rights equivalent to or greater than those of a criminal defendant. The law needs to more adequately address the purpose and timeframe of confinement associated with a civil commitment. Specifically, a civil commitment should not be seen as equivalent to a criminal proceeding and punitive but rather a civil one with the goal of effective treatment and discharge.

Equating civil commitment in its broader sense with criminal confinement has confused the process for all the parties involved and unnecessarily increased stigmatization of the mentally ill. Part of the conflation of civil and criminal processes is due to the similarity of nomenclature and criteria in statutes and regulations. In practice terms, the statutory and regulatory terminology creates the misperception of mental illness than is the actual practice in the courts. The headings of the pertinent sections under Chapter 123 reference proceeding to commit dangerous persons.<sup>24</sup> These same sections are the bases upon which facilities seek to commit non-dangerous patients categorizing such patients as "dangerous" due to the degree of their impairment.<sup>25</sup> More specifically, the statute provides for the court to find the likelihood of

serious harm if there is a very substantial risk of physical impairment or injury to the person himself as manifested by evidence that such person's judgment is so affected that he is unable to protect himself in the community and that reasonable provision for his protection is not available in the community.<sup>26</sup> The statute makes little distinction between being dangerous to oneself and being unable to live safely in the community.<sup>27</sup>

In theory, the standard of proof on the mental health facility in a civil commitment is the same as the burden on the state in a criminal trial, proof beyond a reasonable doubt.<sup>28</sup> Under this most stringent of burdens, one would presume that a majority of non-dangerous patients would prevail in a civil commitment proceeding. It is this writer's experience, however, that it is the facility which prevails on nearly every occasion. This is due at least in part to the court acting more as arbiter/mediator in commitment hearings with recognition of the need for treatment in deference to due process rights. The court has shown in case after case that it will hear all of the evidence taking into account what is in the patient's best interests and balancing the patient's opposition to confinement with his or her need for treatment. The court purportedly takes this position as a matter of practical need because of the inherent conflict of either confining a patient to a mental health facility or releasing him or her to the community without services which in nearly all cases they appear to need. The court is not being dismissive of the patient's civil rights, but rather is sensitive to addressing those rights without the necessity of repeat involuntary confinement of a patient who is mentally ill; thereby consuming further resources for

adversarial litigation rather than focusing on effective treatment and possibly shorter terms of confinement.

There are those who profess strict adherence to patients' civil rights and advocate for discharge from the hospital in every instance.<sup>29</sup> These advocates have opined that there is a lack of due process afforded to involuntary confined mentally ill patients.<sup>30</sup> They cite the location of the hearing (usually at the hospital), the patient's appearance at the time of hearing, and the fact that the patient may be medicated at the time of hearing as factors weighing against a patient's release rather than affording the patient a fair opportunity to be heard in accordance with due process.<sup>31</sup> Patients are afforded a number of procedural remedies under Chapter 123, many of which are analogous to those available in a criminal matter.<sup>32</sup> However, these same advocates when appointed to represent a mentally ill patient, often fail either to seek an independent psychiatric exam or, even when an independent psychiatric exam is obtained, fail to advocate in the patient's best interests when the independent psychiatric examiner agrees with the facility. Such advocacy, although zealous and part of counsel's charge, is arguably not in the patient's best interests and, in many cases, is detrimental based on the stigma of the findings relative to the adversarial hearing process.

The process typically subjects the patient to an order of commitment with the stated findings that the patient is mentally ill and a danger to himself, herself or others.<sup>33</sup> This is in opposition to the patient's need for treatment exacerbated by the patient's view of his/her treating psychiatrist as an adversary and

not as a therapist.<sup>34</sup> There is a direct contradiction between the law in practice and effective medical treatment for the mentally ill. In its strictest sense, the law cannot favor treatment of mentally ill patients because treatment is subjugated to due process.<sup>35</sup> As stated by Justice Learned Hand, litigation is one of the worst things that can happen to a person except for illness and should be dreaded.<sup>36</sup> Respondents in civil commitment proceedings must unfortunately confront both these troubles simultaneously. Due process, though important, presents a barrier to treatment because it forces all parties in the mental health setting to engage in litigation.

## **V. The Need For Further Reform**

Advances in psychiatric medicine as well as safeguards by law have relegated the idea of locking up patients who are mentally ill and throwing away the key, as discussed in the civil context herein, to an antiquated notion. Even with these advances, medicine, particularly psychiatric medicine, is still nowhere near an exact science. Any focus on mental health law has waxed and waned depending on the political climate and the ever increasing competition for funding. Most often, the issue is not addressed until such time as a sensational, catastrophic event such as the Virginia Tech shooting occurs. The issue of reform with regard to civil commitments has been out of vogue for the greater part of this decade.<sup>37</sup> Therefore, there is still a need for reform with respect to mental health law and civil commitments with an emphasis on treatment of the patient without sacrificing due process rights.

One remaining area for reform is the role of a less restrictive alternative placement in commitment proceedings. This criterion has not been clearly defined by the Legislature or courts, and guidance from DMH is lacking. Most other jurisdictions have implemented this protection through authorizing other forms of involuntary treatment beyond simply inpatient commitment and some of which are referenced herein.

In Massachusetts, the legal criteria for civil commitment are several.<sup>38</sup> The patient must be determined to have a mental illness.<sup>39</sup> The patient must demonstrate a substantial likelihood of harm to himself or herself or others if discharged or must be so impaired that they are deemed a very substantial likelihood of harm to themselves if discharged.<sup>40</sup> Lastly, there must not be any less restrictive alternative settings to commitment.<sup>41</sup> Of these criteria for commitment, the most confusing is the last, a determination whether there are any less restrictive alternative settings to commitment. There are not many alternatives, if any, particularly where the patient presents as a substantial likelihood of harm to himself or others. The term “less restrictive alternative setting” is ambiguous and vague, and neither the Legislature, nor the courts, nor DMH has taken occasion to define or clarify this term. Courts have stated the facility must find the least burdensome means of restraint that will protect the patient and others from physical harm, while providing rehabilitation for the patient.<sup>42</sup> The practical aspect is that facilities petitioning for involuntary commitment are doing so because they had insufficient time to properly evaluate a patient’s fitness for discharge, or they simply

have no place for a patient clearly in need of treatment to go to.

Numerous other jurisdictions have been able to carve out a less restrictive alternative to involuntary in-patient commitments. A large number of states have adopted or incorporated into their mental health law legislation the concept of involuntary outpatient commitment.<sup>43</sup> Unlike inpatient commitment, outpatient commitment has been defined as a judicial order entered pursuant to a state’s civil commitment scheme, which compels a person to participate in mental health programs and to comply with a court-approved treatment regimen outside of the walls of a mental institution.<sup>44</sup> This eliminates, at least temporarily, the concerns associated with any “massive curtailment” of the patient’s liberty.<sup>45</sup> Another novel concept, most recently employed in the state of Wisconsin, has modified the criteria for commitment to include care based on a patient’s need for mental health services.<sup>46</sup> This modified commitment standard allows for a maximum inpatient treatment period of thirty (30) days.<sup>47</sup> Massachusetts allows for commitment for up to six (6) months for a first commitment and an even longer period subsequently. It then requires the patient to be discharged to conditional outpatient treatment.<sup>48</sup> The Wisconsin statute has a number of other criteria and procedural safeguards which need to be met but the idea offers an alternative to the prolonged periods of commitment authorized by statute in many states, including Massachusetts.<sup>49</sup>

## **VI. Conclusion**

The concepts described above offer a buffer to the adversarial process of involuntary inpatient commitment which may soften the stigma

associated with commitment, including a court declaration of mental illness. Perhaps the time for these concepts has arrived in Massachusetts. The current state of the law, subsequent to the statutory changes and the ever-increasing liability exposure for psychiatrists and mental health facilities, has seen the number of civil commitment petitions filed annually since 2000 more than double.<sup>50</sup> Clinicians' increasing liability for the violent actions of their patients, even before the most recent amendment, has forced evaluations to err on the side of commitment.<sup>51</sup> The concepts, such as outpatient commitment, can be adopted in Massachusetts, affording patients not only more due process rights, but also a likely reduction in inpatient involuntary commitments in a manner beneficial to the patient, the psychiatric facility and the court.

1 G.L. c. 123, §§ 7 & 12.

2 G.L. c. 123, § 2.

3 77 Mass. 107 (1858).

4 Stavis, Paul F., "Civil Commitment: Past, Present and Future", *Quality of Care News*, Issue 64 (1995).

5 See generally, *Humphrey v. Cady*, 405 U.S. 504 (1972); *O'Connor v. Donaldson*, 422 U.S. 563 (1975); *Thompson v. Commonwealth*, 386 Mass. 811 (1982); *Newton-Wellesley Hospital v. Magrini*, 451 Mass. 777 (2008).

6 See *O'Connor*, *supra* (non-dangerous patient held for 15 years without treatment).

7 *Id.*

8 *Id.*

9 386 Mass. 811 (1982).

10 *Id.* at 816, quoting *O'Connor v. Donaldson*, *supra*, at 576.

11 451 Mass. 777 (2008).

12 *Id.* at 784.

13 104 CMR 27.00 *et seq.*

14 St. 2000, C.249, §5.

15 St. 2000, c. 249, §§ 4 to 8.

16 St. 1992, c. 379, § 29.

17 St. 2000, c. 249, §§ 4 to 8.

18 St. 1992, c. 379, § 29.

19 St. 2000, c. 249, §§ 4 to 8.

20 Robert D. Miller, Ph.D., "Grievances and Law Suits Against Public Mental Health Professionals: Cost of Doing Business?", *Bull. Am. Psychiatry Law* 20:4 (1992).

21 *Id.*

22 *Commonwealth v. Lamb*, 365 Mass. 265 (1974).

23 Committee for Public Counsel Services Performances Standards 1; see also Note 18, *supra*.

24 G.L. c. 123, §§ 7 & 12.

25 *Id.*; see also generally G.L. c. 123, § 1.

26 G.L. c. 123, § 1.

27 See J. Parry, "Involuntary Civil Commitment in the 90's", 18 *Mental & Physical Disability L. Rep.* 320, 324 (1994).

28 *Commonwealth v. Nassar*, 380 Mass. 908 (1980).

29 Note, The Search for Due Process in Civil Commitment Hearings: How Procedural Realities Have Altered Substantive Standards, 61 *Vanderbilt Law Review* 959 (2008).

30 *Id.*

31 *Id.*

32 G.L. c. 123, §§ 5 & 9.

33 G.L. c. 123, § 8.

34 It is the treating physician who provides the substantive testimony against his patient.

35 Note, *supra* at note 18.

36 Fred R. Shapiro, "The Oxford Dictionary of American Legal Quotations" 304 (1993), quoting "The Deficiencies of Trials to Reach the Heart of the Matter", *Lectures on Legal Topics* 89, 105 (1926).

37 Joseph D. Bloom, M.D., "Thirty-Five Years of Working with Civil Commitment Statutes". *J. Am. Acad. Psychiatry Law* 32: 430-9 (2004).

38 G.L. c. 123, §§ 1 & 8; *Commonwealth v. Nassar*, 380 Mass. 908 (1980).

39 G.L. c. 123, § 8.

40 G.L. c. 123, §§ 1 & 8.

41 *Commonwealth v. Nassar*, 380 Mass. 908 (1980).

42 *Id.* at 918.

43 Elizabeth Dickinson Furlong, "Coercion in the Community: The Application of Rogers Guardianship to Outpatient Commitment", 21 *New Eng. J. on Crim. & Civ. Confinement* 485 (1995).

44 *Id.* at 486.

45 *Newton-Wellesley v. Magrini*, 451 Mass. 777, 784 (2008).

46 1995 Wis. Act 292.

47 *Id.*

48 *Id.*

49 G.L. c. 123, § 7.

50 The Boston Municipal Court had approximately 58 civil commitment petitions filed in 2000. As of December 1, in excess of 121 petitions had been filed for 2008.

51 Robert D. Miller, Ph.D., "Grievances and Law Suits Against Public Mental Health Professionals: Cost of Doing Business?", *Bull. Am. Acad. Psychiatry Law* 20:4 (1992).

# Local Health Law Briefs

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## ***Commonwealth v. Kobrin*, 72 Mass. App. Ct. 589, 893 N.E.2d 384 (September 12, 2008)**

The Massachusetts Appeals Court found that a physician convicted of Medicaid fraud under M.G.L. c. 118E § 40 was entitled to a new trial following the post-trial discovery that claims for reimbursement were not submitted to Medicaid but rather to Medicare, as this evidence would likely have been a real factor in the jury's deliberations. The Appeals Court also reversed the physician's conviction for illegally prescribing a controlled substance in violation of the Massachusetts Controlled Substances Act (M.G.L. c. 94C § 32B(a)), finding insufficient evidence of wrongful criminal intent required under the Act (the "Act").

In 2002, Kennard C. Kobrin, a psychiatrist practicing in Fall River, Massachusetts, was convicted of two counts of Medicaid fraud and one count of illegally prescribing a controlled substance. The Commonwealth alleged that Kobrin entered into a complex money-making scheme that included the receipt of inflated rental payments from tenant psychologists in return for the referral of patients for testing and therapeutic services that were not medically necessary. In addition, the Commonwealth alleged that Kobrin prescribed potentially habit-forming drugs, known as benzodiazepines, to substance abuse patients at low dosage levels and in small quantities in order to ensure frequent reimbursable patient visits. Following his conviction, a

trial judge granted Kobrin's motion for a new trial on the two Medicaid convictions but declined to order a new trial on the illegal prescribing conviction. Kobrin subsequently appealed the denial of a new trial on the illegal prescribing conviction and the Commonwealth appealed the trial judge's grant of a new trial on the two Medicaid fraud convictions.

In upholding the trial court's order for a new trial on the Medicaid fraud convictions, the Appeals Court found that the post-trial evidence posed "a substantial risk that the jury would have reached a different conclusion had the evidence been admitted at trial." In reaching this conclusion, the Appeals Court rejected the Commonwealth's argument that the statute did not require the Commonwealth to show that a claim was actually submitted to Medicaid to support a conviction. Instead, the Appeals Court found that the Commonwealth proceeded against Kobrin under the second clause of M.G.L. c. 118E §40, which prohibits "any false statement or representation of a material fact in any application for any benefit or payment." Upon review of the specific language of M.G.L. c. 118E. §40 using the other sections of chapter 118E to provide context, the Appeals Court found that the only way that a false statement could be used in determining rights to benefits or payments is if the statement was submitted as part of a request for reimbursement. The Appeals Court also found the Commonwealth's second argument that the newly discovered evidence was read-

ily available to Kobrin's counsel at the time of trial without merit. The Court agreed with the assessment of the trial court judge, who noted that reasonable diligence would not have led Kobrin's counsel to this new evidence and that the absence of this information deprived Kobrin of significant defenses.

In reversing Kobrin's conviction on the illegal prescribing charge, the Appeals Court found the evidence insufficient to establish that Kobrin possessed the requisite wrongful intent. It is not enough to show that a physician did not comply with accepted medical practice to establish criminal liability under the Massachusetts Controlled Substances Act; there must be proof that a physician acted in bad faith and without a legitimate medical purpose. The Appeals Court set forth a list of missing facts that may have indicated that Kobrin wrote the prescription in bad faith and without a legitimate medical purpose. For example, there was no evidence that Kobrin prescribed the benzodiazepines to the patient at intervals overlapping prior prescriptions or between office visits, wrote new prescriptions to replace any claimed lost or stolen, prescribed dosages beyond the recommended ranges, or instructed the patient to fill prescriptions at different or distant pharmacies to avoid detection. In conclusion, the Appeals Court found that evidence of profitable and bad medical decision making alone without proof of an intent to serve no legitimate medical objective does not satisfy the requirements of the Act.

### **Colby v. Assurant Employee Benefits, 2009 WL 756974 (D. Mass) (February 23, 2009)**

A U.S. District Court judge ruled that a disability insurer's decision to deny long-term benefits to an anesthesiologist who suffered a potential risk of relapse from opioid addiction was arbitrary and capricious under the Employee Retirement Income Security Act of 1974 ("ERISA"). The plaintiff, Dr. Julie Colby, became addicted to the opioid Fentanyl to cope with severe back pain after surgery. Following the discovery of her addiction, the plaintiff received treatment at an inpatient facility during which time she applied for and received long-term disability benefits from Assurant Employee Benefits ("Assurant"). Upon discharge from the inpatient facility, the plaintiff's treating physician recommended that she not return to the practice of medicine for six months to allow her to continue to work on her recovery and stabilize her home situation. Assurant subsequently terminated Dr. Colby's benefits stating that she exhibited no symptoms of active substance abuse and that "risk of relapse [into substance abuse] is not the same as a current disability."

The plaintiff internally appealed Assurant's denial on the grounds that her risk of relapse prevented her from returning safely to work, an argument that was supported by her treating physician, therapist and other consultative physicians. Following the receipt of her second denial from Assurant, the plaintiff sued Assurant in U.S. District Court alleging that the exclusion of the risk of relapse from its analysis of her disability claim was arbitrary and capricious. Both parties filed

motions for summary judgment and subsequently agreed to resolve their dispute as a "case stated." "When deciding a case stated, a court draws such inferences as are reasonable to resolve the case, rather than drawing all inferences against each moving party as it would when evaluating cross-motions for summary judgment."

Where an ERISA disability plan, such as Assurant, grants the plan administrator discretion to determine eligibility for benefits, the administrator's decision must be upheld unless the aggregate evidence demonstrates that the denial of the claim for benefits is "arbitrary and capricious." This standard of review was set forth by the *United States Supreme Court in Firestone Tire and Rubber Co. v. Bruch*, 489 U.S. 101 (1989). In that case, the Supreme Court found that where an ERISA plan explicitly grants discretionary authority for benefit decisions to an administrator or other fiduciary, the review of an ERISA plan's denial of benefits should be subject to an arbitrary and capricious standard, rather than de novo review. As a result of *Firestone*, nearly all ERISA plans grant this type of discretion over benefit decisions to an administrator or other fiduciary. When a plan administrator acts as both the insurer and the administrator, however, the arbitrary and capricious standard must take this conflict of interest into account. In *Metropolitan Life Insurance Co. v. Glenn*, 128 S.Ct. 2343 (2008), the Supreme Court found that administrators that function in a dual role, such as Assurant, are subject to an inherent conflict of interest and that this conflict must be considered as one factor in determining whether the plan administrator has abused its discretion in denying benefits.

The District Court agreed with the plaintiff's primary argument that Assurant acted arbitrarily and capriciously by categorically excluding her risk of relapse from its analysis of her disability for several reasons. First, the District Court found that the terms of Dr. Colby's plan with Assurant did not distinguish between physical and mental disabilities. Furthermore, the plan established that any mental illness recognized in the Diagnosis and Statistical Manual of Mental Disorders ("DSM-IV") could serve as the basis for a disability; and the DSM-IV includes nine pages devoted to opioid-related disorders. These two facts give rise to the inference that disability resulting from opioid dependence was covered by Assurant's plan to the same extent as any other physical or mental disability.

While Assurant argued that the risk of relapse is not the same as a current disability, the District Court found this reasoning unpersuasive given that Assurant admitted that an individual who suffered from a physical illness, such as coronary disease, whose return to work would create a dangerously high risk of a heart attack would receive disability benefits under the plan. In essence, the District Court found that if "the Plan covers future risk of relapse resulting from physical sickness, the terms of the Plan require that future risk of relapse caused by mental illness, such as opioid dependence, be covered as well."

The District Court noted that courts are split on this issue but sided with those courts that recognize risk of relapse as a disability as long as such risk is supported by evidence and not otherwise specifically excluded from the terms of the plan. In rejecting the reasoning of

those courts that do not recognize risk of relapse as a disability, the District Court found this rationale to be a “moralistic error [that separates] risk of relapse from physical sickness from risk of relapse into mental illness.” The District Court remanded the case for Assurant to consider the plaintiff’s risk of relapse should she return to work. In addition, the Court awarded attorney’s fees to the plaintiff based on its desire to deter disability plan administrators from distinguishing between physical and mental disorders where not justified by the plain language of the policy.

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### ***Rhode Island Hospital v. Leavitt, 548 F.3D 29 (2008)***

On November 17, 2008, the United States First Circuit Court of Appeals reversed a district court’s finding that the Secretary of Health and Human Services (the “Secretary”) improperly excluded resident research time from Rhode Island Hospital’s (the “Hospital”) full-time equivalent (“FTE”) count for purposes of the Medicare Indirect Medical Education (“IME”) adjustment. The Court further held that the Secretary’s interpretation was in accord with the statutory language as well as congressional intent to provide additional payments to teaching hospitals for teaching costs.

The Medicare IME adjustment was established to compensate teaching hospitals for the higher inpatient care costs associated with the greater complexity and intensity of services they furnish as compared to non-teaching hospitals. One important factor used in the complex IME adjustment calculation is the ratio of FTE residents to a hospital’s total number of beds meant

to demonstrate a particular hospital’s “teaching intensity.” 42 C.F.R. §412.105(g)(1) sets forth the types of resident activities Medicare will include in its calculation of a teaching hospital’s FTE count. For purposes of this test, a resident must be enrolled in an approved teaching program and must be assigned to (1) the portion of the hospital subject to the Prospective Payment System (PPS), (2) the outpatient department of the hospital, or (3) certain entities under the ownership or control of a hospital. 42 C.F.R. §412.105(g)(1). Medicare counts a resident working in an ineligible area of the hospital as a partial FTE based on the portion of time he or she is assigned to an eligible area of the hospital.

For fiscal year 1996, the Hospital requested that 290 resident FTEs be included in the calculation of its IME adjustment. The Hospital’s fiscal intermediary, an entity contracted by Medicare to pay certain bills, reduced the Hospital’s FTE total by 12.06 finding that the regulations excluded time devoted by residents to research purposes. This finding reduced the Hospital’s IME adjustment by approximately \$1 million. The Hospital appealed this decision to the Medicare Provider Reimbursement Review Board (“PRRB”) which reversed the fiscal intermediary’s decision finding that the regulations governing the counting of FTEs clearly did not exclude educational research time spent by residents from a hospital’s FTE count. Subsequently, the Secretary exercised his right to review the decision of the PRRB and sided with the fiscal intermediary finding that the time residents spend performing research unrelated to patient care cannot contribute to a hospital’s total number of FTEs for purposes of the IME adjustment. The Hospital appealed the

Secretary’s decision to the United States District Court for the District of Rhode Island. The District Court granted the Hospital’s motion for summary judgment finding that the Secretary had misread the plain language of the FTE regulation. In the alternative, the District Court found that even if the Secretary’s reading of the FTE regulation was reasonable, the legislative history surrounding the IME adjustment made such an interpretation unreasonable.

On appeal, the Secretary argued that residents assigned to perform educational research unrelated to patient care were not “assigned” to an “area” or “portion of the hospital subject to the prospective payment system” as required by regulation. In response, the Hospital argued that the regulation does not require that the work a resident performs be reimbursable by the Medicare Inpatient Prospective Payment System (“IPPS”) as long as a resident is “assigned” to an “area” or “portion” of the hospital that is subject to IPPS. The Secretary disagreed, arguing that a resident must be integrated into a hospital unit dedicated to a form of patient care subject to IPPS billing in order to be considered “assigned” to an “area” or “portion” of the hospital subject to IPPS as required by the regulatory text.

Under the Administrative Procedure Act, the Court is required to defer to the views of the agency and may only overturn a decision if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” While the Court found both interpretations of the regulation reasonable, it ultimately gave deference to the Secretary stating that, “we give effect to an agency’s interpretation of its own ambiguous regulation so

long as that interpretation is reasonable.” To support its position, the Court highlighted the fact that the Hospital was unable to produce a scenario where a resident assigned to a patient care unit performed educational research. In addition, the Court rejected the Hospital’s argument that no resident would ever qualify as an FTE because all residents are required to engage in educational research activities and other activities unrelated to patient care. The Court found that Medicare could appropriately count a resident during the time he or she provided patient care services but refuse to count a resident during the time period he or she performed educational research. Furthermore, the Court found support for the Secretary’s argument in the Congressional exclusion of the “costs of approved educational activities” from the listing of Medicare-reimbursable “operating costs of inpatient hospital services.”

The Court also held that the Secretary’s interpretation of the FTE calculation was consistent with the statutory language and congressional intent surrounding the IME adjustment for teaching hospitals. Specifically, the Court rejected the Hospital’s contention that the Secretary was required to determine the number of resident FTEs in accordance with the formula in place in January 1983, the date Medicare transitioned from a cost-based to a prospective payment based reimbursement system. The Court found that nothing in the legislative history required the Secretary to refrain from regulating the method of calculating one or more variables of the IME adjustment, such as a hospital’s ratio of FTEs to beds. Furthermore, the Court was unable to find any evidence of Congressional intent regarding the

type of resident activities Congress wanted the Secretary to include in his FTE calculation. As such, the Court found that the Secretary’s method for calculating FTEs did not run counter to Congressional intent or administrative history and thus was not arbitrary, capricious or an abuse of discretion.

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