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Section Co-Chairs' Corner

Welcome to another edition of The Boston Health Law Reporter, a publication of the Health Law Section of the Boston Bar Association. As usual, our Communications Committee has put together a terrific collection of peer-reviewed articles on a variety of topics, including state H1N1 preparedness, priorities of the Massachusetts Hospital Association during the economic downturn, the recommendations of the Commonwealth's payment reform commission, NIH stem cell guidelines, and health care disparities faced by individuals with disabilities. Please consider writing an article for a future edition of the Reporter, or helping us out as a peer reviewer.

We want to take this opportunity to acknowledge Susan Stayn, Esq., who has stepped down from her many years as Co-Chair of the Reporter. We can't thank Susan enough for all of her hard work, leadership and dedication which have made the Reporter such a fantastic publication. Susan will still stay involved with the Reporter, and in fact has written an article for this issue along with Melissa Lopes, Esq. on the topic of the NIH stem cell guidelines.

This is an extraordinary time for U.S. health policy and health law. As you know, Congress is considering sweeping new federal regulation of health insurers, new federal programs to provide coverage to the uninsured, a possible "public option" for a new national federal health program, and other groundbreaking changes to health care coverage and health care financing. Simultaneously, our own state payment reform commission has proposed to replace the deregulated system dating from the early 1990s with new rules that could profoundly change the roles of health plans and health care providers. The full extent of federal and statewide changes is yet to be determined. It is possible that like President Clinton's proposed Health Security Act, all attempts to rewrite the rules of the game will be turned aside in favor of the status quo. It also is possible that the next twelve months will mark a significant turning point in both federal and state health care policy.

As co-chairs, we want to make the Health Law Section relevant, useful and timely. Health law

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practitioners are already awash in summaries, slide decks, reports, and legislative language. One of our goals for 2009-2010 is to create opportunities for our members to learn about proposed reforms, to convene with experts and each other, and to better understand the key issues driving federal and state health policy. Please let us hear your thoughts and suggestions on how we can better help all of you in this coming year.

We also note the passing of Senator Edward Kennedy, who was a tireless champion of health care access and quality. It is our plan to dedicate a future issue of the Reporter to his memory. The focus of that entire issue will be the federal reform issues currently being debated in Congress, and how those issues may affect our state.

- Dave Szabo, Esq. and Alan Einhorn, Esq.



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Preparing for Pandemic Flu: DPH Emergency Regulations Require Vaccination of Healthcare Workers and Expand Authorized Vaccinators

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Preparing for Pandemic Flu

The Commonwealth of Massachusetts is involved in a full-scale mobilization of resources to ensure that the state is prepared for pandemic H1N1 influenza this fall. As part of this effort, the Department of Public Health (“Department”) filed emergency regulations on September 14, 2009 requiring licensed hospitals, clinics and long-term care facilities (“health care facilities”) to establish influenza vaccination programs for health care workers (HCW), and expand the categories of persons authorized under law to administer influenza vaccine in the event they are needed.^{1, 2} This article describes the rationale for and requirements of the emergency regulations.

Seasonal and H1N1 Influenza

Influenza is a contagious viral infection of the respiratory tract that is easily spread from person to person by respiratory droplets when an infected person coughs or sneezes, or when someone touches a surface contaminated with the virus. Each year, 5% to 20% of the population becomes ill with seasonal influenza.³ Approximately 200,000 hospitalizations and 36,000 influenza-associated deaths occur each year. Children under 2 and adults over 65 or with underlying health conditions are most at risk for influenza-associated morbidity and mortality.

Novel influenza A (H1N1) is a new flu virus of swine origin that first

caused illness in Mexico and the United States in March and April of 2009. It appears that H1N1 flu spreads in the same way that regular seasonal influenza viruses spread. Vulnerable populations have been defined by the Federal Centers for Disease Control and Prevention (CDC) to include pregnant women, infants and children through age 24, and persons aged 25 through 64 years with health conditions associated with higher risk of medical complications from influenza.

On April 26, 2009, the United States Government declared a public health emergency and has been actively and aggressively implementing the nation’s pandemic response plan.⁴ On June 11, 2009, the World Health Organization (WHO) signaled that a global pandemic of H1N1 was underway by raising the worldwide pandemic alert to the highest level. This action was a reflection of the spread of the new H1N1 virus, not the severity of illness caused by the virus.

Since the WHO declaration of a pandemic, the H1N1 virus has continued to spread, with the number of countries reporting cases of novel H1N1 nearly doubling. The Southern Hemisphere’s regular influenza season is winding down and countries there are reporting that the new H1N1 virus has become a more common source of illness than what are regarded as

regular seasonal influenza viruses. In the United States, significant novel H1N1 illness continued into the summer, with localized and in some cases intense outbreaks occurring. The United States continues to report the largest number of novel H1N1 cases of any country worldwide; however, most people who have become ill have recovered without requiring medical treatment. The CDC reports that as of August 29, there were 9,079 hospitalized cases of H1N1 nationally, with 556⁵ deaths.⁶ In Massachusetts, almost 1,400 residents have been lab-confirmed infected with H1N1 virus, and 11 people have died.⁷ Because testing is not done for every case, the true number of individuals infected with H1N1 in the Commonwealth is probably in the tens of thousands.

While the outlook for the 2009-2010 influenza season is uncertain, based on evidence from the Southern Hemisphere, the CDC anticipates that there will be many more cases, hospitalizations and deaths associated with this pandemic in the United States. The co-circulation of seasonal and H1N1 influenza viruses is anticipated to put great demand on the health-care delivery system by making many people sick over a short period of time. The flu season is predicted to occur earlier and be more widespread than usual. Shortly after a New York state court recently enjoined enforcement of the New York regulation, Governor David

Paterson suspended implementation of the regulation.

In response, this summer the Department determined that emergency regulations were needed to promote vaccination of HCWs and to increase the number of HCWs authorized to administer vaccine. Every available HCW may be necessary to provide care and to administer vaccine against both seasonal and H1N1 viruses.

Vaccination of Health Care Workers

Influenza vaccination is the most effective method of preventing influenza virus infection and its potentially serious complications, providing 70% to 90% protection against influenza infection in healthy adults, and reducing the severity of illness and mortality in at-risk populations, such as the elderly and immuno-compromised patients in health care settings.⁸ Vaccination of HCWs minimizes the risk of transmission to patients, coworkers and family members, reduces absenteeism, and reduces “presenteeism”: employees not functioning effectively because they are at work while ill.⁹ While HCWs with direct patient care responsibility are at the frontline of exposure to and transmission of influenza, employees without direct patient care responsibility also must be protected because their work is essential to the efficient and effective delivery of health care.

Despite clear evidence of the effectiveness of vaccination in preventing the spread of influenza, and the recommendation of numerous professional agencies and organizations including the CDC, the National Foundation for Infectious Diseases (NFID), the Infectious Diseases Society of America (IDSA) and The Joint Commission,¹⁰

nationally only 44% of HCWs received influenza vaccine during the 2006-2007 flu season.¹¹ While average employee vaccination rates at acute care hospitals in Massachusetts is better than the national average, the vaccination rates need to be increased significantly to reduce employee and patient susceptibility to influenza illness. At the end of the 2008-2009 flu season – before the emergence of H1N1 – the Department required acute care and state hospitals to report staff seasonal flu vaccination rates through March 2009. Reported vaccination rates ranged from 33% to 78%, with a mean of 51% and a median of 50%.

Why are HCW vaccination rates so low? A recent review of studies assessing the reasons HCWs in hospitals receive or reject influenza vaccination found the two primary barriers to be (1) a wide range of misconceptions or lack of knowledge about influenza infection, and (2) a lack of convenient access to vaccine.¹² Studies show that when HCWs receive vaccine they do so primarily for their own benefit and not for the benefit of their patients. HCW vaccination rates could be improved by educational efforts to dispel misconceptions about the risks and by flexible workplace vaccine delivery.

A handful of states have instituted mandatory vaccination requirements for HCWs. As of May 2009, only Alabama, California, New Hampshire, Maine, Rhode Island and Tennessee required vaccination of HCWs in hospitals.¹³ In anticipation of the 2009-2010 flu season, on August 13, 2009 New York enacted emergency regulations similar to the Massachusetts regulations requiring HCWs at hospitals and other health facilities to be vaccinated.¹⁴ While the Mas-

sachusetts emergency regulations allow an employee to decline vaccination for any reason – after being fully informed of the risks and benefits of vaccination, the New York regulation only provides an exemption when the vaccine is medically-contraindicated for a particular employee.

In anticipation of a severe and early flu season resulting from the co-circulation of seasonal and novel/pandemic H1N1 viruses, the Massachusetts Public Health Council (PHC) approved promulgation of emergency regulations on August 14, 2009, and sent notice to licensed health facilities that they should immediately begin planning for early implementation of the new employee vaccination standards in advance of the September 14, 2009, effective date. The emergency amendments are outlined below.

Seasonal Influenza Vaccination for Health Care Workers

The amendments require licensed hospitals, clinics (including dialysis centers) and long-term care facilities to establish vaccination programs for all employees (including medical staff, contractors and certain volunteers) against seasonal influenza virus, no later than December 15, 2009, and annually thereafter.

The amendments require health care facilities to notify every employee of the seasonal influenza vaccination requirement and the risks and benefits of vaccination. Health care facilities may use a Vaccine Information Statement (VIS) for this purpose.¹⁵ It is the health care facility’s responsibility to provide a copy of the most up-to-date version of the VIS prior to administering vaccine.

The amendments require health care facilities to provide or arrange for vaccination of all employees who cannot provide proof of current immunization against influenza, at no cost to the employee, unless the employee declines vaccination. Employees (such as contractors performing administrative functions) who do not physically work at or come to the licensed health care facility site are not required to be vaccinated under these amendments.

A health care facility is not required to provide for vaccination of an employee if (a) the vaccine is medically-contraindicated for that employee, (b) vaccination is against the employee's religious beliefs, or (c) the employee refuses the vaccine for any reason. An employee who declines vaccination must sign a declination statement and certify that he/she received information about the risks and benefits of vaccination. Guidance provided by the Department to licensed health facilities states that a health care facility may not require an employee to indicate the reason they decline vaccination.

The amendments state that a health care facility is not required to provide or arrange for influenza vaccination when the vaccine is unavailable for purchase, shipment or administration by a third-party, or if the Commissioner of Public Health ("Commissioner") issues an order or guidelines restricting the use of a vaccine.

The amendments require health care facilities to (1) maintain a central system to track the vaccination status of each employee (including declinations) and (2) maintain documentation of vaccination status in each employee's personnel file. If a health care facility is unable

to provide or arrange for influenza vaccination for any employee, it must document the reasons such vaccination could not be provided or arranged.

The amendments require health care facilities to collect and submit data to the Department in accordance with guidelines to be issued by the Commissioner. Department guidelines issued on September 14, 2009, require all licensed health facilities to maintain the following data: the total number of employees subject to the vaccination requirement, the total number of employees vaccinated through any source, and the total number of declinations. Acute care and public health hospitals will be required to report this data to the Department for the 2009-2010 flu season by April 15, 2010. The Department may issue future guidelines requiring other types of licensed health facilities to report vaccination data.

Novel or Pandemic Influenza (H1N1) Vaccination for Health Care Workers

In addition to requiring that health care facilities provide for annual vaccination of all employees against seasonal influenza virus, the amendments authorize the Commissioner to issue guidelines as needed to require health care facilities to establish novel/pandemic (such as H1N1) employee vaccination programs. The emergency regulations allow the Commissioner to issue guidelines in the event of the emergence of a novel/pandemic virus (and availability of vaccine) to require licensed health facilities to provide for vaccination of employees against that novel/pandemic virus.

Any novel/pandemic vaccination guidelines are to address:

1. Categories and priority of employees to be vaccinated
2. Type of vaccine(s) to be administered
3. Date by which employees must be vaccinated
4. Data collection and reporting requirements

Once the Commissioner issues guidelines directing health care facilities to implement a novel / pandemic employee vaccination program, the amendments require health care facilities to comply with the same requirements that apply to seasonal influenza for (1) employee notification of risks and benefits, (2) provision of vaccination without charge to designated employees, (3) declination of vaccination, and (4) documentation of employee vaccination status.

On September 14, 2009, the Commissioner issued guidelines directing health care facilities to provide for vaccination of all employees with the H1N1 2009 vaccine immediately upon receipt of the H1N1 vaccine, which began to be distributed in October. The guidelines provide that health care facilities may determine the order in which employees are vaccinated against H1N1, and should complete vaccination as rapidly as the supply and vaccination schedule allow. In the event of an insufficient supply of either seasonal or H1N1 2009 influenza vaccine, the Department may issue further guidance specifying the categories and priority of employees to be vaccinated.

Administration of Vaccines by Designated Health Care Workers

The Department also filed emergency amendments on September 14, 2009, permitting the Commissioner to authorize additional health care professionals to administer seasonal influenza and H1N1

vaccine in the event the Commissioner determines that there are or will be insufficient health care professionals available for timely administration of vaccine.¹⁶

The amendments were necessary because the Controlled Substances Act, M.G.L. c. 94C and related regulations at 105 CMR 700.000 limit the persons who may lawfully administer controlled substances (i.e., prescription medications, including vaccines). Under the existing regulations, only certain licensed health care providers, such as physicians, nurses, physician assistants, nurse practitioners and pharmacists, may administer vaccine. Section 7(g) of Chapter 94C, however, permits the Commissioner to authorize by regulation the registration of persons for a specific activity or activities, including administration of controlled substances. Under the authority of § 7(g), the amendments enlarge the number of health care professionals authorized to administer vaccines – under specified circumstances – and therefore expedite the administration of flu vaccine in the event that large numbers of people need to be vaccinated in a short period of time.

The emergency amendments authorize the Commissioner to issue an order designating additional health care professionals, licensed or certified by the Department, or medical or nursing students enrolled in approved or accredited programs, to administer vaccine for the prevention of pandemic, novel or seasonal influenza virus. Any order of the Commissioner must specify the conditions under which the vaccine may be administered. The amendments require that the vaccine be administered under an order or prescription of a practitioner authorized to prescribe

vaccines. The vaccinators must administer in accordance with the order/prescription and the Commissioner's order.

On September 14, 2009, the Commissioner issued an order designating dentists, paramedics, pharmacists, and some medical and nursing students as authorized vaccinators. The order references and is accompanied by guidance on the training required, protocols for vaccination and record-keeping as well as other requirements. Those organizing community or facility-based flu vaccine clinics will decide whether to use newly-authorized vaccinators to assist in administering seasonal and H1N1 vaccine.

The Commissioner's order and associated guidelines and protocols may change as needed throughout the flu season dependent upon emerging conditions.

Availability of H1N1 Vaccine

Although a limited amount of H1N1 influenza vaccine was distributed beginning in October, production has been slower than expected, delaying widespread distribution of the vaccine. All H1N1 vaccine will be supplied by the federal government at no cost to providers in both the public and private sectors. State health departments are responsible for allocating all doses of H1N1 vaccine.

The initial shipments of H1N1 vaccine have been directed to priority populations including HCWs and emergency medical personnel, children, pregnant women, and those of all ages at higher risk of complications from influenza infection. The Department will post the latest guidance about priority groups and all other recommendations related to H1N1 vaccine

on the Department's flu website <http://www.mass.gov/dph/flu>.

In order to facilitate allocation of H1N1 vaccine to providers in Massachusetts, the Department has developed an on-line system to register all public and private provider sites interested in receiving and administering novel H1N1 vaccine (including private providers, health care facilities, local health departments, regional public health coalitions, visiting nurses associations, health care facilities, pharmacists and commercial community vaccinators). Information about accessing the registration site will be disseminated broadly through e-mail and in collaboration with professional organizations and trade associations, and will be posted on the Department's flu website <http://www.mass.gov/dph/flu>.

Liability for Vaccine Administration

The federal Public Readiness and Emergency Preparedness Act (PREP) of 2006¹⁷ provides immunity from tort liability under state and federal law for persons authorized under state law to administer vaccines, including health care professionals and students designated as H1N1 vaccinators by the regulations and Commissioner's order.¹⁸ PREP Act immunity does not extend to seasonal flu vaccination. The liability issues surrounding administration of seasonal flu will be no different than in prior flu seasons.

In terms of reimbursement, while the H1N1 vaccine will be provided at no charge, reimbursement for vaccine administration is a matter between providers and third party payers. Seasonal flu vaccine will be available as in previous flu seasons. Reimbursement for seasonal vaccine and administration

is similarly a matter for providers and third party payers.

Regulatory Process

The emergency amendments were approved for promulgation by the PHC at its regularly scheduled meetings on August 14 and September 9, 2009. The emergency amendments became effective on September 14, 2009, when they were filed with the Office of the Secretary of the Commonwealth, and are effective for 3 months after that date. The PHC promulgated these amendments as emergency regulations to provide hospitals, clinics and health care facilities with as much time as possible to implement HCW vaccination programs in advance of the 2009-2010 influenza season. A public hearing is scheduled for October 9, 2009; the comment period closed on October 16, 2009. It is anticipated that the regulations will be presented to the PHC for final promulgation at its meeting on November 18, 2009.

Latest Information on Influenza Outbreak and Vaccination

The task of administering millions of doses of seasonal and pandemic influenza vaccine is enormous. The Department has worked closely with health care facilities, agencies, local health officials, and health care professionals to promote and support enhanced capacity to expedite the provision of flu vaccine.

You will find helpful information about flu vaccine, including the risks and benefits of getting vaccinated, and H1N1 guidance, on the CDC's website at <http://www.cdc.gov/flu>. For the latest updates on influenza also please visit the Department's website at www.mass.gov/dph/flu and www.mass.gov/dph/imm.

Endnotes:

- 1 105 CMR 700.003(H) & 700.004(B)(7) and 105 CMR 130.325 (Hospital Licensure); 105 CMR 140.150 (Licensure of Clinics); and 105 CMR 150.002(D)(8) (Licensing of Long-Term Care Facilities).
- 2 The emergency regulations and related orders and guidelines discussed in this article can be found on the Department's website at www.mass.gov/dph/flu "emergency vaccination regulations."
- 3 <http://www.cdc.gov/flu/keyfacts.htm>.
- 4 <http://www.cdc.gov/h1n1flu/background.htm>.
- 5 <http://www.cdc.gov/h1n1flu/update.htm>.
- 6 <http://www.cdc.gov/flu/weekly/>.
- 7 http://ma-publichealth.typepad.com/files/weekly-report-9_3_2009-1.doc.
- 8 Influenza Vaccination: Strategies from Research & Practice, The Joint Commission (2009) at ix.
- 9 *Id.*
- 10 *Id.*, at 65-72.
- 11 Prevention and Control of Seasonal Influenza with Vaccines, Recommendations of the Advisory Committee on Immunization Practice (ACIP), CDC, MMWR July 31, 2009/58 (RR08), 1-52 at Table 3.
- 12 Influenza Vaccination of Health Care Workers in Hospitals – A Review of Studies of Attitudes and Predictors, H.G. Holmeyer et al., *Vaccine* 27 (2009) 3935-3944.
- 13 <http://www2a.cdc.gov/nip/stateVaccApp/StateVaccsApp/AdministrationbyVaccine.asp?Vaccinetmp=Influenza#235>.
- 14 Health Care Personnel Influenza Vaccination Requirements, Title 10 (Health). Part 66, Subpart 66-3 of the Official Compilation of Codes, Rules and Regulations of the State of New York (August 13, 2009).
- 15 VISs are available at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>.
- 16 105 CMR 700.003(H) & 700.004(B)(7).
- 17 PREP Act, 42 U.S.C. § 247d-6d.
- 18 While the language of the PREP Act appears to confer immunity on medical and nursing students authorized by law to administer vaccine, the PREP Act Declaration for H1N1 vaccine raises a question as to whether the immunity

Massachusetts Hospital Association: 2009/10 Legislative Priorities

Michael Sroczyński, Esq.

The Massachusetts Hospital Association is a voluntary, not-for-profit organization comprised of hospitals and health systems, related organizations, and other members with a common interest in promoting the health of the people of the Commonwealth. Through leadership in public advocacy, education, and information, MHA represents and advocates for the collective interests of its member hospitals and health systems, and supports their efforts to provide high quality, cost effective, and accessible care.

While Massachusetts hospitals and health systems are facing an era of unprecedented change, MHA members remain committed to their most basic mission: caring for people. MHA's 2009/10 legislative and policy priorities focus on five elements essential to reinforcing hospitals' ability to provide this care: 1) universal access and coverage; 2) adequate financing; 3) minimized costs; 4) enhanced quality; and 5) an educated and qualified workforce. A sampling of our legislative package and public policy priorities are highlighted herein (detailed summaries can be found at www.mhalink.org). As the Commonwealth moves toward reform of our payment system, we believe all of these proposals are important complementary pieces.

Universal Access and Coverage

MHA and our member hospitals support universal coverage. In July, Governor Deval Patrick rejected

the Legislature's proposed elimination of Commonwealth Care health insurance coverage for 30,000 tax-paying "special status" legal immigrant residents. Governor Patrick instead recommended \$70 million to develop a new insurance product that would provide "meaningful" coverage for this population. While recognizing that the Legislature explored all available cuts before recommending this cut, MHA supported the Governor's recommendation. As a result of dwindling tax revenues and the fact that the federal government does not currently provide matching funds for legal immigrant coverage, the Legislature subsequently appropriated \$40 million for Governor Patrick's Administration to develop coverage these legal immigrants. The currently allocated funding will not preserve the benefits and access previously available to these individuals. As such, MHA and its member hospitals remain concerned about the impact that scaled down insurance coverage will pose, both to patient care and to the viability of the state's Health Safety Net Trust Fund. As there is a current shortage in the Fund, hospitals will be solely responsible for the cost of care needs for this population. This funding burden creates a risk to community services for some hospitals and will ultimately lead to higher insurance premiums for every resident of the Commonwealth. MHA will be working closely with the administration in an effort to ensure that the \$40 million is employed in a manner

that best ensures meaningful access to services.

One of MHA's priority legislative filings this session seeks to address another inadequacy in coverage for low-income patients. Currently, uninsured individuals who qualify for Commonwealth Care or MassHealth receive 10 days of retroactive coverage (from the date of their application) for services provided in hospitals and community health centers. But low-income uninsured residents who are not eligible for these programs receive six months of Health Safety Net "retroactive coverage". HB1085 will make Health Safety Net "retroactive coverage" uniform and consistent for all eligible low-income patients. This legislation recognizes and supports the initial health care services that are provided to the uninsured low-income patient regardless of which low-income program that they are ultimately enrolled in.

Adequate Financing for Healthcare

As both providers and employers, hospitals have made significant contributions to bolster the Commonwealth's health reform initiative. These include: enrolling thousands of low-income residents; funding the cost of coverage expansion by diverting hospital supplemental payments and uncompensated care funding toward coverage, contributing hundreds of millions of dollars since 2006; increasing accountability through Medicaid pay-for-performance and

numerous new reporting requirements; escalating enrollment in their own employer-sponsored insurance and meeting the new employer responsibilities called for by the Reform law; and providing an additional \$20 million in 2008 to help balance a budget shortfall.

The health care reform law (Chapter 58 of the Acts of 2006) called for a three-year commitment to improve hospital rates for the care provided to MassHealth patients in order to reach a level more closely reflecting the actual cost of the care that hospitals provide to MassHealth patients (often described as “closing the Medicaid gap”). This state investment was intended to reduce or eliminate pressures leading to increasing private insurance premiums. A new trust fund was created to provide an annual increase of \$90 million for three years to acute care hospitals and physicians, with \$76.5 million targeted toward hospitals. Yet, when the state was forced to make difficult budget decisions this year due to declining revenues, hospitals were required to accept reduced reimbursement for care provided to low-income MassHealth patients. MHA now estimates that hospitals, on average, will be paid approximately 70% of cost in 2010 under the Medicaid fee-for-service program – meaning that hospitals rates are now worse than before the reform law was enacted. The failure to close the Medicaid underpayment gap contravenes one of the central tenets of Chapter 58 and, as such, the pressures on private rates remain. As the state now moves toward payment reform, it must recognize that this failure to appropriately pay for care is an essential need that must be addressed.

One MHA priority bill that is related to the changed health care environ-

ment in Massachusetts is SB556. This legislation seeks to create a more equitable assessment on all healthcare providers in support of the administrative operations of the Division of Health Care Finance and Policy (“Division”). Currently, acute care hospitals are solely responsible for at least 65% of the Division’s total expenses, including not only the state’s budget appropriations, but also additional fringe and employee benefits. Yet the Division’s role has expanded to include the development of health care policy, health care payment reform, and data analysis for all health care providers. It is also responsible for administering the operations of the Health Care Quality and Cost Council. While the work performed by the Division is an important resource for the entire health care community, hospitals believe that, with the advent of payment reform and integrated delivery systems, the cost of that work should be apportioned equitably across all providers. SB556 would limit the hospital assessment to FY2008 levels while directing the Division to study the scope of work of the Division and make recommendations to the Legislature for assessments on entities other than hospitals consistent with the Division’s responsibilities.

Minimized Costs

As the both the state and federal governments continue to focus on health care reform and the reduction of health care costs, MHA has identified three “legs of the stool” that must receive balanced, thoughtful and simultaneous attention in order to manage costs. These include: the reduction of clinical variation, payment reform, and administrative simplification. The third leg – administration simplification - is an essential component which can be addressed

immediately. While the Division of Insurance (DOI) recently reported that Massachusetts insurers spend 11% of premiums annually on administration, we know this number does not take into account the downstream effects that varied and uncoordinated administrative burdens place on providers. A recent MHA report on administrative costs found that billing and insurance related activities in Massachusetts exceed \$5 billion a year. Nationally, the U.S. Congressional Research Service estimates that the administrative costs of private insurance and government programs to be about \$465 billion per year – not including the administrative costs borne by healthcare providers to comply with those requirements.

In an effort to address these issues in the Commonwealth, HB1077 seeks to reduce the cost and complexity of accessing health care services for patients, providers, and insurers by encouraging greater consultation and collaboration between providers and insurers through standardizing certain administrative processes in a logical format. It also focuses on the potential for standardizing and streamlining the collection and reporting of clinical information for quality measures – processes that have become more common and widespread as insurance carriers seek to implement pay for performance arrangements. Most importantly, H1077 requires DOI to create an advisory group to develop recommendations and regulations that will simplify the administrative burdens for patients, clinicians, and hospitals and reduce costs at the same time.

Additionally, as health insurers increasingly move towards “consumer-directed” insurance poli-

cies, they are increasingly shedding their responsibility to collect payment from subscribers and instead forcing providers to make these collections. Beyond the co-payment amount highlighted on a patient's insurance card, health care providers generally do not have access to a patient's financial liability until well after services are rendered and the insurer informs the hospital of the co-insurance or deductible amount. SB457/HB974 would require insurance carriers to bear the responsibility of directly monitoring and collecting any payments associated with deductibles and co-insurance. Hospitals believe that insurers, given their financial relationships with subscribers, are better suited to handle the administrative responsibility for the collection of deductibles and co-insurance.

Enhanced Quality

Since January 26, 2005, Massachusetts hospitals have been engaged in Patients First – a sweeping quality-and-safety initiative that creates an important layer of transparency for patients. In addition to 26 different comparable measures of quality care, including pressure ulcer prevalence, falls, heart attacks, heart failures, pneumonia and surgical infections, patients can review the planned and actual patient care staffing plans for every hospital in the Commonwealth. Patients First is an important step forward in enhancing the transparency of hospital care. The information that is collected and posted through this voluntary, first-in-the-nation initiative not only helps patients and their families make informed decisions about their health care, but also provides hospitals with benchmarks that they can use to enhance their own quality and safety efforts.

Over the past several years, one of the more contentious legislative issues related to quality is an effort by one of the state's nursing unions to enact one-size-fits-all mandatory registered nurse staffing ratios (or "limits"). Despite the lack of any scientific evidence that such a mandate would contribute to the quality of care, the political rhetoric associated with this effort has derailed discussion around numerous quality and workforce proposals that could have a positive impact on patient care. In an effort to responsibly address the union's arguments, in 2008 the state senate enacted compromise language that is focused on the acuity of individual patients and takes into account the important contributions of every member of the patient care team. While the Senate's bill failed to get House approval last year, Senator Richard Moore (D-Uxbridge) has re-filed it in the 2009/10 session. MHA believes that this comprehensive approach to staffing regulation is responsible and based on up-to-date studies and best practices from the around the country. The bill requires hospitals to:

- implement acuity models and create nursing care committees to contribute to the development of a board approved staffing plan. These nursing care committees would be comprised of at least 50% direct care registered nurses.
- post and file hospital staffing plans with the Department of Public Health (DPH). Hospitals would have to report on variations from these plans and DPH would publically post each plan and audit compliance.
- monitor and report on nurse-sensitive patient outcome data. DPH would publish and rank hospitals based on these quality measures.

MHA is also highly supportive SB18, legislation that would improve the state's ability to respond to declared emergencies and pandemics. The need for such legislation has been magnified by the recent emergence on the H1N1 influenza virus. SB18, which has already been approved by the Senate, represents the collaborative efforts of MHA, the Massachusetts Medical Society, the Department of Public Health, and other stakeholders to develop this workable approach to comprehensive emergency preparedness in the Commonwealth. SB18 encourages the participation of volunteers and medical professionals to address public health emergencies by extending liability protection and coverage to individual providers responding to these events. It also streamlines administrative requirements for the recruitment and use of volunteers at the local level when pandemic or disaster strikes.

An Educated and Qualified Workforce

As nursing and healthcare workforces shortages are projected to increase over the next several years, ensuring an appropriate supply of qualified health care professionals is a top priority of the hospital community. SB854 would authorize the Commonwealth to join 24 states in the national Nurse Licensure Compact (NLC). The NLC is a mutual recognition model of nurse licensure that allows a nurse to have one license in his/her state of residency and to practice in other states, both physically and electronically, subject to each state's practice law and regulation. It would also enhance the knowledge base needed to address workforce shortages by building a pool of shared data. As average salaries for Massachusetts nurses are second only to California, this legislation would ease the

ability to draw qualified candidates across state borders.

SB1794 will benefit the personal safety of health care providers by establishing a heightened standard of punishment for individuals that commit assault on a provider during the delivery of health care services. The bill broadens the current protections in place for ambulance operators and emergency medical technicians by applying those protections to assaults on any health care provider. This seeks to equally protect all members of the patient care team from violence in the workplace.

The Future: Shared Responsibility for Health Care Payment Reform

As the Commonwealth pursues the reform of the healthcare payment system, Massachusetts hospitals support the general thrust of this initiative. The current system falls short of meeting the reasonable expectations and needs of too many healthcare stakeholders – most importantly patients, but also those who pay for care and those who provide care. The status quo cannot and should not be defended. MHA's members agree that a more integrated and coordinated system of care should have positive results in terms of the access to and quality of care. The general direction of payment reform away from fee-for-service towards a more integrated form of delivery and payment – such as global payment – could be successful. But the ultimate success or failure of payment reform in our Commonwealth, and the productive engagement of hospitals to this end, will depend on thoughtful and responsive answers to certain key issues from policymakers as we make more concrete plans and contemplate the process of implementing a new system. And, as has

been stated in the final report of the State's Special Commission on the Healthcare Payment System, it will require transparency, continuous monitoring and responsive modification of healthcare provider plans as we gain experience with the new payment and organizational arrangements. All stakeholders deserve and expect that this will be the case. We should expect nothing less from our leaders, who deserve great credit for this bold undertaking.

For an overview of critical foundational issues related to payment reform in the Commonwealth, please visit MHA's website at www.mhalink.org.

Recommendations of the Special Commission on the Health Care Payment System: New Challenges for Massachusetts Health Care Providers

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Introduction

In April 2006, the Commonwealth of Massachusetts passed its landmark health reform legislation, An Act Providing Access To Affordable, Quality, Accountable Health Care.¹ Over the next three years, comprehensive health reform has enabled Massachusetts to enroll over 400,000 residents in public and private plans — meaning that over 97% of residents are now insured.²

However, the success in insuring residents has come at a price, as the Commonwealth now faces increasing pressure to control the costs of health care. On July 16, 2009, the Special Commission on the Health Care Payment System (“Special Commission”) released its recommendation: to control costs by abolishing the prevailing fee-for-service based payment model and replacing it with a global payments model. Under the Special Commission’s recommendations, the new payment system would apply to all payors, including Medicare and Medicaid. This article reviews the context of cost containment efforts, summarizes the Special Commission’s recommendations, and analyzes some of the potential implications of these recommendations for Medicare and Medicaid.

I. The Expansion of Coverage and the Context of Cost Containment

Chapter 58 of the Acts of 2006 focused primarily on increasing access to coverage for Massachusetts residents. Its reforms of the public and private insurance markets included Medicaid expansions for children and adults, the introduction of a new state-subsidized plan, the mandate that all adults carry health insurance, the merger of the individual and small group insurance markets, and a requirement that employers “play or pay” by making a financial contribution to the state if they do not offer a certain level of health insurance for their employees. Additionally, the law created the Commonwealth Health Insurance Connector Authority (“Connector”) to oversee the implementation of health care reform. However, Chapter 58 took only modest first steps towards cost containment and improved quality, such as the creation of the Health Care Quality and Cost Council (HCQCC), a representative body tasked with evaluating cost and quality in Massachusetts’ health care system, and making reform recommendations.

The cornerstone of the extension of health insurance coverage in Massachusetts was an expansion to the state Medicaid program and creation of the new state-subsidized plan, Commonwealth Care. Combined with the State Chil-

dren’s Health Insurance Program (SCHIP),³ Medicaid now covers children whose family income is up to 300% of the federal poverty level (FPL). Massachusetts Medicaid also expanded coverage for adults with young children and for the long-term unemployed. This expansion has provided coverage for 99,000 previously uninsured Massachusetts residents.⁴ Commonwealth Care, available to adults up to 300% FPL, has provided coverage for 151,308 additional uninsured residents.⁵ Together, these two programs account for 55% of Massachusetts’ increased access to health insurance coverage.

As noted above, Massachusetts created Commonwealth Choice, a private insurance option for those not purchasing insurance through their employer. Commonwealth Choice has expanded individual plan purchasing options for Massachusetts residents and allows them to compare products easily. Total new enrollment in the commercial market is 96,000 Massachusetts residents. While individual premiums have decreased since implementation of this consolidation, small business premiums have fluctuated significantly. Chapter 58 also merged the individual and small group commercial insurance markets into a single risk pool. The policy reason underlying this merger was that such consolidation should cause premiums to be, on

average, significantly lower for individuals and only minimally higher for small groups.

Having thus addressed the challenge of expanding access, the Commonwealth increasingly recognized the parallel necessity of addressing the challenge of spiraling costs. In August 2008, the Legislature passed Chapter 305 of the Acts of 2008, which aimed to promote health care cost containment and improve the transparency and efficiency of the delivery of quality health care. Chapter 305 included the following cost containment initiatives: The HCQCC Roadmap to Coverage, the RAND report on health care cost containment, a review of hospital and insurer reserves, and a report on health care cost drivers. Another initiative contained in Chapter 58 was the establishment of the ten-member Special Commission charged with examining alternatives to the traditional “fee-for-service” (FFS) payment model, and providing reform recommendations that would “provide incentives for efficient and effective patient-centered care [and] reduce variations in the quality and cost of care.”⁶

II. The Special Commission’s Recommendations

After nine public meetings, the Special Commission released its final report on July 16, 2009, and made a bold recommendation: Abolish the prevailing FFS based payment model and replace it with a global payments model. The Special Commission was charged with three specific responsibilities: (1) to examine payment methodologies and purchasing strategies, (2) to recommend a common transparent payment methodology, and (3) to recommend a plan for the implementation of the common payment methodology across all public and

private payers in the Commonwealth.⁷

Before presenting its recommendations, the Special Commission outlined the context of its appointed task — acknowledging the advances Massachusetts has made in health care reform, but warning that unmitigated growth in health care costs threatens the viability of the 2006 reforms.⁸ The Special Commission first noted that Massachusetts has the highest per capita health care costs in the nation, and that these costs were expected to continue increasing. The Special Commission also observed that access to primary care physicians is declining, and that the operating margins for community hospitals remain perilously low.⁹

The Special Commission then explained that its ultimate recommendations were based on ten “principles for payment reform,” developed in collaboration with key stakeholders. The foremost of these principles was that the FFS payment methodology “rewards service volume rather than outcomes and efficiency,” and thus needed to be replaced by a payment model that was more closely aligned to the delivery of high-quality, patient-centered care.¹⁰ Other guiding principles developed by the Special Commission included the premises that “differences in payments should reflect measureable differences in value,” that “health care per capita costs and cost growth should be reduced [and the] payment system should be transparent,” and that implementation of reforms should be phased in on a clear and predictable timetable.¹¹

Guided by these principles, the Special Commission examined numerous alternatives to FFS, in-

cluding blended capitation rates, episode-of-care payments, medical home models, global budgets, pay-for-performance (P4P) programs, tiering of providers, evidence-based purchasing strategies, episode-based payments, and global payments.¹²

The Special Commission reached two main conclusions. First, the Special Commission concluded that while “modifying” FFS might initially appear to be more attractive than outright replacement, the “pervasive incentives” of FFS (and the added complexity created by grafting new models onto the FFS methodology) rendered such an option wholly inadequate.¹³ Second, the Special Commission concluded that the “global payments” model was the best available option for promoting “safe, timely, efficient, effective, equitable, patient-centered care” while simultaneously reducing “growth and levels of per capita health care spending.”¹⁴

Under the “global payments” approach, providers are compensated prospectively for most (or all) of the care their patients will receive over a set contractual period. The “global payment” is thus designed to reflect the expected cost of the covered services, and is calculated using factors such as a patient’s underlying health conditions and overall patient demographics. While global payments thus place the “performance risk” squarely on providers, they are risk-adjusted to reduce the “insurance risk” shouldered by any given provider.¹⁵ Under the global payments model advocated by the Special Commission, there would be further financial adjustments to incentivize and reward the provision of accessible and high-quality care (particularly primary care), and certain limited

exceptions for providers of very limited and/or specialized services.¹⁶

In articulating its vision for what a fully-implemented global payments model might look like, the Special Commission advocated for the inclusion of several key elements. In terms of patient care delivery, the Special Commission's model would include the development of Accountable Care Organizations (ACOs) to coordinate patient care, a strong focus on primary care, an emphasis on patient choice, and the increased use of P4P incentives to providers.¹⁷ In terms of financial management, the expected model would include required participation by both public and private payers, the sharing of financial risk between ACOs and insurance carriers, an emphasis on strong and consistent risk adjustment, and transparency in both cost and quality via a system of common and available metrics.¹⁸ Finally, the Special Commission endorsed a global payments model that would incorporate the widespread adoption of the "medical home" concept.¹⁹

Addressing the question of timing and implementation, the Special Commission concluded that a global payments model could be implemented statewide within five years.²⁰ Although some providers may adapt to global payments quickly and voluntarily, the Special Commission also recognized that others would need to transition more gradually, and would require greater technical assistance.²¹ The Special Commission therefore emphasized that adoption of global payments would require investments in infrastructure, provider training, and technical support, and recommended several financial incentives that might be implemented to speed this transition.²² Finally, the Special Commission

recommended the establishment of either an independent board or an executive branch agency to oversee the implementation of the new system.²³

In its conclusion, the Special Commission acknowledged that concerns had been raised regarding previous attempts to implement global payments. However, the Special Commission responded to these concerns by including in its recommendations 1) a deliberative and transparent transition process, 2) robust monitoring and oversight, 3) financial incentives for access and quality, 4) improved risk adjustment models, and 5) support for health information technology, it had made significant improvements on previous capitation models. The Special Commission thus argued that any general concerns about adopting global payments had been largely mitigated as a result of these tailored improvements.²⁴

III. The Medicare Question

The Special Commission envisions that the new payment system would apply to all payors, including Medicare and Medicaid.²⁵ Doing so would require waivers from the federal government. Federal law provides the mechanism to alter the otherwise-applicable payment rules under these two programs. Policymakers at the state level will need to decide which of these mechanisms to pursue in order to implement the new payment system across all payers.

Under the Medicare program, payment to acute care hospitals for the cost of providing inpatient hospital services to Medicare beneficiaries "is equal to" an amount determined under the inpatient prospective payment system.²⁶ Payment to hospitals for the cost of providing

covered hospital outpatient department services to Medicare beneficiaries "shall be determined" under the outpatient prospective payment system.²⁷ Payment to physicians for the cost of providing physicians' services to Medicare beneficiaries "shall ... be" determined under the resource-based relative value system.²⁸

Under the recommendations of the Special Commission, however, payment to hospitals and physicians (and, for that matter, most other health care providers) would be made as global payments by ACOs, even with respect to services provided to Medicare beneficiaries. Given that the Medicare statute requires that payment to health care providers be calculated under precise formulae, some mechanism would be necessary to waive the application of the relevant statutes.

One such mechanism is section 402(a)(1)(A) of the Social Security Act Amendments of 1967.²⁹ Under this statutory authority, the Secretary of Health and Human Services ("Secretary"), likely acting through her delegee, the Centers for Medicare and Medicaid Service (CMS), may "determine whether . . . changes in methods of payment or reimbursement . . . for health care and services under health programs established under the Social Security Act . . . would have the effect of increasing the efficiency and economy of health services under such programs . . ." If the Secretary makes such a determination, then she "may waive compliance with the requirements of [Medicare and Medicaid] insofar as such requirements relate to reimbursement."³⁰ Use of a global payment system for inpatient and outpatient hospital services and physician services is a "change[] in methods

of payment and reimbursement . . . for health care services under health programs established under the Social Security Act” because global payments made to an ACO would substitute for the inpatient and outpatient reimbursement systems and the resource-based relative value scale.

The question for the Secretary or CMS would be whether or not the new system “would have the effect of increasing the efficiency and economy of health services under such programs.” The Special Commission report is replete with examples of how the Special Commission members anticipate that a global payment system would reduce the rate of growth in health care spending in Massachusetts. Indeed, the first sentence of the chapter introducing the recommendations states that a global payment system would “promote safe, timely, efficient, effective, equitable patient-centered care, and . . . reduce growth and levels of per capita health care spending.”³¹ It is likely that state officials will attempt to convince CMS officials that the trigger in section 402(a)(1)(A) is met by the new system.

Federal law also provides additional authority for CMS to waive provisions of Medicaid law that might otherwise hinder the implementation of the new payment system. Section 1115 of the Social Security Act permits the Secretary to waive compliance with “any of the requirements” of the Medicaid program in the case of a demonstration project that is “likely to assist in promoting the objectives of” Medicaid.³² The Secretary can also approve costs that would not otherwise trigger federal matching funds in such a demonstration project.

In this regard, the recommendations of the Special Commission specifically note the impact that high health care costs have on the state Medicaid program, requiring the state to spend a third of its budget on Medicaid.³³ Clearly, state officials would argue that a global payment system would “promot[e] the objectives” of Medicaid, one of which is to “furnish . . . medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services.”³⁴ The implication of the recommendations is that the state cannot maintain its commitment to this objective at the current rate of health care spending.

There are many provisions of Medicaid that the state might seek to waive under this authority. For example, Section 1902(a)(13)(A)(i) of the Social Security Act requires that states hold a public process to determine the proposed rates of payment for institutional providers under Medicaid. Under a global payment system, such a process may not be feasible; Section 1115(a)(1) of the Social Security Act, then, would permit the state to waive this requirement. The statute is also prescriptive on rates of payment to federally-qualified health centers; the state may wish to waive this requirement as well.³⁵

IV. Conclusion

Having recognized the importance of both expanding health care access and containing health care costs, the Legislature will now consider the recommendations of the Special Commission, and decide whether Massachusetts will be the first state in the nation to eliminate the FFS payment system for both

public and private payers. One crucial hurdle for the implementation of global payments will be whether the state can successfully obtain Medicare and Medicaid waivers, and the Commonwealth will need to demonstrate that a global payments system would meet the waiver requirements under federal law by either “increas[ing] the efficiency and economy” of Medicare or “promot[ing] the objectives” of Medicaid, respectively. Massachusetts is once again at the forefront of national innovation in health care reform. Its approach to cost containment will be closely watched by policymakers across the country who are seeking ways to bend the health care cost curve.

Endnotes:

- 1 Chapter 58 of the Acts of 2006, available at <http://www.mass.gov/legis/laws/seslaw06/sl060058.htm> (last accessed Aug. 19, 2009).
- 2 See Division of Health Care Finance and Policy (DHCFP), Health Care Indicators in Massachusetts, available at http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/09/key_indicators_aug_09.pdf (last accessed Sept. 22, 2009).
- 3 42 U.S.C. § 13977aa, et seq.
- 4 See DHCFP, supra note 2.
- 5 This figure is as of September, 2009, available at <http://www.mahealthconnector.org>. Commonwealth Care enrollment numbers continue to grow due to the economic downturn.
- 6 Recommendations of the Special Commission on the Health Care Payment System 25 (July 16, 2009), available at http://www.mass.gov/Eeohhs2/docs/dhcfp/pc/Final_Report/Final_Report.pdf.
- 7 *Id.*
- 8 *Id.* at 19-20.
- 9 *Id.* at 21-24.
- 10 *Id.* at 26.
- 11 *Id.* at 26-27.
- 12 *Id.* at 27-48.
- 13 *Id.* at 48.
- 14 *Id.* at 53.
- 15 *Id.* at 46.
- 16 *Id.* at 53.
- 17 *Id.* at 53-54.
- 18 *Id.* at 55-56.
- 19 *Id.*
- 20 *Id.* at 53.
- 21 *Id.* at 56.
- 22 *Id.* at 57.
- 23 *Id.* at 58-61.
- 24 *Id.* at 62-66.
- 25 *Id.* at 10.
- 26 Social Security Act § 1886(d)(1)(A)(iii).
- 27 *Id.* at § 1833(t)(1)(A).

28 *Id.* at § 1848(a)(1)(B).
29 Pub. L. No. 248, 90th Cong., 1st Sess.
(Jan. 2, 1968) § 402(a)(1)(A), codified at
42 U.S.C. § 1395b-1(a)(1)(A).
30 *Id.* at § 402(b).
31 Recommendations of the Special Com-
mission, *supra* note 6, at 53.
32 42 U.S.C. § 1315(a)(1).
33 Recommendations of the Special Com-
mission, *supra* note 6, at 21.
34 Social Security Act § 1901(1).
35 Section 1902(a)(15) of the Social Se-
curity Act generally requires that health
centers be paid under a prospective
payment system that assures them of
receiving their actual costs.

New Stem Cell Research Policies: The NIH Guidelines and State Developments

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I. Introduction

After years of awaiting supportive federal direction, the scientific and medical research community now has national standards governing federally funded human embryonic stem cell research. On July 7, 2009, the National Institutes of Health (NIH) issued final Guidelines for Human Stem Cell Research (“NIH Guidelines”).¹ The NIH Guidelines implement President Barack Obama’s Executive Order in March that permitted the U.S. Department of Health and Human Services (HHS), through NIH, to fund and conduct “responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law.”² Shortly after the NIH Guidelines were issued, the president instructed all federal departments and agencies that support stem cell research to follow the NIH Guidelines, in the interest of promoting a uniform federal policy.³

This article reviews the NIH Guidelines, after a brief summary of the different layers of standards affecting this field to date. It then notes areas of research that the NIH Guidelines do not currently address and discusses state ethical and policy approaches in those areas. Implications of the new federal standards for state policymakers and research entities are also noted.

II. The 2009 NIH Guidelines for Human Stem Cell Research

Context

Before the 2009 federal policy change, a 2001 policy statement by President George Bush set the parameters of federally funded research on human embryonic stem cells.⁴ As announced on August 9, 2001, the statement allowed for federal funding of such research if (i) the stem cell lines already had been created before 9 p.m. on that date, and (ii) the source of the cell lines was excess embryos, which were originally created for reproductive services and were donated to research with voluntary, informed consent and without payment to the donors.⁵ A national stem cell registry stored and made available up to 21 cell lines pursuant to this announcement.⁶

The 2001 policy statement did not provide standards for the use of newer cell lines, several hundred of which since then have been created and used in the U.S. and globally.⁷ The policy statement also did not address the actual collection and use of embryos to create the stem cell lines; this is because a separate federal law, known as the Dickey-Wicker Amendment, bars the use of federal funds in research that would destroy an embryo.⁸

In reaction to these federal restrictions,⁹ about a dozen states including Massachusetts¹⁰ passed legal measures to promote human

embryonic stem cell research, and some states funded the research as well. Through these initiatives, states established their own regulatory and ethical standards. These standards typically covered not only use of cell lines, but also derivation of new cell lines from in vitro embryos donated to research. Some states such as Massachusetts incorporated into their policies key aspects of the federal regulatory framework for human subject research (the “Common Rule”), including requirements for informed consent and oversight of research through institutional review boards (IRBs).¹¹

In addition to state-by-state activity, an expert committee appointed by the National Academies of Sciences issued guidelines for this field (“NAS Guidelines”) in 2005, and an international group of scientists published the International Society for Stem Cell Research (ISSCR) Guidelines in 2006. Many of the state laws and expert guidelines share similar elements, but differ in operational requirements and scope. Accordingly, when NIH drafted its guidelines in 2009, it was not starting from a blank slate. For years, some research entities had collected donated embryos, derived new stem cell lines, and studied and published on cell lines that met existing standards.

Amidst this backdrop, President Obama’s Executive Order in March 2009 gave NIH 120 days – until July – to publish final guidelines for this

field. NIH quickly issued proposed draft guidelines in April. More than 49,000 individuals and organizations submitted public comments in response to the proposed draft guidelines. Within the stem cell research community, while many welcomed federal support of the research, there were concerns about the proscriptive and retroactive nature of the initial draft guidelines.¹² After consideration of all comments received, NIH revised the guidelines and published the final version on July 7, 2009, to take effect on that date.

Content

For lawyers who advise clients that conduct hESC research, at least five aspects of the NIH Guidelines are critical. Keep in mind that the guidelines regulate only federally funded research and do not directly apply to research funded privately or by states. In effect, however, given the central role of NIH and other federal departments and agencies as funders of biomedical research, and the probable desire of states to leverage their own research grants with federal funds, these guidelines likely will have a more expansive impact.

(1) The NIH Guidelines permit federally funded research on hESC lines regardless of their date of creation. (So, the prior Administration's cut-off date of August 9, 2001, is no longer a critical dividing line.) Federal funds, however, still cannot be used for research on in vitro embryos to create cell lines, because the Dickey-Wicker Amendment is currently still in effect.¹³

(2) To qualify under the NIH Guidelines, stem cell lines must have been derived from in vitro fertilization (IVF) embryos that

were originally created for reproductive purposes and were no longer needed for that purpose. This standard means that stem cell lines may be created from IVF embryos that were not suitable or needed for fertility treatment. The embryos must have been donated voluntarily by the individuals who sought reproductive services, with informed consent to the research and without payment for the research donation.

(3) As of July 7, 2009, several requirements must be documented through a consent form, written policies, or other materials. These requirements include, for example: (a) the patients must have been offered all options (which were available at the clinic) for disposition of their embryos - a standard consistent with existing Massachusetts law;¹⁴ (b) no payments, in cash or in kind, were offered for the donated embryos; (c) there was separation between a donor's decision to create embryos for reproductive care and the decision to donate to research; (d) the consent process explained certain unique aspects of hESC research; and (e) the consent process disclosed that the research may have commercial potential and donors will not receive financial or other benefits from any commercial developments.

(4) For embryos donated, and cell lines created, before July 7, 2009, research entities may *either* show that they met the standards of the 2009 NIH Guidelines, or they may provide documentation so NIH can determine if the lines ethically qualify for federally funded use. On September 21, 2009, NIH announced the mem-

bership of a new working group¹⁵ that will review the "provenance" of cell lines (such as the specific nature of the informed consent to the research, and the ethical standards that were in place at the research entity that created the cell lines). The working group will make recommendations to an advisory committee, which will advise the NIH Director, who decides on hESC lines that are eligible for federally funded research. This approach reflects an important change from NIH's prior draft proposal, which had suggested that the new NIH requirements would be applied retroactively; that approach could have disqualified some cell lines even if entities had followed applicable state law or expert guidelines at the time. The NIH's working group review is also available for embryos donated outside of the U.S. to create cell lines.

(5) NIH is creating a registry of approved cell lines. In late August 2009, NIH posted preliminary forms and instructions for submitting cell lines to the new registry, and in late September, NIH finalized the on-line application process and began accepting submissions.¹⁶ This is an important development, as the prior draft proposal had not included a registry, prompting many in the research community to comment on the burden that individual institutions would face to verify the provenance of every cell line proposed for use at their institution.

As explained further below, the NIH Guidelines are also significant for what they do not currently require or permit. In particular, to qualify for federal funding, cell lines must have been created only from IVF embryos made for reproductive

purposes; as explained further below, other techniques, such as somatic cell nuclear transfer (SCNT), cannot have been used. In addition, NIH does not explicitly require IRB oversight of the creation of cell lines from embryos, nor does it require approval of a more specialized embryonic stem cell research oversight (ESCRO) committee. The NAS Guidelines of 2005 had recommended that research entities create ESCROs to oversee this type of research; many institutions voluntarily adopted this recommendation, while others were required to do so by state law, such as in Connecticut, New York, and California.

III. Remaining Ethical and Policy Issues for States

The NIH Guidelines leave open many ethical and policy issues for the states. Will states continue to fund hESC research ineligible for federal funding? Will the limitations contained in the NIH Guidelines concerning what is eligible for federal funding influence what research is deemed responsible and scientifically worthy? Will states maintain policies for the ethical conduct of hESC research, regardless of whether the research is funded by the federal government?

A number of state funding programs were created in the vacuum of federal funding, and these will likely continue, co-existing with the expanded federal funding initiative. There is no indication that the new NIH Guidelines heralded the end of state funding generally. A year after the Life Sciences Initiative was launched in Massachusetts, state funding continues with some vigor. On July 22, 2009, the Massachusetts Life Sciences Center (MLSC)¹⁷ awarded \$600,000 in matching New Investigator Grants to Harvard-affiliated researchers.

This round of funding followed and supplements a \$1.4 million round of New Investigator Grants to seven young scientists working in Massachusetts research institutions, announced on June 24, 2009. On the same day, the MLSC approved \$695,000 in continued funding for the International Stem Cell Registry (ISCR), a significant state initiative described below.

Measures promoting hESC research are also likely to remain in effect across states. The NIH Guidelines seek to expand and provide guidance on federal funding for hESC research, but do not set out ethical guidelines outlining permissible methodologies to create hESCs. Many states that provide state funding for hESC research do both. Massachusetts, in its Biotechnology Statute,¹⁸ seeks to foster stem cell research and sets out what hESC derivation methodologies are permissible in the Commonwealth. A separate bill, the Massachusetts Life Sciences Act, sets out state funding guidelines for life sciences projects, including stem cell research.

Created as the result of a state measure and made possible by a state funding initiative, the ISCR provides an excellent example of how activity at the state level may provide a nice complement to activity at the federal level. The ISCR is a comprehensive database maintained by the University of Massachusetts Medical School in Worcester. The database comprises published and validated unpublished information on all hESC and induced pluripotent stem cell (iPSC) lines from non-profit institutions, academic centers, research enterprises, stem cell banks, and industry based in the United States and abroad, including those lines previously approved by NIH for

federal funding and those derived through other public or private funding sources. This comprehensive state-funded registry has already proven valuable to researchers and may prove to be a valuable resource as NIH moves forward to implement its Guidelines, particularly in its efforts to create or endorse a registry of qualifying stem cell lines.

For research methodologies ineligible for federal funding, the NIH Guidelines provide no legal or ethical guidance to researchers. In Massachusetts, permissible methods of deriving hESCs include parthenogenesis and SCNT, techniques that are currently ineligible for federal funding under the NIH Guidelines. The Massachusetts funding bill does not base funding decisions on which legally permissible derivation technique is used. For Massachusetts researchers who wish to pursue SCNT and secure state or private funding to do so, they must look to state regulators to determine how they can legally and ethically pursue such research. Further, such researchers will face some of the same concerns as before the issuance of the NIH Guidelines. In essence, attention must be paid to ensure that no federal funds are applied to research ineligible for federal funding.

Similarly, researchers engaged in interstate research may discover that the NIH Guidelines have not resolved all issues surrounding the use of certain lines and materials. Prior to the issuance of the NIH Guidelines, researchers who were working together across state lines had to determine whether cell lines derived outside of their state could be used in research conducted in-state. While this issue may be resolved as it relates to feder-

ally funded research – as there are now uniform federal standards to follow – this question remains for research that is only eligible for state or private funding. Recently, the Empire State Stem Cell Board¹⁹ in New York voted to allow state funding of research on stem cell lines derived using oocytes donated solely for research purposes where the donor was compensated for the time, expense, burden, and discomfort associated with the donation process. Such lines would be ineligible for federal funding, as they would run afoul of Section II(A) of the NIH Guidelines. In particular, such lines would not be “derived from human embryos that were created using in vitro fertilization for reproductive purposes,”²⁰ and they involve a “payment.”²¹ Nevertheless, the question remains whether a Massachusetts researcher using only state or private funds could conduct research on such lines.

Massachusetts law²², like California²³ and Connecticut²⁴ law, permits researchers to reimburse gamete donors for the direct medical costs associated with a donation to research. In addition, Massachusetts and California allow for the reimbursement of the attendant out-of-pocket costs, such as childcare and travel, associated with a donation to research. The New York decision goes one step further, to allow for compensation of a donor’s “burden” and “discomfort” resulting from a donation to research. The Massachusetts statute permits reimbursement for “reasonable costs,” but prohibits the provision of “valuable consideration.” The Massachusetts statute does not, however, explicitly state whether compensation of a donor’s “burden” and “discomfort” constitutes an allowable reasonable cost or a prohibited payment of valuable

consideration. Similarly, this issue has not been resolved under Connecticut law. Thus, researchers in Massachusetts and elsewhere²⁵ will seek guidance on whether lines created in New York pursuant to this expanded view of allowable reimbursements to donors are valid for use in research within their own state. This represents an ambiguity that can only be solved at the state level by state interpretation.

In January 2009, Senator Cynthia Stone Creem of Newton filed a bill²⁶ seeking to clarify some of the terms and ethical and legal guidelines contained in the Massachusetts Biotechnology Statute. This bill arose largely out of calls for clarification by the Biomedical Research Advisory Council (BRAC) established pursuant to the original bill.²⁷ Among other clarifications of scientific terms, this bill seeks to incorporate into law the 2006 Advisory Ruling issued by the Massachusetts Department of Public Health, interpreting the statutory term “reasonable costs” to include out-of-pocket costs associated with a donation to research, and to recognize ESCRO committees as legitimate oversight bodies.²⁸ Several Massachusetts research institutions established ESCRO committees on the recommendation of the 2005 NAS Guidelines and sought confirmation that research protocols approved by such bodies were valid under Massachusetts law. The NIH Guidelines do not address or require ESCRO oversight of stem cell research eligible for federal funding. Will this alter how states view ESCROs, particularly the states (such as California, Connecticut, and New York) that require ESCRO oversight? Will research institutions that voluntarily established such committees disband them, or seek to integrate such

expertise into their IRBs?²⁹ Such questions remain as examples of the unfinished work of the states in this area.³⁰

IV. Conclusion: Implications for State Policymakers and Research Entities

The states have a continued role to play, despite the expanded role of the NIH under its new federal funding guidelines. States such as Massachusetts will likely continue to foster and fund hESC research at the state level. Further, state law and state regulation of the ethical issues raised by hESC research will continue to evolve as the science does. New research methodologies and further advancements in the science will prompt new questions, and states that have set their own detailed standards may evaluate how those compare to the new uniform federal standards from a harmonization perspective.³¹ As a result, clarifications will continue to be sought by organizations such as the BRAC, as well as by state- and privately-funded researchers and research institutions.

For some research entities, an immediate implication of the NIH Guidelines is the need to review whether prior research consent forms and related documentation to create stem cell lines will pass muster under the new NIH standards. As the NIH registry becomes operational, research entities presumably will seek specific guidance on how NIH will evaluate lines that met applicable legal requirements at the time, but do not satisfy one or more of the new federal standards. Research entities will also likely be evaluating their policies and oversight procedures to ensure that they incorporate the NIH standards. Further, entities will want to guide their faculty and researchers on NIH developments

with respect to new and pending research grant applications, and specific cell lines that are approved for federally funded use. For now, NIH has advised researchers not to specify in grant applications which hESC line they will use, but rather, say only that they will use a cell line that is on the new NIH registry.³²

As NIH moves forward with implementation of its guidelines and the new registry, it now also must address a federal lawsuit challenging the legality of the guidelines. The lawsuit, filed by a group of plaintiffs in the U.S. District Court for the District of Columbia, seeks declaratory and injunctive relief against NIH, HHS, and other named defendants.³³ States, including Massachusetts and California,³⁴ among others, faced similar legal challenges when they enacted permissive stem cell research policies, and these challenges have failed in the past. NIH has indicated that progress in this field is a priority, and implementation of its new framework is well underway.

Endnotes:

1 National Institutes of Health Guidelines for Human Stem Cell Research, July 7, 2009, available at <http://stemcells.nih.gov/policy/2009guidelines.htm>.

2 Executive Order 13505 of March 9, 2009: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, 74 Fed. Reg. 10667 (March 11, 2009), available at http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-Cells/.

3 Memorandum for the Heads of Executive Departments and Agencies, Guidelines for Human Stem Cell Research, July 30, 2009, available at http://www.whitehouse.gov/the_press_office/Memorandum-from-the-President-for-the-Heads-of-Executive-Departments-and-Agencies-Regarding-Guidelines-for-Human-Stem-Cell-Research/.

4 Human embryonic stem cells are cells derived from the inner cell mass of very early-stage embryos created in vitro (in a petri dish). These cells are not embryos themselves, but are derived from embryos. Ordinarily the embryos are

created for reproductive purposes, such as for in vitro fertilization (IVF) patients. Some patients may decide to donate the embryos to research if the embryos are not healthy for reproductive use or are not needed for their care.

5 <http://stemcells.nih.gov/policy/2001policy.htm>.

6 CT Scott, JB McCormick, J Owen-Smith, And Then There Were Two: Use of hESC Lines, 27 Nature Biotech. 696 (Aug. 2009) (policymakers initially “announced 78 lines could be used. This was later revised downward to 64, then downward again to 21, the number most often cited in the literature.”) (citations omitted).

7 G. Naik, NIH Offers Rules for Embryonic Stem Cell Research, WSJ, Apr. 17, 2009, available at <http://online.wsj.com/article/SB123999343505429693.html>.

8 See Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111-8, Mar. 11, 2009, otherwise known as the Dickey-Wicker Amendment, annually reenacted by Congress since the Balanced Budget Downpayment Act, Pub. L. No. 104-99 § 128, 110 Stat. 26, 34 (1996). The Dickey-Wicker Amendment, passed as part of the federal HHS appropriations bill, bars use of the funds for the creation of a human embryo for research or for research in which a human embryo is destroyed, discarded, or substantially harmed.

9 Congress also tried to expand the scope of federally funded research on human embryonic stem cell lines, but their efforts were vetoed twice, and overrides failed.

10 Ch. 27 of the Acts of 2005.

11 The federal Common Rule applies to federally supported research involving an intervention or interaction with an individual or the use of identifiable information. It technically does not apply to most hESC research for several reasons, including (1) most cell lines used in hESC research have been de-identified (thus, no identifiable information); (2) some embryos used in derivation work are de-identified prior to transfer to the researchers; (3) an in vitro human embryo is not a “human subject” under the Common Rule; and (4) there is no federal funding of research that would destroy an embryo, so collecting donated embryos to create new stem cell lines is not subject to the Common Rule. Notwithstanding the above, many research institutions voluntarily apply the Common Rule to non-federally funded research, including embryo donation for stem cell research.

12 See Advancing the Promise: Leading Research Institutions, Patients and Scholars Comment on the Draft NIH Guidelines for Human Stem Cell Research, June 10, 2009, available at http://www.iascr.org/docs/IASCR_Summary_NIH_Draft_Guidelines.pdf.

13 While Congress could decline to include the Dickey-Wicker Amendment in a subsequent federal appropriations bill, neither the President nor NIH can unilaterally reverse the existing Congressional restrictions.

14 M.G.L. c. 111L, § 4.

15 See <http://www.nih.gov/news/health/sep2009/od-21.htm> (accessed September 22, 2009).

16 See http://grants.nih.gov/stem_cells/registry/NIH_Form_2890_Sample.htm.

17 The Massachusetts Life Sciences Center is a quasi-public agency created by statute in 2006 to promote the life sciences within the Commonwealth of Massachusetts. On May 8, 2007, during a speech at the international BIO 2007 Convention, Governor Deval Patrick announced a new Life Sciences Initiative in Massachusetts. The Massachusetts Life Sciences Center is the primary agency tasked with implementing Governor Patrick’s Life Sciences Initiative. M.G.L. c. 111L.

18 The Empire State Stem Cell Board was created by statute in New York to administer the Empire State Stem Cell Trust Fund and is authorized to “make grants to basic, applied, translational or other research and development activities that will advance scientific discoveries in fields related to stem cell biology.” The Empire State Stem Cell Board is comprised of a funding committee and an ethics committee.

19 National Institutes of Health Guidelines for Human Stem Cell Research, July 7, 2009, available at <http://stemcells.nih.gov/policy/2009guidelines.htm>.

20 See *id.*

21 In May 2006, the Massachusetts Department of Public Health issued an Advisory Ruling interpreting the term “reasonable costs” under M.G.L. c. 111L. The Department opined that reimbursement of the direct medical costs of a donation to research as well as associated out-of-pocket costs such as travel, housing, childcare, lost wages, and time-limited accident insurance coverage are permissible “reasonable costs” reimbursed to a donor consistent with c. 111L. See <http://www.iascr.org/states.shtml#MA>.

22 In November 2006, the Connecticut Attorney General’s Office issued a formal opinion clarifying that donors may be reimbursed the direct medical costs associated with a donation to research. See <http://www.iascr.org/states.shtml#CT>.

23 The California Institute for Regenerative Medicine (“CIRM”) issued regulations stating that “permissible expenses” include “travel, housing, child care, medical care, health insurance and actual lost wages.” CA Code of Regulations, Title 17, § 100020. See <http://www.iascr.org/states.shtml#CA>.

24 California policymakers are also following this New York decision, as they are cognizant of its potential impact on California researchers. CIRM’s regulatory committee invited a New York representative to present at its September 2009 meeting.

25 S. 193, An Act Clarifying Chapter 111L-Biotechnology.

26 Chapter 27 of the Acts of 2005.

27 The proposed bill expands the concept of allowable research to include research conducted upon the written approval of an ESCRO Committee. The original statute allows research to derive hESCs only upon the written approval of an IRB.

28 While many ESCROs generally incorporate standards of the NAS Guidelines,

29

they differ in how they are structured within an institution, what specific scope of research they review, and what specific standards they apply, in light of either state requirements or institutional policies. For anecdotal evidence of similarities and differences among ESCRO committees in their first years of operation, see Krysten Brown and Anne Hiskes, National Survey of Embryonic Stem Cell Research Oversight (ESCRO) Committees, Mar. 27-28, 2007, available at es-cro.uconn.edu/document.php?id=432. *NAS staff compiled anecdotal evidence about ESCRO committees in late 2008 to early 2009 (document on file with authors).*

30 For additional examples of how states are examining their standards in light of the NIH Guidelines, see recent proposed regulatory changes in a briefing and related materials by the California Institute for Regenerative Medicine, available at http://www.cirm.ca.gov/files/SWG_Briefing_Report_3_Appendix.pdf; http://www.cirm.ca.gov/Agenda_10-12-09.

31 See preliminary CIRM materials under consideration, *supra* n.30.

32 See Status of Applications and Awards Under the New NIH Guidelines for Human Stem Cell Research, July 15, 2009, available at <http://grants.nih.gov/grants/guide/notice-files/NOT-0D-09-123.html>.

33 *Sherley et al. v. Sebelius et al.*, U.S. District Court for the District of Columbia, filed Aug. 19, 2009, Case No. 1:09-cv-01575-RCL. On September 14, 2009, the government defendants filed a motion to dismiss the case on several grounds. Certain arguments asserted by the plaintiffs resemble arguments made against HHS and NIH in a 2001 lawsuit arising out of prior NIH guidelines for hESC research. See *Nightlight Christian Adoptions v. Thompson*, Civ. Action No. 01-CV-0973 (RCL) (D.D.C. 2001). The context of the 2001 lawsuit was different, in that NIH had issued guidelines supporting hESC research in 2000, at the end of the Clinton Administration, and the plaintiffs challenged their implementation in early 2001. The incoming Bush Administration then initiated a review of the guidelines, causing the parties jointly to agree to stay the legal challenge; President Bush then announced restrictions on federally funded hESC research on August 9, 2001. See District Court Judge Stays Lawsuit Calling for Restriction of Federally Funded Embryonic Stem Cell Research, Kaiser Network.org Daily Reports, May 11, 2001, available at http://www.kaiser-network.org/daily_reports/rep_index.cfm?hint=2&DR_ID=4542.

34 See R. Lewis, AG Blocks Petition to Repeal Stem-Cell Law, Boston Globe, July 19, 2005, available at http://www.boston.com/news/science/articles/2005/07/19/ag_blocks_petition_to_repeal_stem_cell_law/; CIRM Press Release: Litigation Against California Stem Cell Project Ends: State Supreme Court Refuses Appeal of Constitutional Challenge, May 16, 2007, available at http://cirm.ca.gov/?q=PressRelease_051607.

Civil Rights, Disability, and Health Care: Why Doesn't Anyone Care?

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The landmark 1990 Americans with Disabilities Act (ADA), and its predecessor, Section 504 of the Rehabilitation Act of 1973, established a wide-ranging national mandate prohibiting discrimination based on disability. Collectively, these two vital laws prohibit public and private health care services, programs, and providers from discriminating against people with disabilities, while also ensuring an equal opportunity to participate in and benefit from health care services. Since its enactment, the ADA has had a tremendous impact on people with disabilities. It has literally, and figuratively, opened doors from many Americans. At the same time, health care continues to be inaccessible for many with disabilities, often with detrimental consequences. Despite this, there have only been a small number of cases that have addressed health care access for people with disabilities.¹ Violation of the civil rights of people with disabilities in health care, as well as other sectors of American society, is widespread. On June 26, 2009, disability advocates and their allies reached a groundbreaking agreement with Partners HealthCare ensuring that people with mobility and sensory disabilities people have full access to Massachusetts General Hospital (MGH) and Brigham and Women's Hospital (BWH).² A further discussion of this landmark agreement follows later.

In light of the recent discussions on national health reform, which

so far have not focused on people with disabilities, this article serves as a call to action for the legal community to join in the local efforts to ensure that the civil rights of people with disabilities do not continue to be violated resulting in gross health disparities. This article provides readers with an understanding of a largely overlooked health care crisis through the lens of the disability rights movement. The scope of this crisis at the national level was recognized by the U.S. Department of Health and Human Services, when it included reduction of health disparities affecting people with disabilities as a priority in the health objectives for the nation of the Healthy People 2010 initiative.³ This was followed by the release of "A Call to Action to Improve the Health and Well-being of Persons with Disabilities," in 2005, by the Surgeon General.⁴ In her testimony before the Senate Health, Education, Labor, and Pensions Committee, on January 27, 2009, Lisa I. Iezzoni, MD, Professor of Medicine at Harvard Medical School and Associate Director of the Institute for Health Policy, Massachusetts General Hospital, stated in part, "individuals with disabilities experience high rates of disadvantages relating to the personal, social, economic, and environmental determinants...These disadvantages heighten the risks that persons with disabilities will not achieve the national health goal envisioned by the Committee, of living long and healthy lives."⁵

Although health disparities affecting people with disabilities is a national problem, the scope of this article is primarily on the issue as it affects people with disabilities in Massachusetts. The first section provides an overview of the issue. The following two sections proffer a discussion on what has been achieved locally through litigation as well as proposed legislation that addresses health disparities faced by people with disabilities. Finally, the article concludes with a discussion on how the legal community must join the efforts to eliminate this unjust phenomenon.

Health Disparities and Potentially Discriminatory Practices

Lack of full access to MGH and BWH is just one aspect of a larger systemic problem leading to health disparities and preventable secondary disabling conditions for people with disabilities. One cause of health disparities affecting people with disabilities has been a lack of awareness and responsiveness to preventable secondary conditions in the population by clinical and public health professionals. In March 2009, the Disability Policy Consortium (DPC), with funding from the Blue Cross Blue Shield of Massachusetts Foundation, published a report detailing pervasive health disparities and preventable secondary conditions affecting people with disabilities.⁶ Much of the data, coming from federal and state sources, provides clear evidence of health disparity and associated co-morbidities. As cited in

the DPC report, evidence of these disparities taken from the Behavioral Risk Factor Surveillance Survey, conducted by the Massachusetts Department of Public Health (DPH) in 2006, include:

- 31% of people with disabilities report fair or poor health in comparison to 6% of the general population.
- 15% of people with disabilities report not seeing a doctor due to cost in comparison to 6% of the general population.
- 24% of people with disabilities report being current smokers in comparison to 17% of the general population.

According to the survey, people with disabilities comprise 22% of the state's residents, an increase from 14% in 1998. In spite of the large and growing number of people in Massachusetts affected, the Massachusetts Health Disparities Council excludes people with disabilities from the scope of its work.⁷ Chaired by the Secretary of Health and Human Services, the Council limits its scope solely to ethnic and minority populations. The intentional exclusion of people with disabilities from the Council's efforts to improve the overall health status of all Massachusetts residents is perceived by a growing number of disability advocates as a direct violation of the ADA.

Health disparity, also referred to as inequality, goes beyond simple differences in health status. Health disparities result from social disadvantage and affect women, ethnic and minority populations, people who are poor, people with disabilities, etc. These health disparities include increased prevalence of disease, incidence, mortality, and other negative health conditions or outcomes when compared with

groups with advantage, i.e. wealth, education, etc. Health disparities arise when socially disadvantaged groups "systematically experience worse health or greater health risks than more advantaged social groups."⁸ Disparities are "differences which are unnecessary and avoidable but, in addition, are also considered unfair and unjust."⁹

While barriers to healthcare are often similar to those of other subpopulations, e.g., communication barriers, economic barriers, lack of information and misinformation, disability is often ignored by policymakers and health care advocates. According to a 2007 California Journal of Health Promotion article on health disparities and people with disabilities, "[d]isability has yet to achieve its proper place in the discussion of health disparities."¹⁰ Public health researchers persist in viewing disability as a "consequence of certain conditions... one result of disparities in healthcare" rather than acknowledging that people with disabilities are a legally defined minority population with "characteristic health disparities."¹¹ Epidemiological research, for example, still focuses primarily on "disability free life expectancy" as "essential for examining whether additional years of life are spent in good health."¹² This continued treatment of disability as a solely medical phenomenon perpetuates the myth that poor health is automatically associated with disability.

The lack of data resulting from potentially discriminatory research methodology is a critical barrier to understanding the links between health disparities and secondary conditions impacting people with disabilities. Determining these links requires research to be done that compares people with disabilities

to the general population; a practice rarely undertaken. In addition to lack of data, there seems to be a working assumption that the ADA ensures health access for people with disabilities. However, the ADA is often disregarded by the health care field. As with other subpopulations, other provisions and a level of cultural competency are needed to reduce health disparities affecting people with disabilities.

It was not until 2007, for example, that the Mental Health Parity Act was passed by Congress to ensure equal treatment for Americans with mental health and substance use disorders. Even with this law in place, people with psychiatric disabilities still receive unequal treatment in the medical system. Deborah Nicolellis of the Center for Psychiatric Rehabilitation of Boston University states that, "people with psychiatric disabilities and mental health issues who go to the emergency room with a physical ailment are not taken seriously by emergency room staff. Emergency room personnel often dismiss the person's problem as psychological, so instead of receiving immediate help for their physical problem, a psychiatrist is called in first."

There also seems to be an assumption that people with disabilities are covered by Medicaid or Medicare. To the detriment of people with disabilities, recent discussions with the Commonwealth Connector revealed that the entity does not track data on people with disabilities who are ineligible for Medicaid or Medicare. People with "adult onset disabilities," such as Arthritis, Multiple Sclerosis, Parkinson's Disease, Multiple Chemical Sensitivity, and Diabetes, often are disabled but do not meet Medicaid eligibility criteria.¹³ Members of this population often

receive no assistance unless they forfeit their family, their home, and their careers to meet the poverty level criteria required by Medicaid. It is not uncommon for people with adult onset disabilities to divorce their partner to protect their family from economic ruin, permanently ripping the family apart in the process. People eligible for Medicare often cannot meet the copayments of long hospitalizations, prescriptions, and doctor's visits. The number of homeless, chronically unemployed, and over housed people with disabilities ineligible for Medicaid is unknown.

Partners HealthCare Agreement

As demonstrated above, health disparities affecting people with disabilities is a widespread problem with devastating consequences. The legal community must recognize it for what it is – a civil rights violation – and act accordingly. One approach is litigation which, to date, has been underutilized and yet highly effective. As previously mentioned, Massachusetts recently joined the efforts to make health care accessible to all, including people with mobility and sensory disabilities. In June 2009, the Boston Center for Independent Living (BCIL), with legal representation from Greater Boston Legal Services and Disability Rights Advocates (collectively, the "Claimants"), and Partners HealthCare reached a groundbreaking agreement that will ensure that people with disabilities have full access to MGH and BWH. This agreement ("Partners Agreement") came after 14 months of negotiations between disability activists, people with disabilities, attorneys, and hospital officials. The Partners Agreement, which is in effect July 1, 2009, through June 30, 2015, addresses accessibility in three areas: architectural barrier

removal, policies and procedures and ADA training, and accessible medical equipment.

Both hospitals have agreed to hire a consultant to survey for architectural barriers. Based on survey results, each hospital will develop a "barrier removal plan" beginning with a "pilot survey" of inpatient and outpatient areas prior to the full survey being conducted. Each hospital will then decide what barriers to remove according to the "readily achievable standard" of the ADA. If a hospital determines the removal of a barrier does not meet the "readily achievable standard," it must provide an alternative solution for a patient to be able to have equal access. Barriers at the newest buildings (Yawkey Building at MGH and Shapiro Center at BWH) will be removed according to the strictest ADA standard, the "new construction standard." MGH and BWH's consultant will survey the hospitals' main campuses and outlying facilities, including inpatient areas, outpatient clinics, and public areas. The entire survey is to be completed by December 31, 2010, and each hospital shall remove barriers by the end of the agreement.

Vital to the Partners Agreement, is the section on policies and procedures and ADA training. MGH and BWH must hire a consultant on policies and procedures as well as a training consultant. Hospitals will provide the Claimants copies of any existing policies related to patients with disabilities. Together, each hospital and the consultant will review existing policies and procedures and determine whether changes or new policies are needed. Furthermore, each hospital and training consultant will develop an ADA training program, which will be

required for all hospital employees with patient or family contact.

The final area covered by the Partners Agreement is with regard to accessible medical equipment. Similar to the aforementioned sections, each hospital is required to hire a consultant to create a tool for surveying equipment. Thereafter, MGH and BWH will conduct the equipment survey using the consultant's tool. This survey will include, *inter alia*, exam tables, scales, and diagnostic equipment. Following the survey, each hospital shall create a plan for changing equipment, purchasing new equipment, or providing a reasonable alternative with equal access.

Pursuant to the Partners Agreement, all parties will work collaboratively through each stage of the process. Further, progress of the hospitals will be monitored by the Claimants through semi-annual reports on implementation of the agreement, which will be validated by third-party consultants. Further, each hospital will proffer Claimants a final report on implementation prior to the end of the agreement. Moreover, each hospital shall provide Claimants anonymous reports of accessibility-related complaints. In addition, the agreement contains various mechanisms for dispute resolution.

Legislation

Equally as important as litigation, advocates must push for policy change. Although the ADA broadly covers health care, its breadth does not address many specific areas. Moreover, there are very few Massachusetts laws that effectively ensure people with disabilities receive adequate, appropriate, and accessible health care. In an effort to begin to eradicate the devastating health disparities faced by

people with disabilities, numerous legislation has been filed in Massachusetts in the 2009-10 session. This section provides a brief discussion of four important bills that seek to address and eliminate health disparities faced by people with disabilities.

An Act Relative to the Health Disparities Council

As aforementioned, the Massachusetts Health Disparities Council is charged with making recommendations regarding the reduction and elimination of racial and ethnic disparities in health care and health outcomes in Massachusetts. Senate Bill 858, *An Act Relative to the Health Disparities Council*, introduced by Senator Richard T. Moore, adds disabilities to the list of the disparities looked at by the Council. Disability groups, such as the DPC, urge legislators to also add representation from the disability community to the Council. Inclusion of disability is an important step in acknowledging the problem and subsequently addressing it. This bill was referred to the Joint Committee on Public Health and a public hearing was held on June 9, 2009.

An Act Relative to the Health Care Quality and Cost Council

Similarly, Senate Bill 562, *An Act Relative to the Health Care Quality and Cost Council*, also sponsored by Senator Richard T. Moore, advances the inclusion of people with disabilities into the health disparities field. This bill dissolves and re-establishes the Health Care Quality and Cost Council, whose funding was severely reduced as part of the Governor's 9C cuts in 2008. Further, pursuant to this bill, the Council would be required to establish goals that are intended to reduce health care disparities in racial, ethnic and disabled communities.

A public hearing regarding this bill was held on July 15, 2009, before the Joint Committee on Health Care Financing.

An Act Pertaining to People with Mental Illness in Hospital Emergency Rooms

Given the sheer number of people with disabilities, certain subpopulations are often totally disregarded. For example, people with psychiatric disabilities continue to face enormous disparities in health care, manifesting largely from stigma and ignorance. This population is often overlooked, as demonstrated by their exclusion in the Partners Agreement. House Bill 3585, *An Act Pertaining to People with Mental Illness in Hospital Emergency Rooms*, was introduced by Representative Ruth B. Balse as one step toward eliminating these disparities. This bill would require hospitals to keep records of how often they use restraints in their emergency rooms. Disability activists have found that restraints are frequently overused in emergency rooms. Currently there is no way to hold hospitals accountable because they do not have to keep detailed records of the number of people they restrain, the length of the restraint, or the reason. In contrast, psychiatric inpatient units are required to maintain very detailed data and have significantly reduced use of restraints. House Bill 3585 has been assigned to the Joint Committee on Mental Health and Substance Abuse and a public hearing was held on September 23, 2009.

An Act Relative to Accessible Medical Equipment

Lastly, as demonstrated by the Partners Agreement, a lack of accessible medical equipment is problematic for many with mobility disabilities and causes great suf-

fering, including costly preventable disease and premature death. An Act Relative to Accessible Medical Equipment, Senate Bill 819 (Senator Patricia D. Jehlen) and House Bill 2137 (Representative Denise Provost), requires health care providers to have available medical equipment that is accessible to, and usable by, individuals with disabilities. Further, the legislation would require standards to be established for the minimum technical criteria for medical diagnostic equipment used in health care settings. Both bills are before the Joint Committee on Public Health and a public hearing was held on June 9, 2009.

Conclusion

As this article reveals, there are a number of documented and potentially discriminatory practices in health care leading to preventable secondary conditions for people with disabilities who are possibly the poorest, least educated and most vulnerable residents of Massachusetts. Comprehensive data connecting health disparities and secondary conditions in particular groups of people with disabilities, such as people who are deaf or hard of hearing, people with intellectual disabilities, or people with chronic conditions, such as autoimmune disease, is beyond the scope of this article. What is clear is the need for immediate decisive action to address health disparities affecting people with disabilities.

Leadership is needed within the legal community as well as by state and other health care advocacy groups in Massachusetts. This includes allies such as Health Care For All, whose Executive Director, Amy Whitcomb Slemmer states, "We are excited about working with the disability community to break down barriers to health care and

to eliminate the discrimination that people with disabilities face every day. Health Care For All and the disability community share the mission of creating a patient centered health care system where comprehensive health care is available to all. For people with disabilities, this requires understanding and treating the whole person, not just the disability and we are delighted to have the opportunity to work with disability advocates on the shared goals of raising awareness and enacting important system improvements.”

The Executive Office of Health And Human Services and DPH must take action in follow-up to the Partners Agreement, requiring all hospitals and state contracted health-care entities to undergo the same process required of MGH and BWH. State entities, including the Commonwealth Connector, should develop and implement data collection processes that track people with disabilities. Inclusion of disability advocacy groups, such as the DPC, at the state level on committees that require measurable time frames and outcomes to move comprehensive reduction of health disparities affecting people with disabilities are necessary for real progress to take place. Further, all initiatives must include people with all disabilities, whereas the Partners Agreement was limited to only people with mobility and sensory disabilities.

Action by litigators and research by legal scholars must be undertaken to determine ADA violations that may exist in current state public health initiatives seeking to reduce health disparities for Massachusetts residents yet excluding people with disabilities. The same research must be undertaken to determine if current epidemiological practices,

which purposely exclude “disability” as a minority population, are in their practice discriminatory when funded with tax dollars with the purpose of being used to develop health policy and programs at the state and federal levels.

Presently, people with disabilities are not fully aware of their rights or responsibilities as consumers of health care in the United States because of very basic barriers to their inclusion in the health care system. Only with the same emphasis, funding research and initiatives for women, ethnic and minority populations and other groups, will people with disabilities be empowered to participate in a truly personcentered health care system and health disparities be reduced in this population.

9 http://www.cdc.gov/Pcd/issues/2009/jul/09_0012.htm.
 10 M.A. Nosek & D.K. Simmons, Californian Journal of Health Promotion (2007), Volume 5, Special Issue (Health Disparities & Social Justice), 68-81.
 11 *Id.*
 12 *Id.*
 13 See 105 C.M.R. 501 et seq.

Endnotes:

- 1 See Metzler v. Kaiser Foundation Health Plan, Inc., No. 829265-2 (California Superior Court, Alameda County). (Dismissal Based on Settlement Agreement March 2001) [settlement available at <http://www.dralegal.org/downloads/cases/metzler/settlement.pdf>]; Equal Rights Center, et al. v. Washington Hospital Center, US DOJ No. 202-16-120 (November 2005) [settlement available at <http://www.ada.gov/whc.htm>]; Olson, et al. v. Sutter Health, No. RG06-302354 (California Superior Court, Alameda County). (Dismissal Based on Settlement Agreement April 2008) [settlement available at http://www.dralegal.org/cases/health_insurance/Thompson_v_Sutter.php]; Longo v. University of California, San Francisco and UCSF Medical Center (September 2008) [available at <http://iflegal.com/2008/09/ucsf-settlement-agreement/>].
- 2 Settlement agreements available at http://www.gbhs.org/map/partners_healthcare/partners_healthcare_agreement.htm.
- 3 <http://www.healthypeople.gov>.
- 4 <http://www.surgeongeneral.gov/library/disabilities/>.
- 5 www.asph.org/UserFiles/lezioni.pdf.
- 6 Disabilities and Disparities: Another View of a Health Care Issue, March 2009, available at <http://www.dpcma.org>.
- 7 Mass. Gen. Laws, ch. 6A, §160.
- 8 <http://www.chronicdisease.org/i4a/pages/index.cfm?pageid=3447>.

Local Health Law Briefs

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Muriel Doherty v. Director of the Office of Medicaid, 74 Mass.App. Ct. 439, 908 N.E.2d 390 (2009)

On June 18, 2009, the Massachusetts Appeals Court (“Court”) affirmed the denial of Massachusetts Medicaid (“MassHealth”) benefits to the plaintiff, Muriel Doherty, finding that assets she held in an irrevocable trust were “countable assets” for purposes of MassHealth financial eligibility standards. The Court agreed with the reasoning of MassHealth and the Superior Court that the terms of the irrevocable trust afforded the trustees a certain amount of discretion that would have allowed them to invade the trust assets for Ms. Doherty’s benefit.

MassHealth’s financial eligibility standards provide that the total value of countable assets owned by, or available to, an individual who seeks to qualify for benefits may not exceed \$2,000. 130 CMR §520.003(A)(1). Assets held in a trust are considered “countable assets” if, under any circumstances described in the trust, any of the resources may be made available to or for the benefit of the individual. 130 CMR §520.023.

Ms. Doherty applied for MassHealth long-term care benefits approximately six months after entering a nursing home. MassHealth denied her application, finding that her assets exceeded the \$2,000 threshold because an irrevocable trust formed by Ms. Doherty, which held approximately \$630,000, was available to her. Ms. Doherty dis-

agreed with the conclusion reached by MassHealth, arguing that she did not have access to the trust assets as the terms of the trust did not confer any discretionary authority upon the trustees to invade the principal for her benefit.

In reaching its conclusion, the Court recognized that the express terms of the trust stated that the trustees could “make no distributions of principal from the trust to or on behalf of” Ms. Doherty. However, the Court also found that, when viewed as a whole, the terms of the trust vested a certain amount of discretionary authority in the trustees to invade trust assets, when necessary, to ensure Ms. Doherty’s comfort. For example, the trustees were given the power to “determine all questions as between income and principal,” to save the trust principal for the beneficiary’s “future needs,” and to pay out the entire trust principal to the beneficiary should the trustees determine “in [their] sole judgment” that the trust is of a size which makes it unnecessary or inadvisable to continue. The Court also found that Ms. Doherty retained some limited powers over the trust corpus, including the ability to appoint the principal of the trust to a descendent or sibling. Based on these facts, the Court agreed with MassHealth and the Superior Court that the trust corpus was a “countable asset” for Medicaid eligibility purposes.

In finding that the terms of the irrevocable trust conferred a certain amount of discretion upon its trustees, such that it was possible for the trustees to invade the trust as-

sets for Ms. Doherty’s benefit, the Court further opined that in the absence of the discretion present in Ms. Doherty’s case, a self-settled irrevocable trust may well insulate those assets from the reach of the settlor.

Board of Registration in Medicine v. Hallmark Health Corporation & others, 454 Mass. 498, 910 N.E.2d 898 (2009)

In a significant ruling issued on August 11, 2009, the Massachusetts Supreme Judicial Court (“Court”) sided with the Board of Registration in Medicine (“Board”) regarding the scope of the Massachusetts medical peer review privilege, finding that 111 M.G.L. §205(b) authorized the Board to access certain documents in a physician’s credentialing file prior to the commencement of a formal adjudicatory proceeding – specifically, information and records which, while not necessarily proceedings, reports and records of a peer review committee, are nonetheless necessary to comply with risk management and quality assurance programs established by the Board and which are necessary to the work product of peer review committees.

In this case, the Board’s disciplinary unit began to investigate a physician (“Dr. John Doe”) following a patient complaint of misconduct during a physical examination. In furtherance of its investigation and based on information that suggested that Dr. Doe may have fraudu-

lently obtained renewal of his medical license, the Board subpoenaed Lawrence Memorial Hospital and Melrose-Wakefield Hospital (collectively referred to hereafter under the name of the hospitals' indirect corporate parent, Hallmark Health Corporation, as "Hallmark") to produce materials related to his credentialing, employment, and competence to practice medicine as well as incident reports and complaints. Hallmark declined to produce these documents, asserting that these materials were part of the hospital's credentialing files and were protected either as "records of a peer review committee" under 111 M.G.L. §204(a), or as "information and records necessary to comply with risk management and quality assurance function requirements" under 111 M.G.L. §205(b) and, therefore, were not subject to a Board subpoena prior to the commencement of an adjudicatory proceeding under 30A M.G.L. §1, *et. seq.*

On March 12, 2007, the Board filed a verified complaint for injunctive relief seeking to compel Hallmark to comply with the subpoena. The Board asserted that the subpoena did not require Hallmark to produce materials protected under §204(a), but that the Board was well within its right to request to inspect any materials within the scope of §205(b) prior to the commencement of a formal adjudicatory proceeding. In response, Hallmark provided a privilege log summarizing the documents contained in Dr. Doe's credentialing files.

A subsequent written memorandum issued by a Superior Court judge on April 25, 2007, ordered Hallmark to "produce all documents that are not privileged 'proceedings, records, and reports'" under §204(a). Instead of pro-

ducing the responsive documents, however, Hallmark submitted affidavits from officers at Hallmark, information on Hallmark's credentialing policy, and agreed to produce its chief medical officer for a deposition. The Board filed a motion to compel compliance with the April 2007 order. This motion was allowed on January 10, 2008, and required Hallmark to produce the documents within 10 days.

Hallmark did not comply with the order and instead moved for summary judgment on January 22, 2008. Upon review, the Superior Court agreed that the requested materials were protected by the medical peer review privilege and granted summary judgment in favor of Hallmark. The Board appealed the order of the Superior Court, and the Supreme Judicial Court subsequently granted Hallmark's application for direct appellate review.

111 M.G.L. §204(a) provides that "the proceedings, reports and records of a medical peer review committee" shall be "confidential" and "shall not be subject to subpoena or discovery," except in "proceedings held by [the Board]." The court in *Beth Israel Hosp. Ass'n v. Board of Registration in Med.*, 401 Mass. 172, 181-183 (1987) found that the clause, "proceedings held by the [Board]," referred to formal adjudicatory proceedings under 30A M.G.L. §1, *et. seq.* and, therefore, the Board could not access any documents protected under §204(a) before a proceeding was initiated. This court also concluded that the protections of §204(a) did not extend to "incident reports, patient complaints, . . . credentialing items . . . and other items" or to the raw materials relied upon by a peer review committee if obtained from outside sources. In response

to the *Beth Israel* decision, the Legislature enacted §205(b) to protect materials "necessary to comply with risk management and quality assurance programs . . . and which are necessary to the work product of medical peer review committees" but that might fall outside the scope of the §204(a) privilege.

The Board found error in the Superior Court's interpretation of §§204(a) and 205(b) on two grounds: first, the judge did not fully explore the nuances between the protections of §204(a) and those of §205(b) with respect to what information the Board may have access to prior to a commencement of a formal adjudicatory proceeding; and second, the judge erred in ruling that the documents as a whole were protected without considering each individually. The Court agreed with the Board on the first issue, finding that the protection afforded to medical peer review materials under §204(a), with respect to the Board's right to access such information, is not analogous to qualified patient care assessment materials under §205(b). Rather, the Court referenced the express language of §205(b), which states that information protected under §205(b) "may be inspected, maintained and utilized by the [Board] including but not limited to its data repository and disciplinary unit" and, unlike §204(a), does not require that such access be conditioned on the commencement of a formal adjudicatory proceeding.¹ The Court held that the clear language of §205(b) demonstrates legislative intent that the Board have access to the qualified patient care assessment materials prior to the initiation of an adjudicatory proceeding.

Hallmark also argued that *all* of the materials in Dr. Doe's credentialing

file were protected by §204(a). To determine whether these materials are eligible for protection under §204(a), the Court stated, the proper inquiry is whether the documents were created by, for, or otherwise as a result of a medical peer review committee. The Court found that while the work product of the credentialing committees at Hallmark was protected, the underlying documents used by those committees were not necessarily similarly protected. The Court vacated the lower court's decision on the scope of protection afforded under §205(b) and remanded the case to the Superior Court to determine whether each individual document listed on Hallmark's privilege log was protected from disclosure to the Board under §204(a), required to be made available to the Board for inspection under §205(b), or whether the material was not privileged at all.

Dean Leavitt v. Brockton Hospital, Inc., & others, 454 Mass. 37, 907 N.E.2d 213 (2009)

In a ruling issued on June 9, 2009, the Supreme Judicial Court ("Court") held that a hospital did not owe a duty of care to a police officer who was injured responding to an emergency call that arose when a hospital outpatient, who had been sedated for a procedure at the hospital, was struck by a vehicle while walking home from the hospital.

On November 1, 2004, the plaintiff, Dean Leavitt, was working as a police officer when he responded to an emergency report of an automobile striking a pedestrian. En route to the scene, the plaintiff's police cruiser was struck by another vehi-

cle, seriously and permanently injuring Officer Leavitt. It was later determined that the emergency report to which Officer Leavitt responded involved a patient ("Patient") who had undergone a colonoscopy earlier in the day at Brockton Hospital ("Hospital"). For this procedure, the Patient had been sedated with the narcotics Demerol and Versed, which are known to cause fatigue, weakness, coordination issues, and an inability to think clearly. Due to the effects of the sedatives, the policy of the Hospital was to require colonoscopy patients to be escorted by another individual upon discharge from the Hospital. In this case, however, the Patient was discharged from the Hospital without an escort and began to walk home when he was struck by an automobile and killed.

The plaintiff subsequently filed a negligence claim against the Hospital in Superior Court, arguing that the Hospital and two of its nurses owed him a duty of care and breached this duty by allowing the Patient, who had been sedated, to be released without an escort. In order for Officer Leavitt to prevail on the negligence claim, he needed to show that the Hospital owed him a duty of reasonable care, that the Hospital breached this duty which resulted in damage, and that there was a causal relationship between the breach and the damage. In response, the Hospital filed a motion to dismiss for failure to state a claim, asserting that the Hospital owed no duty to Officer Leavitt. The Superior Court judge agreed with the Hospital that it did not owe a duty to the plaintiff, an unrelated third party. Officer Leavitt appealed the lower court's ruling, and the Supreme Judicial Court granted his application for direct appellate review.

The plaintiff asserted that the Hospital owed him a duty of care under the theory of general negligence, the existence of a "special relationship" between the Hospital, Patient, and Leavitt, or the voluntary assumption of a duty of care by the Hospital to protect third parties from harm. The Court disagreed, finding that none of these theories imposed an affirmative duty of care on the Hospital to an unrelated, nonpatient third party. If a duty was established based on any of the three grounds, the Court reasoned that, at its core, this would impose a duty of care to nonpatient third parties on hospitals and medical providers to detain sedated patients and prevent these patients from leaving hospital grounds unescorted.

In reaching its decision, the Court rejected the plaintiff's contention that the Hospital had "control" over the Patient before he left the Hospital. The Court opined that, absent a special relationship, there is no duty to control another person's conduct to prevent that person from harming a third party. While the Court has recognized such a duty in limited circumstances – such as the special relationship that exists between a prisoner and a parole board, or when imposed by statute – the Court, in accordance with other jurisdictions, has not extended its reach to impose a duty on a medical professional to control a patient for the benefit of a third party arising from any "special relationship" between the medical professional and the patient (excluding a patient of a mental health professional).

The Hospital also argued that even if a duty to a third party existed, its actions did not cause the plaintiff's injury. In order to establish liability, the plaintiff would need to show

not only that the Hospital's actions were the cause in fact of his injuries but also that his injuries were within the scope of foreseeable risk. The Court again agreed with the Hospital that Officer Leavitt's injuries fell outside the scope of a reasonably foreseeable risk caused by the Hospital's alleged negligent actions. While injury to a third party nonpatient directly caused by the Patient may have been foreseeable, injury to a police officer caused by an accident in which the Patient was not involved is not. The Court also rejected the plaintiff's argument that the Hospital is liable under the "rescue doctrine", finding that liability does not arise for injuries suffered as a result of an unanticipated risk from the rescue.

Mary Ann Morse Healthcare Corp. v. Board of Assessors of Framingham, 74 Mass.App.Ct. 701, 910 N.E.2d 394 (2009)

Mary Ann Morse Healthcare Corp. ("Morse"), the non-profit operator of an assisted living facility, successfully appealed the denial of its application for an abatement of real estate tax under 59 M.G.L. §5. Morse's application was denied initially by the Board of Assessors of Framingham and on appeal by the Appellate Tax Board ("Board"). The Massachusetts Appeals Court ("Court") reviewed the Board's decision for errors of law and found that Morse served an inherently charitable purpose and provided a sufficiently broad community benefit to qualify for tax exemption under the statute.

Morse is a §501(c)(3) charitable organization that operates an assisted living facility known as Heritage

of Framingham ("Heritage"). Heritage consists of Building A, which contains assisted living apartments and common areas, and Building B, which contains assisted living apartments that serve individuals with Alzheimer's Disease, dementia, and memory impairment (the "Homestead Residents"). In its exemption application, Morse asserted that all of Building B, as well as the common areas of Building A used by the Homestead Residents, were exempt from taxation. The Board, however, found that Morse met neither the community benefit test nor the occupancy test used to determine whether an organization qualifies for property tax exemption pursuant to 59 M.G.L. §5. Following the Board's decision in September 2007, Morse requested a report (the "Board's Report") with findings of fact which the Board issued on August 19, 2008.

Community Benefit Test

In reaching its conclusion that Morse did not meet the community benefit test, the Board relied on the guidelines set forth in the Supreme Judicial Court case, *Western Mass. Lifecare Corp. v. Assessors of Springfield*, 434 Mass. 96 (2001), to determine whether Morse provided a sufficiently broad public benefit to justify tax exemption. *Western Mass. Lifecare* focused on the number and diversity of the individuals served by the charitable organization, the fees charged to the individuals the organization serves, and the cost to the organization as indicators of a broad enough community benefit to justify tax exemption.

The Board's Report relied on the *Western Mass. Lifecare* factors in finding that the fees charged by Morse, along with the unavailability of Medicaid to cover these fees, placed Morse beyond the reach

of a large section of the elderly population. Notably, however, the Board's Report did not take into account a recent Supreme Judicial Court case, *New Habitat, Inc. v. Tax Collector of Cambridge*, 451 Mass. 729 (2008). *New Habitat* provided new focus to the community benefit factors set forth in *Western Mass. Lifecare*, conditioning the importance of the *Western Mass. Lifecare* factors on the extent to which the main purpose of an organization is traditionally charitable in nature. For organizations where this is the case, *New Habitat* provides that the *Western Mass. Lifecare* factors play a lesser role in the evaluation of the community benefits conferred by such an organization for purposes of tax exemption.

Upon review, the Appeals Court applied the refinements set forth in *New Habitat* and found error in the Board's decision that Morse did not meet the community benefits test. The Appeals Court recognized that Morse served a traditionally charitable function despite the fact that it might not have met the *Western Mass. Lifecare* factors and thus provided a broad public benefit sufficient to meet the community benefits test.

Occupancy Test

In terms of whether Morse met the occupancy test, the Board found that it was the Homestead Residents and not Morse that occupied the property. In reaching this conclusion, the Board relied on its interpretation of the Massachusetts Assisted Living Statute, 19D M.G.L. §1, *et. seq.*, finding that this statute conferred the legal status of tenants on the Homestead Residents only, not on Morse. In addition, the Board noted that certain provisions set forth in the Homestead residency agreement evidenced that it was

the Homestead Residents, and not Morse, that were the occupants of the property, namely the resident's privacy rights, insurance requirements, and grievance process.

In rejecting the Board's conclusion, the Appeals Court found the Board's reliance on 19D M.G.L. §1, *et. seq.* to be misplaced, stating that the Board was attempting to "deriv[e] a tax implication from a statute governing an unrelated area." The Appeals Court also rebutted the Board's argument that the protections included in the Homestead residency agreement regarding the resident's right to privacy meant that it was the Homestead Residents alone that occupied the property. The Appeals Court noted that the concept of occupancy does not necessarily equate to exclusivity, and that residency and occupancy are not equivalent concepts under the law, such that Morse would be excluded from shared occupancy with the Homestead Residents.

The Appeals Court vacated the decision of the Board, finding that Morse met both the community benefit and occupancy tests necessary to qualify for tax exemption under 59 M.G.L. §5, and remanded the matter to the Board to determine the taxable status of Building A's common areas.

Endnotes:

1 The Court noted that § 205(b), however, does shield the information protected thereunder from the *general public* and *other third parties* to the same extent that § 204(a) does.

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