



Boston Bar
ASSOCIATION



The Boston

Health Law Reporter

SPRING 2010

VOLUME 5, ISSUE 2

A PUBLICATION OF THE BOSTON BAR ASSOCIATION HEALTH LAW SECTION

VOLUME 5, ISSUE 2

SPRING 2010

Section Co-Chairs' Corner

Hello and welcome to the Spring Issue of The Boston Health Law Reporter, a publication of the Health Law Section of the Boston Bar Association. Once again, our Communications Committee has assembled an impressive array of articles that will both educate you and help keep you abreast of some of the many changes we confront on a regular basis as health care lawyers.

Matt Buehler's article examines two recent judicial decisions about Medicaid reimbursement issues, the U.S. District Court case *Commonwealth of Massachusetts v. Sebelius* and the SJC case *Atlanticare Medical Center v. Commissioner of the Division of Medical Assistance*. Both cases deal with the issue of retroactive reimbursement for dually-eligible individuals and the conflict between Medicare and Medicaid payment rules.

Meghan Cosgrove and Patrick Leeman's article reports on a new Medicare rule that will soon require technical component suppliers of advanced diagnostic imaging services to be accredited by HHS-approved accreditation organizations. This requirement was imposed by CMS as part of the 2010 Medicare Physician Fee Schedule Final Rule, and becomes effective January 2, 2012.

Meghan Cosgrove's article covers a recent clarification/modification to CMS' policy on physician supervision of hospital outpatient services. The clarification was published as part of CMS' annual Hospital Outpatient Prospective Payment System Final Rule in October, 2009.

Rounding out the Spring Issue are our "Local Health Law Briefs," written by Melissa Lopes and Mark Rogers; an article on the Physician Payment Sunshine Act and its effect on the Massachusetts Gift Ban and Reporting Law, prepared by Bill Mandell; and Julia Hesse's Policymaker Profile interview with Barbara Ferrer, Executive Director of the Boston Public Health Commission.

We want to thank our Communications Committee chairs and members, and all of the contributors to the Spring Issue, for their wonderful and timely work. We would also like to thank all of the other members of the Health Law Section who have

helped to make this year (beginning in September) a great success. We have sponsored nine brown bag educational sessions, two free AHLA programs (at the BBA's Offices), and five CLEs, including sessions on Hot Topics in Provider Reimbursement, Surrogate Decision-Making, and the new Federal Health Care Reform legislation. As a special membership event, on March 8, 2010, we hosted a great Evening for Health Lawyers with Congressman Mike Capuano. Still to come this year are programs on Health Care Fraud, HIPAA/HITECH and the Massachusetts Data Security Regulations, Medical Malpractice, and Massachusetts' Payment Reform Initiatives. And, with new legislation and regulations expected on both the federal and state levels, you can rest assured that there will be much more to come.

It is an exciting time in the health law world, and we, in the Health Law Section, are committed to apprising you as new developments occur. We urge you to join us, quite literally--by becoming a member of the Health Law Section, joining one or more of our committees, and/or offering us your ideas (including by offering to write for the Reporter or speak at one of our events). We look forward to seeing you and/or hearing from you.

Dave Szabo and Alan Einhorn

Section Co-Chairs



David S. Szabo, Esq.

Edwards Angell Palmer
& Dodge LLP
111 Huntington Avenue
Boston, MA 02199
(617) 239-0414
dszabo@eapdlaw.com



Alan H. Einhorn, Esq.

Foley & Lardner LLP
111 Huntington Avenue
Boston, MA 02199
(617) 342-4094
aeinhorn@foley.com

Inside this Issue:

End of Assumptions: Physician Supervision of Outpatient Hospital Services
Page 4

Policymaker Profile: Barbara Ferrer: Executive Director, Boston Public Health
Commission
Page 12

Alice in MassHealth-Land: Does the SJC's Decision in *Atlanticare* Prevent
MassHealth From Being Made Whole For Services Covered by Medicare?
Page 18

Implementation of Accreditation Standards for Suppliers Furnishing the Technical
Component of Advanced Diagnostic Imaging Services
Page 22

Here Comes the Sunshine Act: Impact on the Massachusetts Gift Ban and
Reporting Law
Page 23

Local Health Law Briefs
Page 28

Editors
Page 31

Authors
Page 32

Section Leadership
Page 34

End of Assumptions: Physician Supervision of Outpatient Hospital Services

By Meghan Cosgrove, Esq.

I. Introduction.

In its annual Hospital Outpatient Prospective Payment System (“OPPS”) Final Rule issued on October 30, 2009¹, the Centers for Medicare and Medicaid Services (“CMS” or the “Agency”) clarified and somewhat expanded its policy on physician supervision of hospital outpatient services in an effort to address confusion that arose following changes to the Medicare Benefit Policy Manual and a policy clarification in the Preamble to the CY 2009 OPPS rule. In certain cases, these changes will require hospitals to explicitly designate supervising physicians for outpatient services, ensure that these physicians understand their supervision responsibilities, and make sure that hospital staff are knowledgeable about who the supervising physician is and how to contact him or her.

Under Part B of the Medicare program, CMS makes payment for two types of outpatient hospital services — services that are diagnostic² in nature and those that are therapeutic³. Both diagnostic and therapeutic outpatient services may be furnished directly by a hospital or critical access hospital (collectively referred to hereafter as “hospital”) or a hospital may contract with a third party to provide the service to its patients under “arrangements.”⁴

Most therapeutic services are covered under the OPPS as “incident to” the services of a physician in the treatment of a patient. How-

ever, some outpatient therapeutic services, such as physical therapy, occupational therapy or speech language pathology, are payable separately under their own statutory benefit category.⁵ For therapeutic services to be covered as “incident to” physicians’ services, the services and supplies must be furnished as an integral, though incidental, part of a physician’s professional service in the course of treating a patient and must be furnished on a physician’s order (or non-physician practitioner within their scope of practice under state law) by hospital personnel under a physician’s supervision.⁶ Therapeutic services furnished under “arrangements” made by a hospital may only be furnished in a hospital or in a provider-based department of a hospital.

Diagnostic services provided to outpatients are covered if furnished by a hospital for the purpose of diagnostic study and if the services would have been covered as an inpatient hospital service if furnished to an inpatient.⁷ Unlike therapeutic services, diagnostic services furnished under “arrangements” made by a hospital are not restricted by a location requirement and may be furnished at other locations, such as an independent diagnostic testing facility (“IDTF”).

II. Supervision of Outpatient Therapeutic Services

In the 2000 Medicare OPPS Final Rule⁸, CMS set forth its supervision policy for outpatient thera-

peutic services, which varied depending on where the service was rendered—either in the hospital or in a provider-based department of a hospital. For provider-based departments⁹ of a hospital, CMS amended 42 C.F.R. §410.27 to require the services to be provided under the direct supervision of a physician. Direct supervision in the outpatient setting requires that a physician be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure.¹⁰ It does not mean that the physician must be present in the room when the procedure or service is rendered.¹¹

For services provided in on-campus settings, CMS stated in the 2000 OPPS Preamble that the requirement of direct supervision was “assumed” to be met. Specifically, CMS opined that:

“Our proposed amendment of §410.27 to require direct supervision of hospital services furnished incident to a physician service to outpatients *does not apply to services furnished in a department of a hospital that is located on the campus of that hospital.* For hospital services furnished incident to a physician service to outpatients in a department of a hospital that is located on the campus of the hospital we assume

*the direct supervision requirement to be met. . . We assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital.*¹²

From these statements, most hospitals understood that while therapeutic services provided in off-campus provider-based departments were required to be provided under the direct supervision of a physician as set forth in §410.27(f), physician supervision was “assumed” to be met for outpatient departments located within the hospital and those located on the hospital’s campus. Based on this interpretation, many hospitals did not designate or document the specific supervising physician for their on-campus outpatient departments.

III. Supervision of Outpatient Diagnostic Services

The Agency’s policy on physician supervision of outpatient diagnostic tests also was set forth in the CY 2000 OPPTS Rule.¹³ In that Rule, CMS finalized its proposal to apply the existing supervision requirements for diagnostic tests paid for under the Medicare Physician Fee Schedule (“PFS”) to diagnostic tests furnished at provider-based outpatient departments and payable under the OPPTS.¹⁴ The adoption of this proposal required diagnostic services furnished in provider-based hospital outpatient departments to be rendered under one of three levels of physician supervision — general, direct, or personal¹⁵—depending on the specific Healthcare Common Procedure Coding System code as set forth in the Physician Fee Schedule Relative Value File.¹⁶ For example, while an outpatient

sleep study only requires general physician supervision, an MRI or CT with contrast requires the direct supervision of a physician and thus a physician must be present in the office suite where the test is performed and immediately available to furnish assistance and direction throughout the performance of the procedure. For those diagnostic tests not listed on the PFS, CMS indicated that fiscal intermediaries (now Medicare Administrative Contractors or “MACs”) would set the appropriate level of supervision. There was no indication by CMS in the 2000 Rule, however, as to whether the PFS-imposed supervision requirements applied to diagnostic tests furnished in an outpatient department located on a hospital’s campus. Accordingly, many hospitals did not follow the PFS supervision requirement for diagnostic tests rendered in on-campus outpatient departments. In other circumstances, the supervision requirement was not a notable issue in the on-campus hospital outpatient setting because many diagnostic tests only require a general level of physician supervision.

IV. The CY 2009 OPPTS Rule

In November 2008, CMS issued a “Nonrecurring Technical and Policy Clarification” statement on physician supervision of hospital outpatient department services in its CY 2009 OPPTS Rule.¹⁷ One of the stated purposes of the policy clarification was to resolve confusion that arose in the industry following changes made to the Medicare Benefit Policy Manual related to physician supervision, which incorporated the regulatory provision set forth in 42 C.F.R. §410.27(f) that therapeutic services provided in a provider-based department of a hospital are expected to be rendered under

the direct supervision of a physician.¹⁸ In its statement, CMS not only took the position that all outpatient therapeutic services, including those provided in the hospital or in an on-campus hospital department, require direct physician supervision, but also that this requires the supervising physician to be located “in the department” rather than simply “on the premises of the entity.”¹⁹ These statements appeared to contradict the Agency’s position in the CY 2000 OPPTS Final Rule that physician supervision of therapeutic services provided in the hospital or in an on-campus department of the hospital was “assumed” to be met. In the Preamble to the CY 2009 OPPTS Rule, CMS addressed this issue stating that its use of the word “assume” in 2000 did not mean that no physician supervision was required for therapeutic services rendered in on-campus hospital departments, or that only general physician supervision was required. Furthermore, while CMS acknowledged that it would continue to focus on physician supervision requirements in the off-campus provider-based setting, the Agency reiterated its “expectation of direct physician supervision of all hospital outpatient therapeutic services, regardless of their on-campus or off-campus location.”²⁰

The Agency’s position on the supervision requirements for diagnostic tests rendered in provider-based outpatient departments, whether on or off-campus, was similar to its position on therapeutic services. Specifically, CMS stated that its regulation regarding the supervision of provider-based diagnostic services²¹ “does not distinguish between on-campus and off-campus provider-based departments. Therefore, all provider-based departments providing

diagnostic services, whether on or off the hospital's main campus, should follow the requirements of the MPFS or their Medicare contractor, as appropriate, for individual diagnostic services."²²

In response to the Agency's statements in the 2009 OPSS Rule, 12 industry organizations, including the American Association of Medical Colleges, the American Hospital Association, and the Federation of American Hospitals, wrote to CMS expressing concern that the requirement of direct supervision for services furnished in a hospital or in an on-campus provider based department of a hospital was inconsistent with the Agency's prior guidelines as well as the longstanding industry understanding of physician supervision requirements. In addition, CMS received comments from hospitals concerned about the supervision requirements as they related to: (i) therapeutic services provided on a hospital campus but not in a provider-based department; (ii) difficulties determining which areas of a hospital are provider-based; (iii) budgetary and access to care issues stemming from the supervision requirements, particularly for rural hospitals; (iv) diagnostic services provided in the main buildings of a hospital that are not provider-based; (v) the qualifications of the supervising physician; and (vi) physician supervision of diagnostic services provided under "arrangement" by a hospital.

V. The CY 2010 OPSS Rule

In response to the comments following the CY 2009 OPSS Rule and in recognition of the operational and financial burdens posed by the Agency's "clarification," CMS revised its position on physician supervision of outpatient hospital services in the CY 2010 OPSS

Final Rule. While CMS reiterated its expectation that outpatient therapeutic services provided in the hospital²³ or on the campus of a hospital must be rendered under the direct supervision of a physician, the Agency dropped its restrictive "in the department" requirement to allow a supervising physician to be located anywhere on the hospital campus, including in a physician's office or other non-hospital space, as long as such physician is "immediately available."²⁴ The Agency did not define immediate availability, other than to note that this generally means "without interval of time."²⁵ For example, it would be difficult for the supervising physician to promptly intervene if he or she were performing another procedure that could not be interrupted or was in an on-campus location far away from the location where the outpatient service was being furnished.²⁶

For therapeutic services provided off the hospital's main campus, the supervising physician must be in the provider-based department²⁷ and immediately available to furnish assistance and direction throughout the performance of the therapeutic service.²⁸ The practical effect of this language is that a supervising physician cannot supervise multiple off-campus provider-based departments at one time or be outside of the department location in the off-campus building, such as in another office across the hall. Instead, CMS appears to indicate that physicians tasked with supervising off-campus hospital outpatient therapeutic services, such as those provided in an infusion suite, must be physically located in that infusion suite and be available to render assistance and direction through-

out the time during which services are rendered to patients.

Moreover, CMS interprets direct supervision to also require the supervising physician "to furnish assistance and direction throughout the performance of the procedure."²⁹ Perhaps the most problematic discussion in the 2010 Rule was in regard to this requirement. In order to be able to "furnish assistance and direction" the "physician or nonphysician practitioner must have, within his or her State scope of practice and hospital-granted privileges, the ability to perform the service or procedure. [CMS believes that its] interpretation of the requirement means that the supervisor must be a person who is 'clinically appropriate' to supervise the service or procedure."³⁰ This means that hospital-designated supervising physicians must have the requisite knowledge, skills, licensure, or hospital-granted privileges to be able to step in and perform the procedure being supervised, as opposed to simply being capable of responding appropriately in the event of an emergency.³¹

To provide further flexibility for hospitals, CMS also expanded the physician supervision requirement for outpatient therapeutic services in the 2010 OPSS Rule to allow non-physician practitioners including licensed clinical social workers, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives to directly supervise outpatient therapeutic services that these individuals personally perform in accordance with State law, scope of practice and hospital-granted privileges.³² The Agency made clear that non-physician practitioners directly supervising services they personally

perform must continue to meet any applicable collaboration or supervision requirements.³³ For example, in Massachusetts, the professional services of a physician assistant must be supervised by a licensed physician under 263 C.M.R. § 5.05. Finally, the expansion of supervision to non-physician practitioners does not extend to cardiac rehabilitation, intensive cardiac rehabilitation or pulmonary rehabilitation services, which are required to be supervised by physicians only, or to services performed by pharmacists, registered nurses, or other medical professionals.

For diagnostic services, the 2010 rule clarifies that all hospital outpatient diagnostic services, whether provided on or off campus, directly by a hospital or under arrangements, must follow the physician supervision level for individual tests listed in the Medicare PFS Relative Value File.³⁴ For diagnostic tests requiring direct supervision under the Medicare PFS Relative Value File and provided on-campus, “direct supervision” has the same meaning as it does in the context of on-campus therapeutic services (*i.e.*, the supervising physician needs to be “on the campus” and immediately available to render assistance and direction throughout the performance of the test or service but does not need to be located “in the department”).³⁵ Where such tests are performed in a provider-based off-campus outpatient department, “direct supervision” has the same meaning as it does in the context of off-campus therapeutic services (*i.e.*, the supervising physician needs to be “in the department” and immediately available to render assistance and direction throughout the performance of the test or

service).³⁶ Finally, CMS clarified that the Medicare PFS supervision requirements also apply to hospital outpatient diagnostic tests provided under arrangements in an off-campus non-hospital setting such as an IDTF.³⁷ “Direct supervision” in this context follows the PFS definition in 42 C.F.R. §410.32(b)(3)(ii)— the “physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure.”³⁸

On a related note, in the 2010 Medicare Physician Fee Schedule Final Rule, CMS finalized its proposal that suppliers of the technical component of advanced diagnostic imaging services must be accredited by an accreditation organization approved by the Secretary of the United States Department of Health and Human Services as a condition of Medicare payment. Given that CMS often uses the regulatory requirements for diagnostic services paid for under the Medicare PFS as a model for its regulation of hospital outpatient diagnostic services, it will be interesting to see what effect, if any, this new accreditation requirement may have on possible further regulation of advanced diagnostic imaging services delivered in the hospital outpatient setting.

On the pages following this article is a chart which provides a helpful summary of the applicable physician supervision requirements for hospital outpatient services provided on or off-campus.

VI. Conclusion.

In attempting to provide the industry with a restatement and clarifi-

cation of its policies on physician supervision of outpatient hospital services, CMS has presented the industry with more questions than answers. For example, what does it truly mean for a physician to be considered “clinically appropriate” to supervise an outpatient therapeutic or diagnostic service? Certainly, it appears to mean that hospitals can no longer rely on hospitalists, internists, or emergency department physicians to directly supervise outpatient specialty services as oftentimes these individuals may not have the necessary privileges to step in and perform the procedure or service that they are contemplated to be supervising. Many had hoped that CMS would provide further guidance to the industry, either formally or informally, on how best to comply with this expansion, but this has yet to occur. As such, many hospitals are in the untenable position of choosing between risking non-compliance with existing physician supervision arrangements, or restructuring existing arrangements, often with an accompanying financial burden, to comply with the 2010 rule. Some in the industry have questioned whether these changes will eventually lead hospitals to retain physicians simply to provide the requisite physician supervision of outpatient hospital services as some in the industry have dubbed them “outpatientalists”.

In advising hospital providers on these new provisions, effective January 1, 2010, health law practitioners should keep in mind the overarching concern of the Agency that led to this policy restatement, which was a lack of a timely physician response to a problem in a hospital outpatient department. However, the restatement and clarification does present most

hospitals, particularly smaller community and rural hospitals, with difficult compliance considerations particularly in this economic environment. As such, hospitals should be advised to (i) continue to review and evaluate existing and contemplated physician supervision arrangements, (ii) place an added emphasis on the tracking and scheduling of supervising physicians, (iii) perform a review of a supervising physician's privileges to ensure that he or she is clinically appropriate to supervise, (iv) evaluate outpatient services provided in off-campus locations to determine whether the supervising physician will be considered located in the provider-based department, (v) ensure that any outpatient services provided under "arrangements" are rendered under the appropriate level of physician supervision, and (vi) consider opportunities to move off-campus hospital outpatient services back on-campus.

1 Published in the Federal Register on November 20, 2009. 74 Fed. Reg. 60316.

2 Section 1861(s)(2)(C) of the Social Security Act authorizes payment for diagnostic services that are furnished to a hospital outpatient for the purpose of diagnostic study.

3 Section 1861(s)(2)(B) of the Social Security Act authorizes payment for hospital services "incident to physicians'" services rendered to outpatients.

4 Section 1861(w)(1) of the Social Security Act defines "arrangement" as arrangements under which receipt of payment by the hospital, critical access hospital, skilled nursing facility, home health agency, or hospice program (whether in its own right or as agent), discharges the liability of such individual or any other person to pay for the services. See also, Medicare General Information, Eligibility, and Entitlement Manual (100-01), Chapter 5, Section 10.3.

5 42 C.F.R. §410.27; Medicare Benefit Policy Manual (100-02), Chapter 6, §20.5.; Sections 1861(s)(2)(D),(p) and (II) of the Social Security Act. 6 Id.

7 42 C.F.R. §410.28; Medicare Benefit Policy Manual (100-02), Chapter 6, §20.4.

8 65 Fed. Reg. 18434. The Medicare OPSS was implemented August 1, 2000, via a final rule published on April 7th of that year.

9 Under the Medicare provider-based regulations, set forth at 42 C.F.R. §413.65, providers may claim departments, remote hospital locations and other entities as being a part of the main hospital for reimbursement purposes by demonstrating

that the entity in question is a subordinate and integral part of the main provider.

10 42 C.F.R. §410.27(f).

11 Id.

12 65 Fed. Reg.18525 (emphasis added).

13 65 Fed. Reg.18524.

14 42 C.F.R. §410.28(e); 42 C.F.R. §410.32.

15 General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. The training of the non-physician personnel who perform the procedure and the maintenance of the equipment and supplies are the continuing responsibility of the physician. 42 C.F.R.

§410.32(b)(3)(i). Direct supervision in the office setting means that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. 42 C.F.R. §410.32(b)(3)(ii). Personal supervision means a physician must be in attendance in the room during the performance of the procedure. 42 C.F.R. §410.32(b)(3)(iii).

16 Physician Fee Schedule Relative Value File available at <http://www.cms.hhs.gov/Physician-FeeSched/>.

17 73 Fed. Reg. 68702.

18 CMS Transmittal 82, Change Request 5496, Changes to Medicare Benefit Policy Manual (100-02), February 8, 2008.

19 73 Fed. Reg. 68703. CMS further interpreted the definition to state that "on the premises of the location" meant that a physician must be present on the premises of the entity accorded status as a department of the hospital, and therefore, immediately available to furnish assistance and direction for as long as patients were being treated at the site. The Agency declined to define "immediate availability" but did note that the lack of timely physician response to a problem in a hospital outpatient department would raise quality concerns.

20 73 Fed. Reg. 41519.

21 42 C.F.R. §410.28(e).

22 73 Fed. Reg. 68704.

23 CMS also finalized its proposal to define "in the hospital" to mean "areas in the main building(s) of a hospital or [critical access hospital] that are under the ownership, financial, and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital's or [critical access hospital]'s CCN." 74 Fed. Reg.60588.

24 74 Fed. Reg. 60588.

25 74 Fed. Reg. 60580.

26 74 Fed. Reg. 60580.

27 42 C.F.R. §413.65; "Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term "department of a provider" does not include

an RHC or, except as specified in paragraph (n) of this section, an FQHC."

28 74 Fed. Reg. 60588.

29 74 Fed. Reg. 60584.

30 74 Fed. Reg. 60584.

31 Id.

32 Clinical psychologists were already eligible to provide direct supervision of certain outpatient therapeutic services. 42 C.F.R. §410.32(b)(2)(iii).

33 74 Fed. Reg. 60578.

34 74 Fed. Reg. 60590.

35 Id.

36 Id.

37 74 Fed. Reg. 60590.

38 Id.

PHYSICIAN SUPERVISION OF OUTPATIENT HOSPITAL SERVICES

On-Campus Therapeutic Services (Incident to Physician's Services)	Location	Supervision Level	Meaning of Direct Supervision	Who May Supervise?	Relevant Citations
	<p>1. In the Hospital, or</p> <p>2. In an on-campus provider-based department of the Hospital</p>	<p>Direct Supervision</p>	<p>Physician is present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure/service. It does not mean that the physician must be present in the room when the procedure/service is performed.</p>	<p>Physicians, or physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical psychologists, and licensed clinical social workers who operate within the scope of practice under State law and hospital granted privileges.</p>	<p>1. 42 C.F.R. §410.27</p> <p>2. MBPM (100-2), Chapter 6, Section 20.5.1</p> <p>3. Section 3112.4 of the Medicare Intermediary Manual (Paper-based)</p> <p>4. 42 C.F.R. §410.71- §410.77; Chapter 15, Section 190(c), 200(D), and 210(D) (Nonphysician Practitioner Collaboration or Supervision Requirements)</p>
Off-Campus Therapeutic Services (Incident to Physician's Services)	<p>Off-campus provider-based departments of a Hospital</p>	<p>Direct Supervision</p>	<p>Physician must be present in the off-campus provider-based department of the hospital and immediately available to furnish assistance and direction throughout the performance of the procedure/service. It does not mean that the physician must be present in the room when the procedure/service is performed.</p>	<p>Physicians, or physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives who operate within the scope of practice under State law and hospital granted privileges.</p>	<p>1. 42 C.F.R. §410.27</p> <p>2. MBPM (100-2), Chapter 6, Section 20.5.1</p> <p>3. Section 3112.4 of the Medicare Intermediary Manual (Paper-based)</p> <p>4. 42 C.F.R. §410.71- §410.77; Chapter 15, Section 190(c), 200(D), and 210(D) (Nonphysician Practitioner Collaboration or Supervision Requirements)</p>
On-Campus Diagnostic Services	<p>1. In the Hospital, or</p> <p>2. In an on-campus provider-based department of the Hospital</p>	<p>Supervision levels by individual HCPCS code from the Medicare Physician Fee Schedule as either General, Direct, or Personal. If no supervision level designated, the Medicare Administrative Carriers determine.</p>	<p>Physician is present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure/service. It does not mean that the physician must be present in the room when the procedure/service is performed.</p>	<p>Physicians*</p>	<p>1. 42 C.F.R. §410.28</p> <p>2. 42 C.F.R. §410.32; MBPM (100-02), Chapter 15, Section 80</p>

PHYSICIAN SUPERVISION OF OUTPATIENT HOSPITAL SERVICES

Off-Campus Diagnostic Services	Location	Supervision Level	Meaning of Direct Supervision	Who May Supervise?	Relevant Citations
	In an off-campus provider-based department of the Hospital	Supervision levels by individual HCPCS code from the Medicare Physician Fee Schedule as either General, Direct, or Personal. If no supervision level designated, the Medicare Administrative Carriers determine.	Physician must be present in the off-campus provider-based department of the hospital and immediately available to furnish assistance and direction throughout the performance of the procedure/service. It does not mean that the physician must be present in the room when the procedure/service is performed.	Physicians*	1. 42 C.F.R. §410.28 2. 42 C.F.R. §410.32; MBPM (100-02), Chapter 15, Section 80
Off-Campus Hospital Outpatient Diagnostic Services provided "under arrangements"	Nonhospital location (e.g. IDTF)	Supervision levels by individual HCPCS code from the Medicare Physician Fee Schedule as either General, Direct, or Personal. If no supervision level designated, the Medicare Administrative Carriers determine.	Physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure/service. It does not mean that the physician must be present in the room when the procedure/service is performed.	Physicians*	1. 42 C.F.R. §410.28 2. 42 C.F.R. §410.32; MBPM (100-02), Chapter 15, Section 80
On-Campus Cardiac Rehabilitation, Intensive Cardiac Rehabilitation, or Pulmonary Rehabilitation Services	1. In the Hospital, or 2. In an on-campus provider-based department of the Hospital	Direct	A physician must be immediately available and accessible for medical consultations and emergencies at all times when services are being provided under the program. This provision is satisfied if a physician is present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure/service. This does not mean that the physician must be present in the room when the procedure/service is performed.	Physicians	1. 42 C.F.R. §410.27(a)(1)(iv)(A) and (B) 2. Pulmonary Rehabilitation Programs- 42 C.F.R. §410.47(d)(2)(ii) 3. Intensive Cardiac or Cardiac Rehabilitation Programs – 42 C.F.R. §410.49(b)(3)(ii)
Off-Campus Cardiac Rehabilitation, Intensive Cardiac Rehabilitation, or Pulmonary Rehabilitation	In an off-campus provider-based department of the Hospital	Direct	A physician must be immediately available and accessible for medical consultations and emergencies at all times when services are being provided under the program. This provision is satisfied if a physician	Physicians	1. 42 C.F.R. §410.27(a)(1)(iv)(A) and (B) 2. Pulmonary Rehabilitation Programs- 42 C.F.R. §410.47(d)(2)(ii)

PHYSICIAN SUPERVISION OF OUTPATIENT HOSPITAL SERVICES

Services	Location	Supervision Level	Meaning of Direct Supervision	Who May Supervise?	Relevant Citations
			is present in the off-campus provider-based department of the hospital and immediately available to furnish assistance and direction throughout the performance of the procedure/service. It does not mean that the physician must be present in the room when the procedure/service is performed.		3. Intensive Cardiac or Cardiac Rehabilitation Programs – 42 C.F.R. §410.49(b)(3)(ii)

* Clinical psychologists may supervise psychological and neuropsychological tests under 42 C.F.R. §410.32(b)(2)(iii).

Policymaker Profile: Barbara Ferrer

Executive Director, Boston Public Health Commission

Interviewed by Julia Hesse, Esq. (December 2, 2009)

As the City of Boston's Public Health Commissioner, Dr. Ferrer manages a \$172 million budget and oversees 1,200 employees. In addition to operating public health programs, the Commission provides oversight of Boston Emergency Medical Services, several substance abuse treatment facilities, and the second largest homeless services program in New England. A high school principal in the Boston Public Schools from 2004 to 2007, Dr. Ferrer returned to the Commission in 2007 after having previously served as the Deputy Director for six years. During that time she spearheaded a broad-based and comprehensive campaign to reduce racial and ethnic health disparities. Dr. Ferrer has more than 25 years of experience working in healthcare. Prior to joining the Boston Public Health Commission, she spent five years at the Massachusetts Department of Public Health – first as Director of Health Promotion and Chronic Disease Prevention and later as Director of the Division of Maternal and Child Health. In 1988, Dr. Ferrer received a master's degree in public health from Boston University, and was awarded a Pew Foundation doctoral fellowship to attend Brandeis University. She wrote her doctoral thesis on hospital length-of-stay determinants for AIDS patients and, in 1994, received her doctor-

ate from Brandeis University's Heller School for Advanced Studies in Social Welfare. Dr. Ferrer also holds a master's degree in education from the University of Massachusetts, Boston.

An Interest in Public Health

What got you interested in public health, and how did you come to the Commission?

I was actually a community organizer for many, many years. My passion is around social justice. There are two issues that I have focused a lot of attention on in my personal life and in my work: one has been education and one has been health care. Both of these issues are fundamental to people's ability to do well and flourish. When you think about what makes a tremendous difference in our ability to live our life to our full potential, it has a lot to do with how healthy we are able to be and what kind of educational opportunities that are offered to us. I feel passionately about both those issues, and feel that the great thing about public health is that it's really a discipline that is rooted in social justice. At the heart of it all, it really is about working closely with the community and trying to make sure that we are supportive of what it means to be healthy as an individual, and to help people

who you live with and love to be healthy, and what it means to have a healthy community.

I did a lot of organizing around health care, housing, and welfare rights. I worked a lot with lawyers – Greater Boston Legal Services and Mass Law Reform for many, many years, because they were very helpful to community organizers working on these issues.

Then I had a couple of children, but I was frustrated by some reports I saw circulating from folks who were academic researchers that were received very well by the general public and the media and spoke a lot about the issues around homelessness. I felt they were way off the mark, to be honest.

How so?

I felt that there was a lot of victimization – i.e., “these are disturbed people, or troubled people, or people with a lot of problems, and that is why they are homeless.” The conclusion that the researchers were drawing was that the solutions to homeless lie in fixing these people.

So if it's mental health issues, you have to fix mental health issues.

Or if substance abuse, you have to fix substance abuse issues. I'm not disagreeing that many times people who are homeless have complex lives and have many issues, but I was frustrated because I think that you need to have a systems approach. I wonder – who wouldn't be depressed or somewhat crazy if they were trying to raise a family on \$500/month (a Transitional Aid to Families with Dependent Children payment)? So I asked: "What are we doing about making sure that people really have conditions that support their ability to live well and to flourish?" I remember at the time saying: "These researchers have so much credibility, they have a Ph.D. next to their name, but they really are looking at this issue with a very narrow focus." It's not like people don't need services (I'm a firm believer that people do need services), but the way in which they are provided with services, and the opportunity for them to be empowered to take over their lives and tell service providers what it is they need and how they would like to receive those services, is really important.

The same thing applies for health. When I first came into public health, one of the things I thought of doing was getting a Ph.D. because I want to be sure the real stories get told. I also toyed with being a doctor.... Someone said to me: you could do public health. It's really the best of medicine, because it's about preventing illness and tackling problems at their root, and I thought, this is great, and that's how I got on the road to doing public health.

The dilemma of looking at individual behavior plagues a lot of

fields, including academia. In public health, our strategies have been about changing personal behavior for decades, even though our roots go to cleaning up a water supply and making system changes. But we, too, have fallen prey to this American dream that if you behave well, and toe the line, and pull yourself up by your bootstraps, that everything will be okay – including that you will be very healthy. So if you would just eat well and exercise and go to the doctor, you won't have these problems – but that's not true.

Addressing Disparities

In fact, the Commission has done some very interesting work on racial disparities in healthcare in particular.

Right, so when you start looking at it, you see a disproportionate burden. What causes this? Health behaviors? Health behaviors are very important. We know that smoking is linked to bad health outcomes. So let's look at the issue of infant mortality. Black babies in this city die at something around three or four times the rate of white babies. This is a city with 26 community health centers, 12 teaching hospitals, and near universal coverage. Before we had near universal health coverage, we had pretty much free care at all the hospitals and health centers. So we neither have an access issue (we are not in the rural south, people don't have to drive forever), nor do we necessarily have a finance deterrent (although there are problems there). But we're not in the situations that so many people in the country are, where they really do not have access to

or can't afford care and yet we still have this horrible outcome.

You start looking at it and ask, maybe it is behavior. So let's look at smoking: black women who don't smoke – who have never smoked – have a greater chance of having their baby die than white women who are smoking during their pregnancy. Black women who start prenatal care early, and stay in prenatal care during their entire pregnancy have a greater chance of losing their baby in the first year of life than white women who either never get into prenatal care or who got into prenatal care in the last trimester.

So then we say maybe it's income, because we do know that there is an income gradient and there is something to say about it in a capitalist country. Money really matters, and what you can buy with money really matters. But it turns out that black women, college educated, are one and a half times more likely to lose their baby in the first year of life than white women who haven't even gone to high school. So these things that we think are protective factors are not necessarily protective factors.

So we have to start looking at what else is going on. I always say: one place to start is place matters. Where people live matters, and it matters for a lot of reasons. One fundamental reason is that it really is a proxy in our country for racism. Residential segregation is alive and well both in Boston and in most urban centers in the United States and we still have institutional policies that protect white privilege and really discriminate against people of color. I don't think it's any

surprise that 75% of the people who lost their homes in the city of Boston with this latest foreclosure crisis and sub prime markets were Blacks and Latinos. And I don't think it's any surprise that these sub prime markets were fairly unregulated and able to target without any oversight very vulnerable people.

For me, you cannot talk about the health and well-being of people without understanding that there are social determinants that play into their health. For example, you do studies about how important it is for people to eat well and to get exercise. But you can't really eat well if you can't afford healthy foods or don't have access to healthy foods. What a shame it is that in Boston, all of these kids go to our public schools and eat breakfast and lunch there because they are low income and those meals are subsidized – but the breakfast and lunch feeding programs that the government sponsors through their subsidized food products are not really healthy products. They are high in fat content, high in sugar content, and high in salt. We have an obesity epidemic, particularly among people of color and particularly among poor people. So, in our schools, where people of limited incomes are getting free meals, they are getting unhealthy meals. That's two meals a day – two-thirds of what they eat. Those are systems issues. Yes, people do need to make good choices and people do need good information, but we need to make sure conditions support them in making good choices and make it easy to make the good choices. Even those of us that are blessed with money and opportunity don't

always make good choices, so imagine the task in front people who don't have any of that. I tell people: drive down Blue Hill Avenue and count the number of alcohol ads and tobacco ads, then drive down Center Street through Jamaica Plain through West Roxbury and tell me which community has more ads. We have conditions in communities that promote bad health, and make it difficult for people to eat healthy and get exercise, and then we want to blame individual people because they are not in good shape, or have high rates of diabetes? It doesn't make a lot of sense. I'm happy that a lot of researchers are looking at the issue of racism as well because there is so much evidence about the detrimental effects that racism has on health and well-being of folks, but people are afraid to talk about it. But if you don't talk about it, you're never going to fix it. You have to identify the problem and then constructively figure out what are our next steps.

Promoting Opportunities for Healthy Living

Being in this position gives you the opportunity to re-examine and test assumptions in how systems are set up.

Absolutely, and also to ask everyone to do that. The good thing about public health – and the hard thing about public health – is to do it well would mean that you are constantly in partnership – in partnership with residents, in partnership with community-based organizations, and in partnership with the other city departments. This issue of the built environment supporting healthy lifestyles and healthy communities – that's an

issue for the transportation department, for the public works department, for the Boston Redevelopment Authority – everyone has a role to play in that. You need folks who will say: "This is why it's important to look at health; this is what you can do that really makes a difference – and a huge difference – in health status." If you look at the data on cardiac arrests and deaths due to cardiac arrest, and when we started passing tobacco regulation – there is a direct correlation. You make these steps and you pass these policies that really reduce people's exposure to a dangerous carcinogen and a dangerous substance for their hearts, and within a few years, you see a dramatic decrease in deaths.

If you pay attention, if you have cities where people can easily walk and can easily ride their bikes, and have a lot of green space... we're really lucky in Boston, we have a mayor who really believes in this. It's not like we have a Public Health Department saying: please, Mayor, listen to me – it is the Mayor saying: we are going to get around this, we are going to find ways to have more community gardens, because that's an easy way to make sure people have easy access to fresh fruits and vegetables; we're going to put full-service grocery stores in every single neighborhood and make sure that there are easy bus routes to get to and from those stores; we're going to have safe recreational programs at all of our community centers, and we're going to support 26 community health centers; so people have easy access to care. From where I'm sitting, it is less about telling people how to behave, and more about work-

ing in partnership with people to create conditions that allow them to succeed and be healthy and academically successful and live life to their potential, find meaning in their lives and relationships they have with people.

Adjusting to the Economic Environment

The Commission has such a broad range of issues that it looks at from health and welfare, to education, homelessness, and other types of social supports. The general question is: how are you doing in the economic environment, and what impact are you feeling? What has surprised you with the continued cuts on the federal and state side, and how is it playing out from your perspective?

These are difficult times for every agency - I am certainly not alone. We are struggling to ensure that essential services are there - and not only that essential services are there, but we transform the way we deliver services now. We are trying to use new models, and to be broader in our scope. When you have diminishing resources, that is difficult. But I am going to be honest: that's not the biggest challenge. The biggest challenge is having coherent policies that make sense in the long run for promoting health. We spend a lot of money in this state on medical care for people. A lot of that medical care would not be necessary if we had better prevention-oriented programs, if we were really doing a better job at promoting health, and if we were, in fact, able to reduce the consumption of sugar-sweetened beverages, for example. The pie doesn't expand infinitely. At some point, there are

fixed costs. I would agree with an analysis that says: in our country, the proportion of money that goes to support the well-being of people is rather small, in comparison with the proportion of money that goes for defense spending, for example, military spending, but that's really a national debate about how you allocate your dollars so that they accomplish the goals of your country.

One thing that feels really clear to me is that we should apportion the dollars spent on health differently and we should be promoting policies and programs that reduce the burden of chronic disease and promote good health, so that we would have more money coming in to the entire system, whether it gets diverted to education, social services, or public health, the fact of the matter is, medical care eats up a lot of money. My biggest concern right now is that in times where your immediate reaction is to retrench, could you join with others and say: this is an opportunity to reexamine how we prioritize and refocus where we are spending our money and how we are spending our efforts so that we are being more efficient with the resources we have.

These are challenging times. I'm constantly out there; now we face a dramatic cut in funding for our homeless shelters. I will say one thing: there is terrific talent here and longstanding-partnerships with other folks who help us provide this broad range of services and hopefully advocate for us to get additional funding at the federal and state level, but also help us raise money. We have Friends of Boston Homeless, and maybe together we can come up with

other solutions. But these are everyday problems, and we look at every single opportunity.

Promoting a Well Informed Citizenry

Behind all of that, I think is really working closely with the community and with people who vote, so that decisions get made differently through the ages. That means doing our work differently, and really taking seriously, for example, our obligation to do voter registration. Not because we want to tell people how they should vote, but because we think it's really important to vote, to know your issues, to know what you want for your community, and then vote for those candidates who you think are going to support you. That's where you have those debates about how money is going to get allocated. If I thought there were going to be more people who were going to get engaged, and felt supported in getting engaged, then maybe there would be different decisions getting made about how money is getting allocated. I think the advocates are constantly getting pitted against each other for the crumbs because, frankly, we don't do our jobs well. We don't have a model that really promotes a well-informed citizenry. The number one goal for every program is: make sure the participants in your program are fully engaged, fully aware, are fully involved in understanding what they would like in evaluating your program. In other words, there are ways to say: people aren't just vessels; we don't just fill them with information or fill them with a service. We try to engage them, to have them be part of that service. If everyone were trying

to do that, then I think people may in fact get more involved because they would have skills and feel that they have a voice. You're not going to get involved if you think that no one is listening and if you don't have the skills to get involved. So, for example, our homeless shelters: whenever there are issues about the budget, a team of folks from our Intergovernmental Relations Office and Policy and Planning Office will go out with homeless guests and will talk about the issues, help them do a letter-writing campaign. They are the ones who really know what the problems are and what the solutions are. Somehow in this service delivery model that we have (and I think that services are important), we must have some time where we deliver them not from a medical model, which tends to be paternalistic, but from an empowerment model, where you try to get people involved in the care and the services we are providing but also in making it absolutely accessible for them to have a voice in larger concerns and larger issues.

H1N1 Preparedness and School Health

The other issue I'd like to talk about is not just H1N1 and the city's response and the Commission's response, but also the coordination with schools. In the spring, and through the fall, we were seeing such tight coordination between the Commission and the schools; I was hoping you could comment on how that evolved, and what you're seeing as the arc for this coming school year.

One thing is, I was a principal a few years ago, so I'm both aware and very sympathetic to the tremendous responsibility that schools have around protecting and promoting health, and that they have to be partners in this. Because I was part of that system, it's pretty easy for me to understand what a partnership would need to look like in order for people to feel involved. From the very beginning, I've been involved in the Mayor's Cabinet and so is the Superintendent, so we have a relationship at that level. But I also know a lot of the principals and I know how the system works in terms of data collection, resources that are available, and I know there are a lot of strengths involved in working very closely with that system.

From the very beginning, we were able to say: "Here's what we can do to be helpful" and "What do you need?" Also, make it really clear that we could be very helpful, but we needed to get reliable information. One good thing about the Boston Public Schools is that they have an electronic data attendance tracking system, which makes it easy for us not to rely on schools reporting to us if there are clusters of illness, but being able to see clusters of illness and then being able to send a team to a school. We were really hard-hit last spring, so that tested us and we were not prepared at the level of detail because we had no advance warning to put systems in place. The good thing was we did really well in terms of working well together and we learned a lot of lessons that we were then able to put into place in the fall.

It looks like 11% of school-age children in Boston were actually infected by the virus in an 8-week period last spring. We really only saw a decline was when we saw schools close. We had many cases where schools had hundreds of kids out. Many, many schools – we closed 20, but we had a bunch of other schools that didn't close, were able to stay open, were able to stay operational, but had high levels of absenteeism. This past fall, we built on many of the lessons we had learned. For example, we had really good information about student absenteeism, but we didn't have good information on a daily basis about teacher absenteeism or about visits to the nurses, so we would have to make the calls to get that information. We set up a system over the summer to allow us to track in the fall on all three markers: teacher absenteeism, student absenteeism, and visits to the nurse's office, including what percentage of those were for influenza-like illness. One thing that makes it easy for a school and a health department to work well is if the school has really good systems. It makes it easy to look at the data. There are 136 schools in Boston, so you could imagine – if there was not a good, centralized data collection system, it would have been impossible. Right now, they just send us attendance and we monitor it here. We put it into a system here that sets certain thresholds, and when they go over a threshold, it is easy to say: "Call this principal" and "Call this school."

We also figured out we needed to do a better job about com-

munication. I don't want to fault anybody on that because it was so hard. We had two weeks to try and figure out how to communicate with everybody, but we spent a lot of time this summer making a plan and making sure that information went out to everybody before school started. Parents needed to know: Here's what you can expect and here are the kinds of plans you need to be making: If your kid gets influenza-like illness, they are going to need to stay out of school for four days. So what's the plan for caring for this child? We know that many parents do not have sick leave, but we need them not to send their child back to school, because the likelihood is that if they send their child back to school, and they are contagious, not only will they have already lost some days, but the possibility of spread in that school may lead to closure, and then they are going to have additional days off because the school is going to be closed anyway. To prevent schools from closing, parents really have to help. Giving them a head start on that, and also identifying other resources; working with churches, so churches can help support families was really important. Working with businesses, so businesses would not penalize folks who needed to take time off. We were able to do a lot of that and get that communication out before school started.

We also did more training. We trained all the principals, all the nurses, spoke with all the union reps for the custodians, the bus drivers – things we missed on the first go-around. The bus drivers and custodians had real concerns, and we just missed it. Because they had big concerns that didn't

get addressed, there was a slight bout of panic in the spring about their exposure. We're shutting down buildings and telling them to clean, but they don't have any protective equipment – so are we creating risk? They didn't have information that would make them feel comfortable with that assessment.

We were able to do a lot more planning and training in the summer, and we've had a magnificent school year. First of all, parents have listened, and so have teachers, about staying out of school if they feel sick. We have had flu everywhere, but we had no big clusters in any of the public schools. A couple of the parochial schools have, but the public schools have done a phenomenal job about getting the word out and limiting the number of sick kids in a building. I give a lot of credit to the Superintendent, her leadership team, the principals, and the team here who have had weekly meetings with the school department to coordinate. We made sure, for example, that we got H1N1 vaccine and seasonal flu vaccine for school nurses. For seasonal flu, we vaccinated the teachers. Every time we do a public clinic for H1N1 with the community health centers, we notify all the elementary schools that are in that area, so that they can send notices home to their parents.

The second side of it is the prevention message: keep your kids home, cover your mouth, wash your hands, and get vaccinated.

On the vaccination side, are you coordinating with the state Department of Public Health about when more of the vaccine will

become available and how it will be distributed?

We get vaccine every week from the state; we are a distribution center and have a big allocation order. We, like everybody else, are struggling right now because the lack of certainty about when you will get vaccine makes it really difficult to plan. Nonetheless, we are really lucky here in Boston. We have 26 community health centers, and we have used our partnership with them to do a lot of free clinics. We have already vaccinated through the public clinics over 11,000 people, and two large clinics in the two neighborhoods that don't have community health centers. Every week, we'll continue to have around ten clinics in the City of Boston.

Alice in MassHealth-Land: Does the SJC's Decision in *Atlanticare* Prevent MassHealth From Being Made Whole For Services Covered by Medicare?

By Matthew Buehler, Esq.

The United States District Court recently grappled with a conflict between state and federal law with regards to the MassHealth program in *Commonwealth of Massachusetts v. Sebelius*.¹ This conflict arises out of the Massachusetts Supreme Judicial Court's ("SJC's") interpretation of the federal Medicaid Act² in *Atlanticare Medical Center v. Commissioner of the Division of Medical Assistance*.³

Under the Medicaid Act, MassHealth pays for an individual's care only after all other resources have been exhausted. If an individual is covered by both the Medicare and MassHealth programs, Medicare must pay first. It is possible, though, that MassHealth can pay for an individual's care and then learn that Medicare also covers that individual. Under *Atlanticare* and *Sebelius* Medicare does not have to reimburse MassHealth in such situations, and no other sources of recovery exist. This article reviews the relevant statutory background, the *Atlanticare* and *Sebelius* decisions and what might happen next.

Statutory Background

Medicaid is a joint state and federal program that provides medical assistance to low-income individuals. Participating states administer their own Medicaid programs, and the federal govern-

ment reimburses these states at specified rates. MassHealth is the Massachusetts Medicaid program.⁴

In order to receive federal funding, the MassHealth program must meet certain requirements, including making reasonable efforts to find legally liable third parties and pursue claims against these parties. If MassHealth pays a provider claim and later discovers a liable third party, it must seek reimbursement where cost-effective to do so.⁵ These provisions "further[] an ultimate goal of Medicaid – that the program 'be the payer of last resort, that is, other available resources must be used before Medicaid pays for the care of an individual.'"⁶ (These two provisions are referred to collectively as "the payer-of-last-resort requirements.")

In addition to funding Medicaid programs, the federal government administers the Medicare program, which provides medical assistance to elderly or disabled individuals.⁷ Medicare does not base eligibility on financial need. Low-income elderly or disabled individuals can thus be dually eligible for Medicare and Medicaid benefits. "When [dual eligibility] occurs, federal law dictates that Medicare, not Medicaid, bear the cost, because Medicaid

is designed to be a payer of last resort."⁸

Medicare, however, may only make payments to "providers of [medical] services."⁹ The federal agency that oversees the Medicaid and Medicare programs, the United States Department of Health and Human Services ("HHS"), has taken the position that a state Medicaid program such as MassHealth is not a medical services provider. As a result, Medicare will not make reimbursement payments to MassHealth.¹⁰

If MassHealth wrongly provides medical assistance when another liable party exists, it must recover its costs. According to HHS, though, MassHealth cannot meet these requirements if it wrongly provides medical assistance to dual eligibles (i.e., individuals who are dually eligible for Medicare and Medicaid). HHS claims that, in such situations, MassHealth cannot recover its costs from Medicare.

Atlanticare

To ensure that Medicaid is the payer-of-last-resort, MassHealth regulations require health care providers to make "diligent efforts" to obtain payments from other resources¹¹ before billing MassHealth. MassHealth regulations further provide that "[i]f a third party resource is identified

after the provider has already billed received payment from [MassHealth], the provider must return any payment that it received from [MassHealth]. The provider must bill all third-party resources before resubmitting a claim to [MassHealth].”¹²

The 2003 *Atlanticare* case dealt with the application of the above regulations to retroactive dual eligibles. In that case, several health care providers billed MassHealth for services provided to certain individuals after determining that they had no other coverage. After MassHealth paid these bills, Medicare granted retroactive eligibility to these individuals back to their original dates of service.

Medicare's retroactive grant of coverage triggered MassHealth's duty to seek reimbursement. HHS had taken the position that Medicare will not reimburse state Medicaid agencies so MassHealth went after the only other source of recovery – the providers. Pursuant to its regulations, MassHealth issued recovery orders to the providers requiring them to return the funds that they received for the retroactively eligible patients and submit their bills to Medicare.¹³

The providers appealed these orders on the ground that the underlying regulation was inconsistent with the payer-of-last-resort provisions of the federal Medicaid Act and hence invalid. Specifically, the payer-of-last-resort provisions include the requirement that state Medicaid seek reimbursement for payments made where other sources of coverage exist.¹⁴ The providers argued that, under this provision, MassHealth had to recover the payments at issue from Medicare.

The SJC held that the natural reading of this provision is that a state Medicaid agency can only try to recover funds from a liable third party if it is cost effective to do so.¹⁵ MassHealth argued though that liable third parties included health care providers. The SJC, however, rejected this argument.

The SJC reasoned that MassHealth bore minimal costs in seeking reimbursement from a provider. As a result, the cost of pursuing recovery would exceed the amount the state reasonably expected to recover in only a few instances. Including providers as liable third parties would thus render superfluous the statute's cost-effectiveness requirement. Based on this analysis, the SJC held that providers were not third parties under the payer-of-last-resort provisions.¹⁶

MassHealth argued that it could not recover payments from Medicare. As a result, it could not comply with the payer-of-last-resort requirements in cases involving dual eligible individuals unless it could recover payments from providers. The SJC, however, concluded that MassHealth could recover from Medicare.

The SJC acknowledged that MassHealth appeared to lack standing under HHS's regulations to seek reimbursement. The SJC though discounted these regulations as they did not “seem[] to apply to a situation where Medicare has acknowledged a mistake in denying liability for a claim or has agreed to pay a claim retroactively.”¹⁷ The SJC instead found persuasive two federal decisions – *New York State Department of Social Services v. Bowen*¹⁸ and *Michigan Department of Social Services v. Shalala*.¹⁹ In *Bowen*,

the court found that a state Medicaid agency could file appeals of Medicare benefit denials on behalf of dual eligible individuals.²⁰ The court in *Shalala* extended this reasoning to hold that a state Medicaid agency could file Medicare appeals and sign Medicare claims on behalf of nursing home residents.²¹

Both *Bowen* and *Shalala* essentially applied traditional subrogation principles.²² Subrogation typically occurs when a health insurer pays an individual's medical bills. The insurer/subrogee then stands in that individual's shoes and assumes any legal claims that he or she has against liable third parties.²³ By analogy, MassHealth must seek reimbursement for retroactive dual eligibles from the liable third party (i.e., Medicare) instead of providers.²⁴

A subrogee cannot, however, possess rights outside those possessed by the victim. The state Medicaid agencies in *Bowen* and *Shalala* filed appeals with Medicare on behalf of beneficiaries. These beneficiaries had statutory rights to appeal denials of Medicare benefits.²⁵ Beneficiaries though cannot file claims with Medicare²⁶ so, under subrogation analysis alone, a state Medicaid agency also cannot file such claims.²⁷ The SJC did not address this discrepancy but instead seemed to emphasize the equities of the situation.

Specifically, the SJC “hesitate[d] to assign the burden of recovery to the hospitals, particularly where the hospitals have exercised diligent efforts to identify third-party liability in the first instance and, through no fault of her own, liability was discovered after they were properly paid.”²⁸ Put another

way, Medicare more fairly bore the onus of reimbursing MassHealth as it created the dilemma before the court by granting retroactive coverage. For these reasons, it is fair to read *Atlanticare* as actually being based on equitable, rather than subrogation, principles, despite the SJC's citations of *Bowen* and *Shalala*.

HHS, however, was never added as a party in *Atlanticare*. As a result, HHS maintained its position that Medicare did not have to reimburse MassHealth. This ultimately led MassHealth to file suit against HHS in *Commonwealth v. Sebelius*.

Commonwealth v. Sebelius

In *Commonwealth v. Sebelius*, MassHealth filed several claims with HHS for reimbursement for payments made to dual eligibles. HHS denied these subrogation claims and MassHealth challenged these denials in federal District Court. The District Court, however, dismissed MassHealth's appeal.

Specifically, the District Court found that HHS' regulations were based on a reasonable interpretation of the Medicare statute and hence entitled to deference.²⁹ The District Court further held that the payer-of-last-resort provisions created a duty for MassHealth to seek reimbursement but not a right to receive it.³⁰ The District Court based this holding on *Connecticut Department of Social Services v. Leavitt*³¹ and *New York v. Sebelius*.³² The courts in both of these cases held that state Medicaid agencies could not pursue claims against Medicare where the beneficiaries themselves had no rights to demand payments.³³

In effect, these courts declined to use *Atlanticare*'s equitable approach.³⁴ They instead applied the subrogation analysis discussed above.³⁵ Under this analysis, MassHealth cannot recover from Medicare payments made to dual eligibles, as the Medicare statute³⁶ does not allow these individuals to file payment claims on their own.

The *Commonwealth v. Sebelius* decision thus only sharpened MassHealth's dilemma with regards to retroactive dual eligibles. The SJC held that, in such situations, MassHealth cannot seek reimbursement from providers.³⁷ The federal District Court has now held that MassHealth may not directly recover from Medicare either.³⁸ No other party exists that MassHealth can seek reimbursement from. The question is now what MassHealth should do next.

What next?

Atlanticare and *Commonwealth v. Sebelius* have essentially created a class of individuals – retroactive dual eligibles – for whom MassHealth cannot seek reimbursement despite their coverage by Medicare. As a result, it is theoretically possible that MassHealth could lose federal funding, i.e., HHS could determine that MassHealth is not complying with the payer-of-last-resort requirement³⁹ with regards to retroactive dual eligibles. This seems unlikely, though. To make such a determination, HHS would essentially have to admit that it is required to reimburse MassHealth.

On a more practical level, these decisions prevent the state from recouping funds that it is entitled to. The state is currently facing another budget crisis, fueled in part by the rising use of MassHealth.⁴⁰ These funds alone

would not come anywhere close to resolving this crisis but the state (and MassHealth) nonetheless needs any revenues that it can get.

The most likely strategy for recouping these funds would be to use the District Court's decision as a basis for challenging *Atlanticare* in state court. MassHealth could, among other things, file a motion for relief from judgment asking the court (and ultimately the SJC) to reconsider *Atlanticare* in light of *Commonwealth v. Sebelius*.⁴¹ In particular, the SJC emphasized in *Atlanticare* that MassHealth "had cited no case that support[ed] the proposition that it cannot pursue reimbursement from Medicare."⁴² Such case law now exists.

Moreover, as mentioned above, the SJC applied a subrogation analogy in *Atlanticare* to the relationship between MassHealth and provider, i.e., like a subrogee, MassHealth must seek reimbursement from the third party insurer instead of the provider. Subsequent case law has instead applied a buyer-seller analogy in such situations. Since the provider sold healthcare services that the Medicaid agency paid for, the agency is treated as a buyer instead of as a subrogee.

Under this analogy, a provider could not retain payments that it received because it wrongly billed Medicare. "Normally, when a seller collects from a buyer money that the buyer did not actually owe to the seller, the buyer seeks a refund from the seller. [A state Medicaid agency], the buyer, should be able to secure appropriate refunds from [providers], the sellers."⁴³ "When Medicare covers services already paid for by Medicaid, Medicare pays the provider for

the services, and then Medicaid can seek reimbursement from the provider for Medicaid's initial erroneous payment."⁴⁴

Application of this analysis to the facts in *Atlanticare* would reverse its outcome. MassHealth incorrectly paid the providers at issue for services that they should have billed to Medicare. Like a buyer, MassHealth should be able to demand a refund from providers for these wrongful payments.⁴⁵

Conclusion

Atlanticare addressed a statutory conflict between the Medicaid Act's payer-of-last-resort provision and the Medicare Act's provider-payment provision. The SJC and the federal courts have tried to sort out this conflict but have reached conflicting conclusions. As a result, MassHealth cannot recoup medical payments that it made on behalf of retroactive dual eligibles. Given its tight budget, MassHealth has a strong incentive to continue litigating this issue. Most likely, that means that MassHealth will again seek to recover such funds from providers.

1 U.S.D.C. C.A. No. 07-11930-MLW (D. Mass. December 31, 2009). The District Court had previously issued a similar, albeit shorter, decision in the same case. See *Commonwealth v. Sebelius*, 2009 WL 310850 (D. Mass. September 23, 2009).
2 42 U.S.C. § 1396 et seq.
3 439 Mass. 1 (2003).
4 See generally G.L. c. 118E (the state MassHealth statute).
5 42 U.S.C. § 1396a(a)(25)(A)&(B). See also G.L. c. 118E, §§ 22 & 23.
6 *Shweiri v. Commonwealth*, 416 Mass. 385, 388-89 (1993) (quoting S. Rep. No. 146, 99th Cong., 2nd Sess. at 312 (1986)).
7 See generally 42 U.S.C. § 1395 et seq. (the federal Medicare Act).
8 *Connecticut Department of Social Services v. Leavitt*, 428 F.3d 138, 141 (2nd Cir. 2005).
9 42 U.S.C. § 1395f(a).
10 42 U.S.C. 424.33 & 424.51. See also 433.146(b) (assignment of rights to state Medicaid programs does not include assignment of rights to Medicare benefits).
11 130 C.M.R. 450.316.
12 130 C.M.R. 450.316(F).
13 MassHealth issued the recovery orders in *Atlanticare* under 130 C.M.R. 450.316(E). At the time, this regulation contained identical language to

130 C.M.R. 450.316(F). MassHealth did not claim in the recovery orders that the providers had failed to exercise diligent efforts. In fact, the SJC noted that no amount of diligence would have sufficed as Medicare coverage was retroactive, i.e., it did not actually exist at the time of service. *Atlanticare Medicare Center*, 439 Mass. at 5.
14 42 U.S.C. § 1396a(a)(25)(B).
15 *Atlanticare Medical Center*, 439 Mass. at 6 (discussing 42 U.S.C. § 1396a(a)(25)(B)).
16 *Atlanticare Medical Center*, 439 Mass. at 6-7. The SJC also cited other legislative and regulatory materials. The portions cited though merely reiterated that state Medicaid agencies had to seek reimbursement from legally liable third parties. The SJC appears to have simply assumed that such third parties included insurers but not providers. *Id.* at 7-11.
17 *Atlanticare Medical Center*, 439 Mass. at 11 (discussing 42 C.F.R. 424.51 & 433.146).
18 846 F.2d 129 (2nd Cir. 1988).
19 859 F. Supp. 1113 (W.D. Mich. 1994).
20 *Bowen*, 846 F.2d at 134.
21 859 F. Supp. at 1118.
22 *Shalala*, 859 F. Supp. at 1121. See also *Bowen*, 846 F.2d at 132 (describing state Medicaid agency as a "subrogee").
23 See generally *Frost v. Union Labor Life Insurance Co.*, 386 Mass. 425, 426-27 (1982).
24 *Atlanticare Medical Center*, 439 Mass. at 12-14. MassHealth can recover payments from providers that have failed to make diligence efforts to find other sources of coverage. *Id.* at 14-15. In addition, MassHealth "is entitled to recoup ... those Medicare payments that 'reflect[] what amounts to double coverage,' i.e., those payments received for services that have also been paid for by Medicaid." *Jewish Home and Hospital for Aged v. Wing*, 91 F.Supp.2d 593, 597 (S.D.N.Y. 2000) (citations and quotations omitted).
25 42 U.S.C. § 1395ff(b).
26 42 U.S.C. § 1395f(a).
27 The state Medicaid agency in *Shalala* also signed provider claims on behalf of beneficiaries. Although the court at times characterized this action as the agency seeking reimbursement, providers filed the actual payment claims. 859 F. Supp. at 1117.
28 *Atlanticare Medical Center*, 439 Mass. at 14.
29 *Commonwealth v. Sebelius*, slip op. at pgs. 7-13. As mentioned above, the Medicare statute provides for payment of claims made by medical services providers. In its regulations, HHS has interpreted this provision to prohibit payment of claims by state Medicaid agencies. Oddly, HHS has stated in sub-regulatory materials that a state Medicaid agency can recoup payments from Medicare where "Medicare has determined that it is liable for the service at issue." See April 8, 2003 State Medicaid Director Letter #03-004. The decision in *Commonwealth v. Sebelius* however does not refer to this letter and HHS appears to have abandoned the letter's position.
30 *Commonwealth v. Sebelius*, slip op. at pg. 15.
31 428 F.3d at 138.
32 2009 WL 1834599 (N.D.N.Y. June 22, 2009).
33 *Leavitt*, 429 F.3d at 144-145; *New York v. Sebelius*, 2009 WL 1834599 at *9.
34 *Commonwealth v. Sebelius*, slip op. at pgs. 16-17. MassHealth also sought a declaration that providers must return payments for retroactive dual eligibles to MassHealth and seek reimbursement from Medicare. The District Court declined to act on this request as no providers were parties to the case. *Id.* at pg. 17.
35 See, e.g., *New York v. Sebelius*, 2009 WL 1834599 at *9 (a state agency "may pursue claims against Medicare as the statutory subrogee of a

beneficiary [only] where the beneficiary could do so himself").
36 42 U.S.C. § 1395f(a).
37 *Atlanticare*, 439 Mass. at 14-15. See also *Petition of Maxi Drug, Inc.*, 915 A.2d 480 (N.H. Supreme Ct. 2006) (State Medicaid agency could not use underpayments to drug companies to recoup prior payments made by agency to dual eligibles).
38 *Commonwealth v. Sebelius*, slip op. at pg. 17.
39 42 U.S.C. § 1396a(a)(25)(B).
40 March 19, 2010 *Boston Globe*, pg. A1, "More Cuts Looms as State Faces \$295m in Red Ink".
41 MassHealth could also try to implead HHS as a third party.
42 439 Mass. at 13.
43 *Leavitt*, 428 F.3d at 150. See also *Spectrum Health Continuing Care Group v. Anne Maries Bowling Irrevocable Trust*, 410 F.3d 304, 314 (6th Cir. 2005) ("Medicaid is a contract between a service provider and the government, in which the Medicaid recipient is a third party beneficiary").
44 See *Leavitt*, 428 F.3d at 142.
45 It should also be added that this does not necessarily foreclose MassHealth from appealing *Commonwealth v. Sebelius* in federal court. In state court, MassHealth would be arguing that it recoup funds from providers; in federal court it would be arguing that it could recoup funds from Medicare. MassHealth could argue in its federal appeal that, in *Atlanticare* situations, subrogation principles clash with the statutory relationship of Medicare and Medicaid. The statutory regime should trump these principles in such situations. Cf. *Oubre v. Entergy Operations, Inc.*, 522 U.S. 422, 427 (1998) (federal Older Workers Benefit Protection Act "sets up its own regime ..., separate and apart from contract law").

Implementation of Accreditation Standards for Suppliers Furnishing the Technical Component of Advanced Diagnostic Imaging Services

By Meghan Cosgrove, Esq., and Patrick Leeman

As of January 1, 2012, suppliers of the technical component¹ of advanced diagnostic imaging services must be accredited by an accreditation organization (“AO”) approved by the Secretary of the U.S. Department of Health and Human Services (“Secretary”) as a condition of Medicare payment. The Centers for Medicare and Medicaid Services (“CMS”) published this requirement in the 2010 Medicare Physician Fee Schedule Final Rule, implementing Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (“MIPPA”), in order to improve the quality of advanced diagnostic imaging services.² CMS has designated the following national accrediting bodies as AOs: the American College of Radiology (“ACR”), the Intersocietal Accreditation Commission (“IAC”), and The Joint Commission (“TJC”).³ Although the accreditation requirement is nearly two years away, unaccredited suppliers of advanced diagnostic imaging services should choose an AO by familiarizing themselves with the standards used and fees charged by these AOs,⁴ and begin to assess operational areas of concern as well as the financial burden associated with accreditation.

This Final Rule applies to suppliers, both fixed and mobile,⁵ that furnish the technical component of diagnostic magnetic resonance imaging (MRI), computed tomogra-

phy (CT), positron emission tomography (PET), and nuclear medicine services. At this time, the new standard does not apply to suppliers of x-ray, ultrasound or fluoroscopy services. In addition, the accreditation requirement does not apply to advanced diagnostic imaging services provided in hospital settings because hospitals receive payment for diagnostic tests under the outpatient prospective payment system, not the physician fee schedule.⁶

The AOs must use the minimum MIPPA-imposed standards in evaluating suppliers of advanced diagnostic imaging services. However it is important to note that an AO could adopt standards that are more stringent.⁷ At a minimum, the regulation requires AOs to establish and maintain a quality control program to ensure that the diagnostic images produced by a supplier are sufficiently reliable and accurate, to ensure that the equipment used meets certain performance specifications, and to ensure the safety of the medical personnel as well as patients.⁸ Furthermore, the AOs will set the standards for the qualifications of medical directors, supervising physicians, and other medical personnel.⁹ The regulation also contains a provision regarding unannounced site surveys.¹⁰ In the final version of the Rule, the agency included a provision which requires an AO to notify CMS within two business

days of the identification of a supplier deficiency that “poses immediate jeopardy to a beneficiary or the general public.”¹¹

Suppliers accredited by an existing accrediting body as of January 1, 2010, do not need to be re-accredited by a CMS-designated AO until the expiration of the supplier’s existing accreditation period.¹² Suppliers of advanced diagnostic imaging services who are not accredited by January 1, 2012, however, will have their billing privileges revoked as CMS does not have the authority to delay the statutory accreditation requirement.¹³

1 The technical component covers the cost of the equipment, supplies, and personnel, including technicians, used to perform the imaging service as opposed to the professional component which covers the cost of the professional services of the physician who interprets the imaging study.

2 Implementation of Accreditation Standards for Suppliers Furnishing the Technical Component (TC) of Advanced Diagnostic Imaging Services, 74 Fed. Reg. 61,861 (Nov. 25, 2009) (codified at 42 C.F.R. § 414.68); Medicare Improvements for Patients and Providers Act of 2008, 42 U.S.C. § 1395m.

3 Medicare Program; Approval of Independent Accrediting Organizations To Participate in the Advanced Diagnostic Imaging Supplier Accreditation Program, 75 Fed. Reg. 4088-89 (Jan. 26, 2010).

4 Although CMS does not have any direct input on the fees that the AOs will charge suppliers, these fees must be reasonable. 42 U.S.C. § 1395m(e)(2)(A)(v).

5 42 C.F.R. 414.68(b); 74 Fed. Reg. 61,865 (Nov. 25, 2009) (referencing mobile units).

6 42 C.F.R. 488 (providing the requirements that hospitals, including inpatient radiology departments be accredited as a condition of Medicare payment).

7 42 C.F.R. 414.68(c)(2).

8 42 C.F.R. 414.68(c)(1)(iii); 42 C.F.R. 414.68(c)(1)(iv).

9 42 C.F.R. 414.68(c)(1)(i); 42 C.F.R. 414.68(c)(1)(ii).

10 42 C.F.R. 414.68(c)(6)(iv).

11 42 C.F.R. 414.68(g)(4).

12 74 Fed. Reg. 61,867 (Nov. 25, 2009).

13 Id. at 61,866.

Here Comes the Sunshine Act: Impact on the Massachusetts Gift Ban and Reporting Law

By William M. Mandell, Esq.

Among the myriad of provisions included in the final federal health reform law¹ is a first time broad national disclosure mandate on the interactions between industry and medicine. What was once known as the Physician Payment Sunshine Act² is now the law of the land.

Starting with calendar year 2012, and annually thereafter, payments or transfers of value worth over \$10³ made by pharmaceutical, medical device and biotechnology manufacturers operating in the U.S. or its territories⁴ to physicians⁵ or teaching hospitals must be tracked and will become reportable to the United States Department of Health and Human Services (“HHS”). The reported information,⁶ which will identify the recipient, amount, and nature of each payment, will become part of an on-line searchable and downloadable public data base which is to “go live” on September 30, 2013.

The federal Sunshine data base is specifically designed to be “user friendly” to the “average consumer.”

HHS is required to make the public data base searchable and in a format that is clear and understandable. It is to contain information that is presented by the name of the reporting company, the name, business address and specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the

payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, the nature of the payment or other transfer of value, and the name of the covered drug, device, biological, or medical supply, as applicable.

The data base must contain information that is able to be easily aggregated and downloaded; including a description of any enforcement actions or penalties imposed on the reporting entity for violating the Sunshine reporting mandates during the preceding year⁷, plus background information on industry-physician relationships. In the case of information submitted with respect to a payment or other transfer of value related to research, the data base must list such information separately from the other reported information and designate such separately listed information as funding for clinical research. HHS is granted authority to have the data base contain any other information helpful to the average consumer.

Reporting companies will be given an opportunity to review and submit corrections to the information submitted for at least 45 days prior to such information being made available to the public.

Under the federal “Sunshine” reporting requirements there is a broad preemption clause. As of January 1, 2012, when companies must begin tracking their interac-

tions reportable under the federal reporting system, this federal law will preempt any state laws that require manufacturers to disclose or report the same type of information that is reportable to HHS.

However, the federal “Sunshine” reporting law does not totally preempt state reporting mandates. It does not preempt any state laws that require the disclosure or reporting of information that is not reportable to HHS or that cover a broader category of reporting parties or recipients than defined under the federal law.

The federal reporting system will not preempt any state laws that require the reporting of information that is exempt from reporting under the federal law (e.g. payments or transfers of value worth less than \$10) but it will preempt state laws to the extent that they exempt payments or transfers of value worth \$10 or more.

Furthermore, there is no preemption of state laws that require reporting to federal, state, or local governmental Agencies for public health surveillance, investigation, or other public health purposes or health oversight purposes.

For states like Massachusetts, that have already enacted reporting and gift bans laws regulating interactions between drug and medical device manufacturers and distributors and health care providers, the preemptive effect of the federal law must be analyzed

to understand the level of federal and state mandates regulated parties will need to follow starting in 2012.

An overview of this preemption analysis as it applies to the Massachusetts gift ban and public reporting law and the implementing Massachusetts Department of Public Health (“DPH”) regulations⁸ is set forth below.

I. Massachusetts Gift Ban

While federal health reform did eventually include the Physician Payment Sunshine Act reporting provisions that had been previously proposed by Senator Charles Grassley and others, it did not include any “gift ban” type restrictions on industry interactions with physicians and other health care providers.

Federal policy – for now – on the regulation of industry conflict of interest is not to enact a mandatory gift ban or code of conduct as some states, like Massachusetts and Vermont, have done. Instead, it embraces the mechanism of public disclosure as a means to bring to light those physicians who are entering into financial relationships with pharmaceutical and medical device companies that could be in conflict with their clinical, research and academic duties.⁹

Thus, state level regulation of industry interactions with physicians, hospitals and other providers through prohibitions and limits on payments is not preempted by the federal Sunshine reporting system.

In terms of the Massachusetts law this means that manufacturers and certain distributors must still adopt and comply with a compliance program and a Marketing

Code of Conduct that conforms to the DPH regulations, 105 CMR 970.000,¹⁰ and annually submit compliance plan information and certifications to DPH.

For instance, the Massachusetts limits on company gift giving to physicians – which is not a total gift ban as it permits certain educational items worth less than \$100 – or the Massachusetts requirements for permissible consulting and other service relationships will not be preempted. Conversely, the federal law will not alter the fact that Massachusetts law does not prohibit physicians from participating on company speaker’s bureaus.¹¹

Additionally, there is no preemption of the requirements under the DPH regulations that require pharmaceutical manufacturers and distributors to (i) comply with limitations and requirements on the use of non-patient identified prescriber data, including an “opt out” for physician and other prescribers on having their prescriber data used for marketing purposes, and (ii) obligate all contracted speakers and consultants who serve on a formulary or clinical guideline committees to disclose their company relationship to the committee.

Massachusetts, and other states, will continue to be able to pass state laws prohibiting and regulating interactions between industry and health care providers that do not involve governmental or public disclosure without any level of federal preemption.

II. Pre-2012 Massachusetts Reporting

State level governmental or public disclosure mandates, however, will be preempted starting with inter-

actions and payments taking place in calendar year 2012. This means that states which already have laws that require disclosure to state agencies or to a public data base¹² may continue to operate those disclosure systems without any level of preemption through calendar year 2011.

Thus, the Massachusetts reporting system established under DPH’s regulations is not preempted until 2012. This means that on July 1, 2010 (for the period July 1, 2009 through December 31, 2009) and on July 1, 2011 (for calendar year 2010) manufacturers and certain distributors are still required to disclose to DPH – for posting on its public website – the value, nature, purpose, and recipient of any sales and marketing activity payment, or other benefit, with a value of at least \$50 to physicians (and other Massachusetts licensed professionals who are authorized to prescribe), hospitals, nursing homes, and pharmacists.

Of course, DPH could delay or modify its disclosure mandate and reporting system in reaction to the enactment of the federal Sunshine reporting system. But, the current DPH plan is to review the first batch of data submitted on July 1, 2010, and have the Massachusetts public data base “go live” some time in the fall of 2010.¹³

Companies are still required to pay an annual fee of \$2,000 to DPH every July 1 through 2011. For 2012 and beyond, the scope of the federal preemption as to the DPH filing fee is not entirely clear.

III. Preempted Massachusetts Reporting

Starting in 2012 the federal “Sunshine” law preempts any state statute or regulation that requires

any entity that comes within the federal definition of “manufacturer” to disclose or report, in any format, the type of information reportable to HHS regarding payments or other transfers of value to physicians or teaching hospitals worth over \$10.

Under the federal reporting system covered manufacturers will be required to track and report to HHS in their annual submissions the following data for each reportable payment or transfer of value:

- (i) The name of the covered recipient.
- (ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient (the NPI will not be included in the public data base).
- (iii) The amount of the payment or other transfer of value.
- (iv) The dates on which the payment or other transfer of value was provided to the covered recipient.
- (v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—
 - (I) cash or a cash equivalent;
 - (II) in-kind items or services;
 - (III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
 - (IV) any other form of payment or other transfer of value (to be defined in HHS regulations).
- (vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

- (I) consulting fees;
- (II) compensation for services other than consulting;
- (III) honoraria;
- (IV) gift;
- (V) entertainment;
- (VI) food;
- (VII) travel (including the specified destinations);
- (VIII) education;
- (IX) research;
- (X) charitable contribution;
- (XI) royalty or license;
- (XII) current or prospective ownership or investment interest;
- (XIII) direct compensation for serving as faculty or as a speaker for a medical education program;
- (XIV) grant; or
- (XV) any other nature of the payment or other transfer of value (to be defined in HHS regulations).

HHS is granted further authority to establish other categories of information that must be disclosed regarding each reportable payment or other transfer of value.

The federal reporting system will also require disclosure of the name of the drug, device, biological, or medical supply if the reportable payment or other transfer of value is related to marketing, education, research specific to a covered drug, device, biological, or medical supply. Once the HHS public data base goes on-line in 2013, the level of interactions by any physician or teaching hospital related to a certain drug or device will be more easily searchable.

Also, in the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient (e.g. a pay-

ment made to a charitable disease organization at the request of a physician), the applicable manufacturer is required to disclose that payment or other transfer of value under the name of the covered recipient.

The federal “Sunshine” reporting system will also require disclosure of any ownership or investment interests held by any physician (or immediate family member) in any group purchasing organization or “manufacturer” as defined under the federal law, other than interests in publicly traded securities or mutual funds.¹⁴

Beginning in 2012, the federal reporting law will preempt the Massachusetts DPH disclosure regulations to the extent they replicate the federal mandate. To the extent that any sales and marketing activity¹⁵ interactions with Massachusetts physicians or teaching hospitals are reportable to HHS they no longer will be reportable to DPH.

Also, the broad reporting exemption established by DPH under the Massachusetts disclosure rules for clinical trials¹⁶ and genuine research¹⁷ will not apply to the federal reporting system. Starting in 2012 manufacturers will be required to track and report in the following year to HHS any payment or transfer of value worth \$10 or more related to research or pre-market approval activities. However, such reported interactions do not become immediately public.

In the case of information submitted to HHS with respect to a payment or other transfer of value made pursuant to a product research or development agreement for services furnished in connection with research on a potential

new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, such information, while reportable to HHS annually, will not be made immediately available on the public data base.

Such research related payments and transfers of value become public on the earlier of the FDA approval date or four calendar years after the date such payment or other transfer of value was made. During the non-public phase of such reported date, the information in the hands of HHS is not subject to the Freedom of Information Act.

IV. Non-Preempted Massachusetts Reporting

The Massachusetts disclosure system is broader in many respects compared to the new federal Sunshine reporting system. These aspects of the DPH rules will not be preempted and companies will still be required to track sales and marketing activities and file reports to DPH notwithstanding the commencement of the federal tracking and reporting requirements beginning in 2012.

For instance, while the federal law only require reports from distributors that are under common ownership with a manufacturer of a drug, device, biological, or medical supply, the Massachusetts disclosure mandate applies to independent distributors that take title (verses consignment) to products.

The Massachusetts definition of covered recipients of reportable interactions is also much broader than the federal system. While most payments and transfers of

value to physicians, dental surgeons, podiatrists, optometrists, chiropractors and teaching hospitals will no longer be reportable to Massachusetts after 2011, companies will still be required to fully report all reportable sales and marketing activities under DPH's regulations made to other non-physician licensees who are authorized to prescribe, non-teaching hospitals, nursing homes and pharmacists.

Also, the federal law exempts the following interactions from the public reporting system:

- product samples that are not intended to be sold and are intended for patient use (although the federal law will require separate non-public data base reporting to HHS);
- educational materials that directly benefit patients or are intended for patient use;
- the loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient;
- items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device;
- a transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient;
- discounts (including rebates);

- in-kind items used for the provision of charity care;

- a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund;

- in the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan;

- in the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional; and

- in the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

These federal exemptions are noteworthy because they are broader in many respects than the Massachusetts reporting exemptions. Yet under the rules of preemption the states can continue to require state reports of these types of transactions exempt from federal reporting. As one example, while payments to physicians for expert witness services will be categorically exempt from federal reporting, notwithstanding the enactment of the federal "Sunshine" reporting system companies subject to Massachusetts reporting will still have to continue

to determine whether such interactions come within the broadly ambiguous definition of “sales and marketing activity” under the DPH rules.

V. Other New Federal Transparency Requirements

Federal health reform has not only established a national reporting system for interactions between drug and device manufacturers and physicians and teaching hospitals, it also has established for the first time patient disclosure obligations on physicians.

The Stark Law is amended for services furnished on or after January 1, 2010, to require referring physicians, with respect to permitted referrals for magnetic resonance imaging, computed tomography, positron emission tomography, and any other Stark covered radiology services designated by CMS, to inform the patients in writing at the time of the referral that the patient may obtain the radiology services for which the patient is being referred from a person other than the referring physician, or his group practice and colleagues, and the patient must be provided with a written list of other suppliers who furnish such services in the area in which the patient resides.

In summary, these features of federal health reform, intended to shed light upon and mitigate possible conflicts of interest that could be unduly influencing physicians and other providers, will have a major impact on federal/state disclosure systems as well as patient access to information that previously was not public. Companies, physicians, hospitals and other parties regulated by these new federal provisions must be prepared to add them to their on-going efforts toward compliance.

1 Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002) which was signed into law on March 23, 2010, modified by the Health Care and Education Affordability Reconciliation Act of 2010

(the House Reconciliation package) signed into law on March 30, 2010.

2 See, Section 6002 of the Patient Protection and Affordable Care Act of 2009 entitled “Transparency Reports and Reporting of Physician Ownership or Investment Interests” which adds a new section to the United States Code, 42 U.S.C. §1128G.

3 Transfers of value worth less than \$10 are not reportable unless the aggregate amount transferred to, requested by, or designated on behalf of the recipient by the manufacturer during a calendar year exceeds \$100. These thresholds will be increased annually by the CPI.

4 “Manufacturer” is defined broadly to include any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply covered under Medicare, Medicaid, or Children’s Health Insurance Program (“CHIP”) (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply). Group purchasing organizations are also subject to the reporting requirements.

5 The law references the definition of physicians found in 42 U.S.C. §1395x(r) which includes dental surgeons, podiatrists, optometrists, chiropractors and physicians.

6 The first reporting submission date (for 2012 reportable payments) is March 31, 2013. Thereafter, the annual reporting date is the 90th day of each calendar year for reportable payments taking place the prior calendar year, with the past year’s reported transactions added to the public data base each June 30.

7 Inadvertent violations of the federal reporting requirements can result in civil money penalties between \$1,000 and \$10,000 per non-reported transaction, up to \$150,000 per year. Knowing violations can result in civil money penalties between \$10,000 and \$100,000 per non-reported transaction, up to \$1 million per year.

8 Massachusetts General Law, Chapter 111N; Chapter 111N and implementing agency rules, DPH regulations 105 CMR 970.000.

9 Comments of Stephen Cha, MD, MHS, Professional Staff Member, Energy and Commerce Committee, US House of Representatives, Washington, DC, The Second National Disclosure Summit, March 4, 2010. See www.disclosuresummit.com.

10 The Massachusetts mandated Marketing Code of Conduct in many respects is more stringent than the standards set forth in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, revised in July, 2008 and effective January 1, 2009, and the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals, revised in December, 2008 and effective July 1, 2009. The Massachusetts mandated Marketing Code of Conduct also requires CME programs to adhere to the Accreditation Council for Continuing Medical Education (“ACCME”) Standards for Commercial Support (even if ACCME accreditation is not secured).

11 Although Massachusetts law does not prohibit companies from hiring physicians to present at non-CME programs and meetings on a fair market value basis set forth in a written contract, (See, 105 CMR 970.008 2. a.), participation on a company

speaker’s bureau is increasingly becoming prohibited under conflict of interest policies adopted by academic medical centers, see e.g., Partners HealthCare Conflict of Interest Policy as described in the April 2009 Partners Commission on Interactions with Industry Report.

12 Massachusetts and Minnesota require disclosure to both a state agency and a public data base; the District of Columbia, Maine, Vermont and West Virginia require disclosure to a state agency.

13 Comments of Melissa Lopes, Deputy General Counsel, Massachusetts Department of Public Health, The Second National Disclosure Summit, March 4, 2010. See www.disclosuresummit.com.

14 The exemption from this reporting requirement tracks the publicly traded company ownership and investment interest exception under the Stark Law.

15 “Sales and marketing activity” is defined under 105 CMR 970.004 as sales and marketing activities including “advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force . . . [as well as] any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose.”

16 105 CMR 970.009 states that reportable “sales and marketing “activity” does not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or “new use” or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. “Clinical trial,” is defined by 105 CMR 970.004 as “a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board (“IRB”) after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or equivalent standards of another federal agency.”

17 “Genuine Research Project” is defined under 105 CMR 970.004 as “a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry.”

Local Health Law Briefs

Melendez-Diaz v. Massachusetts, 557 U.S. ____ (2009)

By Melissa Lopes, Esq.

Melendez-Diaz determined that the admission of documents certifying laboratory test results absent confrontation in a criminal drug trial violated the Petitioner's Sixth Amendment right to confront witnesses against him. On June 25, 2009, the United States Supreme Court reversed the judgment of the Appeals Court of Massachusetts concerning the admission of laboratory analysts' certificates asserting that material seized by police from Petitioner Melendez-Diaz was cocaine of a certain quantity.

Acting upon a tip, Boston police officers placed a Kmart employee under surveillance and observed suspicious activity involving the employee and two men in a blue sedan. When the Kmart employee exited the sedan, the officers searched the Kmart employee and found four clear plastic bags containing a white substance resembling cocaine. The Kmart employee, along with the two men in the blue sedan, were placed under arrest and ordered into a police cruiser. During the short drive to the police station, officers observed the three men fidgeting and making other furtive movements in the back seat of the police cruiser. Upon arrival at the police station, the three men were ushered into the police station while the officers searched the back of the police cruiser. The officers found a plastic bag containing 19 smaller plastic bags

hidden in the partition between the front and back seats of the police cruiser. Officers seized this evidence and submitted it to a state laboratory required by law to conduct chemical analysis of substances upon police request. The state laboratory issued three "certificates of analysis" sworn to by lab analysts, reporting the weight of the seized bags and stating that the substance within the bags was cocaine. Petitioner Melendez-Diaz was later charged with distributing cocaine and with trafficking in cocaine in an amount between 14 and 28 grams.

At trial, the prosecution placed into evidence the clear plastic bags seized in the search of the Kmart employee and the clear plastic bags seized as a result of the search of the police cruiser. Additionally, the prosecution submitted three "certificates of analysis" detailing the results of the laboratory analysis of the substance within the seized clear plastic bags. Petitioner Melendez-Diaz objected to the admission of the certificates, asserting that the Sixth Amendment Confrontation Clause decision in *Crawford v. Washington*, 541 U.S. 36 (2004) required the lab analysts to testify in person. Petitioner's objection was overruled and Petitioner was found guilty by jury decision. Petitioner appealed. The Appeals Court of Massachusetts rejected Petitioner's argument that admission of the certificates violated the Sixth Amendment, under the Massachusetts Supreme Judicial Court's decision in *Commonwealth v. Verde*, 444 Mass. 279 (2005), which held that authors of certifi-

cates of forensic analysis are not subject to confrontation under the Sixth Amendment. The Massachusetts Supreme Judicial Court denied review¹ and the United States Supreme Court granted certiorari.²

Writing for the Court, Justice Scalia relied on the premise set out in *Crawford v. White*, that a witness' testimony against a defendant is inadmissible unless the witness appears at trial, or if the witness is unavailable, the defendant had a prior opportunity for cross-examination. Concluding that the state lab analysts' certificates were affidavits, the Court determined that they constituted testimony under *Crawford*. Further, the Court determined that the evidentiary nature of the certificates was clear to the lab analysts who swore to them, as it was clearly enunciated in the certificates themselves.

Respondent raised a myriad of legal arguments for the proposition that the lab analyst certificates were not subject to the Confrontation Clause. Respondent opened with the argument that lab analysts are not subject to the Confrontation Clause because they are not accusatory witnesses. The Court rejected this argument as unsupported by the Sixth Amendment and by case law, pointing out that there are two classes of witnesses contemplated in the Constitution, witnesses in favor of the defendant and witnesses against the defendant. Witnesses against a defendant often provide one piece of the puzzle in the case against the defendant. Similarly, the lab analysts, through their certificates, provided one fact

necessary for the conviction of the Petitioner. Thus, the Court concluded that the lab analysts constitute witnesses against the Petitioner, subject to the Confrontation Clause.

Respondent also maintained that the lab analysts at issue in this case are not conventional witnesses, in that they did not observe the crime or any human action related to it. The Court rejected both the relevancy of this argument as unsupported in the language of the Sixth Amendment, and the rationale, as applying this distinction would possibly lead to the absurd result where a police officer who drafts a report of the crime scene and an expert witness against the defendant would not be subject to the Confrontation Clause.

Respondent further argued that there is a relevant distinction between the reliability of testimony based on neutral scientific testing and testimony recounting historical events, which is prone to distortion and manipulation. Respondent's argument relied on the holding in *Ohio v. Roberts*, 448 U.S. 56 (1980), that evidence with "particularized guarantees of trustworthiness" is admissible notwithstanding the Confrontation Clause, a holding that the Court determined was overturned by *Crawford*. According to *Crawford*, the Sixth Amendment demands not that the evidence itself be reliable, but that the reliability of the evidence be assessed within "the crucible of cross-examination." Thus, even seemingly reliable evidence may be subject to the Confrontation Clause, as was determined by the majority in this case.

Drawing a connection between the business and official records

hearsay exception and the Confrontation Clause, Respondent also argued for a business records exemption to Confrontation Clause requirements, asserting that the lab analysts' certificates were documents kept in the regular conduct of business of the State Lab. Similar to the argument discussed above, this argument relies upon a premise established in *Ohio v. Roberts*, that "reliability can be inferred without more in a case where the evidence falls within a firmly rooted hearsay exception." The Court, relying on its decision in *Palmer v. Hoffman*, 318 U.S. 109 (1943), distinguished business records created for the purposes of establishing or proving some fact at trial and those created for the administration of a business entity's affairs. The Court asserted that the latter is admissible absent confrontation, whereas the former is subject to confrontation.

The Court also rejected Respondent's claims that Petitioner's power to subpoena the lab analysts sufficed for the lack of confrontation and that the Sixth Amendment right to confrontation should be relaxed in this instance so as not to unduly burden the trial process.

In a concurring opinion, Justice Thomas wrote separately to clarify that his joining in this decision did not alter his position that the Confrontation Clause is "implied by extrajudicial statements only insofar as they are contained in formalized testimonial materials, such as affidavits, depositions, prior testimony, or confessions." Thomas acceded to the Court's decision because he also considers the lab analysts' certificates at issue in this case to be affidavits within "the core class of testimo-

nial statements" governed by the Sixth Amendment.

Joined by Justices Roberts, C.J., Breyer and Alito, Justice Kennedy wrote a dissenting opinion, asserting that the majority abandoned a well-established principle of jurisprudence that scientific evidence may be introduced into evidence without testimony from the analyst who produced it. The dissent would have limited the holding in *Crawford* to cases involving ordinary witnesses, who have personal knowledge of some aspect of the defendant's guilt, rather than extending the decision to anyone who makes a testimonial statement, as the majority does. The dissent further suggested that the majority's decision leaves the states with little guidance and has "vast potential to disrupt criminal procedures that already give ample protections against the misuse of scientific evidence."

1 449 Mass. 1113 (2007).
2 552 U.S. ____ (2008).

**Vasa v. Compass Medical, P.C.,
SJC-10457 (2010)**

By Mark C. Rogers, Esq.

The Massachusetts Supreme Judicial Court (“SJC”) recently issued a decision finding that a claim that a health care provider caused injury to a third party by failing to warn a patient about the effects of medical treatment must be presented to a Medical Malpractice Tribunal. The decision upholds a Superior Court decision granting the request of the healthcare providers that a Medical Malpractice Tribunal be convened in such a case.

The case, *Vasa v. Compass Medical, P.C., et al*, results from a motor vehicle accident in October of 2007. Jane Berghold lost control of her motor vehicle and drove into a Brockton Hospital building crushing to death Mark Vasa, an employee of Brockton Hospital. Mr. Vasa’s estate brought suit against Berghold in Superior Court. The claims against Berghold were eventually settled. The plaintiff, however, then amended her Complaint to add Compass Medical, P.C. (“Compass”) and four employed physicians of Compass as Defendants. The employed physicians of Compass were treating providers of Berghold. The Amended Complaint alleged that the physician defendants knew, or should have known, that the medication they had prescribed Berghold was likely to impair her physical and mental abilities to operate a motor vehicle. Furthermore, the Amended Complaint alleges that the defendants committed a breach of their duty to Berghold and the public by failing to advise her not to drive.

At that time the defendants answered the Complaint, they

requested that a Medical Malpractice Tribunal be convened pursuant to Massachusetts General Laws, c. 231, § 60B the Medical Malpractice Tribunal Statute.

The Medical Malpractice Tribunal Statute (or “Statute”) provides that every action for malpractice error or mistake against a provider of healthcare should be heard by a tribunal consisting of a Single Justice of the Superior Court, a physician licensed to practice medicine in the Commonwealth and an attorney authorized to practice law in the Commonwealth. The tribunal determines whether the evidence presented by the plaintiff, if properly substantiated, is sufficient to raise a legitimate question of liability appropriate for judicial inquiry or whether the plaintiff’s case is merely an unfortunate medical result. If the tribunal finds that a case represents merely an unfortunate medical result, the plaintiff must file a bond with the Superior Court before proceeding with the case. In response to the defendants’ request for a tribunal, the plaintiff objected on the grounds that the claims were based on simple negligence rather than medical malpractice and, furthermore, there was no doctor-patient relationship established between the plaintiff and the defendants. The Superior Court judge overruled the objection of the plaintiff and the plaintiff appealed.

In its ruling upholding the Superior Court’s allowance of the tribunal, the SJC noted that its case law has defined the Medical Malpractice Tribunal Statute to encompass “all treatment-related claims”. The Court noticed that the Statute contains no language limiting its coverage to suits brought by recipients of medical treatment.

Furthermore, the Court pointed to its decision in *Santos v. Kim* in which it held that a doctor-patient relationship is not a prerequisite to applying the Medical Malpractice Tribunal Statute.

The Court held that it is the defendant’s status as a health-care provider, not the presence of a doctor-patient relationship that triggers the Statute. Focusing on the status of the defendant as a healthcare provider is consistent with the Statute’s purpose “that there be expert screening of cases which directly implicate the professional judgment or competence of a provider.”

Editors

Catherine L. Annas, Esq.

Catherine L. Annas is the Director of the Eastern Massachusetts Healthcare Initiative (EMHI), a group of hospitals, health plans, provider groups and universities working together to create a high performance health care system in Eastern Massachusetts. She oversees projects related to patient safety, quality and cost in health care. Prior to joining EMHI, Ms. Annas served for five years as the Director of Patient Safety at the Department of Public Health and the Betsy Lehman Center for Patient Safety and Medical Error Reduction. Before that, Ms. Annas worked for five years on the House staff of the Massachusetts Legislature's Joint Committee on Health Care. Ms. Annas received her J.D. from the Columbus School of Law at the Catholic University of America in 1995, where she was a staff member of the Journal for Contemporary Health Law and Policy, and her Bachelor's Degree in English from the Catholic University of America in 1992. Ms. Annas serves on the board of Our Bodies Ourselves, a non-profit, public interest women's health education, advocacy, and consulting organization.

Mark C. Rogers, Esq.

Mark C. Rogers is a member of The Rogers Law Firm's Health Care, Corporate and International Practice Groups. Although he has extensive experience representing a variety of clients with regard to regulatory, compliance, employment and corporate matters, Mr. Rogers focuses his practice on health care contractual matters, regulatory compliance, and fraud and abuse investigations. He has published and lectured extensively on legal issues in the health care industry and is an adjunct faculty member at New England School of Law where he teaches Health Law. Mr. Rogers earned his undergraduate degree from the College of the Holy Cross and his law degree (cum laude) from Suffolk University Law School, where he served as the Chief Managing Editor of the Suffolk Transnational Law Review. Mr. Rogers is admitted to practice in both the state and federal courts in Massachusetts, as well as the United States First Circuit Court of Appeals and the United States Supreme Court.

Contributors To This Issue

Matthew S. Buehler, Esq.

Matthew S. Buehler graduated from Suffolk University Law School in 1995 and subsequently worked in the public sector until 2008. This included two years at the Executive Office of Health and Human Services, Office of Medicaid and five years at the Office of the Attorney General, Insurance Division.

While at the Office of Medicaid, Mr. Buehler brought enforcement actions under the ‘payer-of-last-resort’ provisions of the Federal Medicaid Act and G.L. c. 118E and represented the agency in the State Superior, District, Probate and Land Courts. Mr. Buehler further defended appeals of agency audits of providers. In these capacities, Mr. Buehler recovered over \$3 million in funds owed to the MassHealth program.

While at the Attorney General’s Insurance Division, Mr. Buehler brought enforcement actions under the consumer protection and health insurance statutes. In addition, Mr. Buehler has worked as an attorney for the Attorney General’s Civil Rights Division and the Massachusetts Commission Against Discrimination. Mr. Buehler has been in the private sector since 2008 and is currently doing contract work while looking at long-term opportunities.

Meghan M. Cosgrove, Esq.

Meghan M. Cosgrove is an associate in the Health Care Department at Donoghue Barrett & Singal, P.C. representing hospitals, clinics, nursing homes, home health agencies, physician groups,

assisted living residences, and ambulatory surgery centers.

Prior to joining the firm, Ms. Cosgrove served at the Centers for Medicare and Medicaid Services (CMS) in Boston and in Baltimore, Maryland as a Health Insurance Specialist in the Division of Medicare Financial Management and the Division of Technical Payment Policy, respectively. During her tenure at CMS, she worked on the Stark Law Phase III regulations, the Specialty Hospital Report to Congress, the EMTALA Technical Advisory Group Report, the Compliance Effectiveness Pilot project, as well as Medicare reimbursement and coverage issues.

Prior to law school, Ms. Cosgrove was the Director of Project Development at the Federated Ambulatory Surgery Association in Alexandria, VA. Ms. Cosgrove received a Juris Doctorate with a concentration in Health and Biomedical Law with Distinction from Suffolk University Law School, where she was one of the Founding Editors of the Suffolk Journal of Health & Biomedical Law. She received her undergraduate degree in English from the College of the Holy Cross, and is licensed to practice law in the Commonwealth of Massachusetts.

Julia R. Hesse, Esq.

Julia R. Hesse is Associate General Counsel at Tufts Medical Center, Inc. and formerly practiced as an associate in the Health Care practice groups of Ropes & Gray LLP and Choate, Hall & Stewart.

Ms. Hesse’s practice focuses on the full range of health care-related regulatory issues and other business and transactional matters important to academic medical centers and affiliated faculty and community physicians, including the implementation of quality-related programs and systems, negotiating and implementing managed care agreements that tie reimbursement to the achievement of quality goals, and advising health care institutions and faculty practice plans on the development and implementation of compensation systems that reward the achievement of quality-related goals. She is a graduate of Williams College and the University of Pennsylvania, where she received degrees in both law and bioethics.

Ms. Hesse recently co-authored the article “Legal Impediments to Implementing Value-Based Purchasing in Healthcare” with Anne Claiborne and Dan Roble, which was published in the December 2009 issue of the American Journal of Law & Medicine.

Patrick Leeman

Patrick Leeman is currently a law clerk in the Health Care Department at Donoghue Barrett & Singal, P.C. and is a candidate for a juris doctor from Suffolk University Law School.

While in law school, Mr. Leeman has been the recipient of an Academic Leadership Scholarship, and Suffolk Jurisprudence Awards in the subjects of Constitutional Law, Professional Responsibility, and Secured Transactions. He also serves as a staff member

on the Suffolk Journal of Health & Biomedical Law. Mr. Leeman earned his undergraduate degree in Classics from Boston College in 2005. Prior to law school, he served as a Ward Public Service Fellow and was an intern with the Suffolk County District Attorney's Office.

Melissa J. Lopes, Esq.

Melissa Lopes is Deputy General Counsel for the Massachusetts Department of Public Health. In the life sciences arena, Ms. Lopes has provided advisory rulings on egg donation in the human embryonic stem cell research context, and drafted Department regulations under the Massachusetts Stem Cell bill and the Pharmaceutical and Medical Device Manufacturer Conduct bill.

Ms. Lopes works with the Biomedical Research Advisory Council and serves as Co-Chair of the Interstate Alliance on Stem Cell Research convened by the National Academies of Sciences. Ms. Lopes also serves on the Stem Cell Advisory Committee for the UMASS Medical School International Stem Cell Registry and the Massachusetts Human Embryonic Stem Cell Bank. Additionally, Ms. Lopes provides legal advice and guidance to the Determination of Need program, the Office of HIV/AIDS, the Clinical Laboratories Program and on matters including blood banking and body art in the Commonwealth.

Prior to joining the Department of Public Health, Ms. Lopes was a Kellogg Fellow with Community Catalyst, a national healthcare advocacy group. In this capacity, Ms. Lopes worked with grassroots community groups across the country to secure and preserve

needed healthcare resources. Ms. Lopes also worked as an associate attorney with the law firm Choate, Hall & Stewart in the corporate and healthcare departments.

Ms. Lopes is a graduate of Boston College and Boston University School of Law, where she was an editor for the American Journal of Law and Medicine. Ms. Lopes was named a "Hero From the Field" at the 2009 Rx for Excellence Awards and was a recipient of the 2009 Commonwealth Citation for Outstanding Performance.

William M. Mandell, Esq.

William M. Mandell is a partner in the Boston law firm of Pierce & Mandell, P.C.

Mr. Mandell has over 20 years of experience representing health care providers, medical societies, biotech companies, and research and educational companies, on all aspects of health and business law.

Mr. Mandell is a graduate Cum Laude of Brandeis University and Boston College Law School. Prior to the formation of Pierce & Mandell, P.C. in 1995, he practiced health and business law at two large law firms and also served at the Medicaid Fraud Control Unit in the Massachusetts Attorney General's Office.

Mr. Mandell is also the author of several works on legal compliance, including, Managing Relationships with Industry A Physician's Compliance Manual; Massachusetts Health and Hospital Law Manual; and Making Sense of the Stark Law: Compliance for the Medical Practice.

Mr. Mandell is a member of the American Health Lawyers Association, the American Bar Association and the Boston Bar Association Health Law Section Steering Committee.

Mark Rogers, Esq.

Mark Rogers is a member of The Rogers Law Firm's Corporate, Health Care and International Practice Groups. Although he has extensive experience representing a variety of clients with regard to regulatory, compliance, employment and corporate matters, Mr. Rogers focuses his practice on health care contractual matters, regulatory compliance, and fraud and abuse investigations. He has published and lectured extensively on legal issues in the health care industry.

Mr. Rogers is Co-Editor of The Boston Health Law Reporter, and is also an adjunct faculty member at New England School of Law where he teaches Health Law. He earned his undergraduate degree from the College of the Holy Cross and his law degree (cum laude) from Suffolk University, where he served as the Chief Managing Editor of the Suffolk Transnational Law Review.

Mr. Rogers is admitted to practice in both the state and federal courts in Massachusetts, as well as the United States First Circuit Court of Appeals and the United States Supreme Court.

Peer Review Coordinator:

Julia Hesse, Esq.

Peer Reviewers:

Nate Brown, Esq.

Alexis Finkelberg, Esq.

Julia Hesse, Esq.

Edward Zacharias, Esq.

Section Leadership

Section Co-Chair

Alan Einhorn
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 342-4094
aeinhorn@foley.com

David Szabo
Edwards Angell Palmer & Dodge LLP
111 Huntington Avenue
Boston, MA 02199
(617) 239-0414
dszabo@eapdlaw.com

CLE

David Abelman
Tufts Health Plan-Watertown
705 Mount Auburn Street
Watertown, MA 02472
(617) 923-5838
david_abelman@tufts-health.com

Robin Johnson
Johnson & Aceto, LLP
67 Batterymarch Street
Boston, MA 02110
(617) 728-0888
johnson@johnsonaceto.com

Leslie Joseph
Mount Auburn Hospital
330 Mount Auburn Street
Cambridge, MA 02138
(617) 499-5752
ljoseph@mah.harvard.edu

Communications

Catherine Annas
Eastern Massachusetts Healthcare
Initiative
14 Story Street, 2nd Floor
Cambridge, MA 02138
(617) 495-2966
catherine_annas@harvard.edu

Mark Rogers
The Rogers Law Firm
50 Braintree Hill Officepark
Suite 302
Braintree, MA 02184
(781) 794-1600
mrogers@therogerslawfirm.com

Legislative

Thomas Barker
Foley Hoag LLP
Seaport World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2600
(617) 832-1111
tbarker@foleyhoag.com

Garrett Gillespie
Mintz, Levin, Cohn, Ferris, Glovsky
and Popeo P.C.
One Financial Center
Boston, MA 02111
(617) 348-4499
GGGillespie@mintz.com

Membership

Diane Moes
Donoghue, Barrett & Singal, P.C.
One Beacon Street
Suite 1320
Boston, MA 02108
(617) 598-6700
dmoes@dbslawfirm.com

Lawrence Vernaglia
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 342-4079
lvernaglia@foley.com

Social Action

Sarah Anderson
Greater Boston Legal Services
197 Friend Street
Boston, MA 02114
(617) 371-1234
sanderson@gbls.org

Barbara Anthony
10 Park Plaza
Suite 5170
Boston, MA 02116
(617) 973-8702
barbara.anthony@state.ma.us

Linda Landry
Disability Law Center, Inc.
11 Beacon Street
Suite 925
Boston, MA 02108
(617) 723-8455
llandry@dlc-ma.org

At-Large Members

Joshua Greenberg
Office of Child Advocacy
300 Longwood Avenue, BK120
Boston, MA 02115
(617) 919-3063
Joshua.Greenberg@tch.harvard.edu

Matthew Herndon
Harvard Pilgrim Health Care, Inc.
93 Worcester Street
Wellesley, MA 02481
(617) 509-3077
Matthew_Herndon@harvardpilgrim.org

Eve Horwitz
Archstone Law Group P.C.
245 Winter Street
Suite 400
Waltham, MA 02451
(781) 314-0111
ehorwitz@archstonelaw.com

Donna Levin
Massachusetts Department of
Public Health
250 Washington Street
Boston, MA 02108
617-624-5220
donna.levin@state.ma.us

Susan Stayn
Stanford University – Office of the
General Counsel
PO Box 20386
Stanford, CA 94305
(650) 723-4323
sstayn@comcast.net

Lawrence Litwak
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 502-3224
llitwak@foley.com

Susan Williams
Massachusetts Eye and Ear Infirmary
243 Charles St.
Boston, MA 02114
(617) 523-7900
Susan_Williams@meei.harvard.edu

Clare McGorrian
22 Putnam Avenue
Cambridge, MA 02139
(617) 871-2139
cdmccgcounsel@verizon.net

William Mandell
Pierce & Mandell, P.C.
11 Beacon Street
Suite 800
Boston, MA 02108
(617) 720-2444
bill@piercemandell.com

Dianne McCarthy
Massachusetts Eye and Ear Infirmary
243 Charles St.
Boston, MA 02114
(617) 381-5880
dianne_mccarthy@MEEI.harvard.edu

Michael Sroczynski
Massachusetts Hospital
Association - Boston
101 Arch Street
Suite 1741
Boston, MA 02110
(617) 513-9907
msroczynski@mhalink.org



A PUBLICATION OF THE BOSTON BAR ASSOCIATION HEALTH LAW SECTION



Boston Bar
ASSOCIATION

16 Beacon Street
Boston, MA 02108
Phone (617) 742-0615
Fax (617) 523-0127
www.bostonbar.org