Joint Committee on Health Care Financing

Committee Report 2007-2008

Sen. Richard T. Moore, Chair
Rep. Patricia A. Walrath, Chair

A Message from Sen. Moore and Rep. Walrath, Chairs

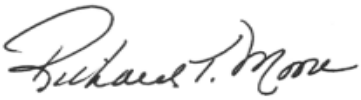
This report summarizes the 2007-2008 activities of the Joint Committee on Health Care Financing (Committee). The Committee held numerous hearings, reviewed over 450 pieces of legislation, participated and completed a final report on the Special Commission on Ambulatory Surgical Centers and Medical Diagnostic Services, and produced a briefing paper for Committee Members on the cost containment and quality landscape in Massachusetts. The Joint Committee staff worked extensively to produce a final draft of the "Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care" bill originally introduced by Senate President Murray and often referred to as 'health reform, phase two'. After many months of work and a brief but intense conference committee, the bill was signed by the Governor in August 2008 and became Chapter 305 of the Acts of 2008. This law will lay the groundwork for serious cost containment initiatives and quality improvement activities necessary to ensure the ongoing success of Chapter 58, the groundbreaking health care reform law of 2006.

In the pages that follow, you will find an overview of Committee activities, brief summaries of legislation reviewed by the Committee that became law in 2007 and 2008, the ASC and MDS final report, and the report on Quality and Cost in Massachusetts. We have also included a section on legislation that, while it did not become law in the 2007-2008 session, was significant enough to warrant comment.

We would like to thank the Chairs, members and staff of the various joint committees whose bills came to Health Care Financing as secondary referrals for their collegiality in working together on health care legislation. We would also like to thank House and Senate Counsel for their support of the Committee's work.

And, finally, we extend heartfelt thanks to President Therese Murray and Speaker Salvatore DiMasi and their staffs, especially David Seltz and Christie Hager for their assistance and support on health care legislation.

Sincerely,



Senator Richard T. Moore

Representative Patricia A. Walrath

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Joint Committee on Health Care Financing
2007- 2008 Members

Senator Richard T. Moore, Senate Chair
Representative Patricia A. Walrath, House Chair

Senate members:

Senator Marc R. Pacheco, Vice Chair
Senator Patricia D. Jehlen
Senator Susan C. Fargo
Senator Karen Spilka
Senator Gale D. Candaras
Senator Bruce E. Tarr

House Members:

Representative Stephen Kulik, Vice Chair
Representative Steven J. D'Amico
Representative Frank M. Hynes
Representative Robert M. Koczera
Representative Kay Khan
Representative David Paul Linsky
Representative Michael F. Kane
Representative Peter V. Kocot
Representative Angelo J. Puppolo, Jr.
Representative Christopher N. Speranzo
Representative Susan W. Gifford
Representative Robert S. Hargraves

Committee Staff:

Caroline Fisher, General Counsel and Health Care Policy Advisor (Senate)
Sarah Nolan, Research Director (House)
Melissa Thuma, Research Analyst/Counsel (House)
Jenny Nathans, Research Analyst (House)

Former Staff

Jessica Taubner, Senior Research Analyst (House)(Resigned)
Caitlin Young, Research Analyst (House)(Resigned)
Paul Jones, Research Analyst (House)(Resigned)

Joint Rule 1E, establishing the joint standing committee on Health Care Financing, adopted January 26, 2005; amended May 19, 2005 and February 20, 2007.

1E. The joint standing committee on Health Care Financing shall review all legislation relating to health care to evaluate the appropriateness and fiscal effect of such legislation. A matter within the jurisdiction of said committee may, if appropriate, initially be referred to another joint standing committee sharing jurisdiction of the subject-matter. Any matter reported favorably by such joint standing committee shall be referred to the joint committee on Health Care Financing, provided, however, that notwithstanding the provisions of any rule to the contrary, any such matter so reported shall not be read a first time in the branch in which the report was received. The next favorable report on any such matter, if made by a joint committee, may be made to either branch. Such next favorable report shall be considered the first reading. The branch of origin for any such bill so reported shall be the branch receiving such favorable report.

For all matters initially referred to the joint committee on Health Care Financing and not previously referred to another joint committee, the joint committee on Health Care Financing may make favorable reports to either branch, at the discretion of the committee, except that reports on money bills shall be made to the House.

In compliance with the provisions of section 38A of chapter 3 of the General Laws, the joint committee on Health Care Financing when reporting on bills referred to them shall include therewith a fiscal note prepared in accordance with the provisions of section 3A of chapter 29 of the General Laws, showing the estimated cost or the fiscal effect of the proposed legislation, if, in the opinion of said committee, such cost or fiscal effect exceeds the sum of one hundred thousand dollars ; provided, however, that any matter reported by the committee on Health Care Financing with a fiscal effect that does not exceed one hundred thousand dollars shall not be referred, under the rules, to the committee on Ways and Means.

Summary of Committee Activity 2007-2008:

Referrals

During the 2007 and 2008 Legislative Session four hundred and fifty seven (457) bills were referred to the Committee on Health Care Financing.

126 bills were *primary referrals*. The range of subject matters included: health care access, health care financing, hospital financing, uncompensated care, pharmacy, MassHealth (eligibility, covered services, providers, waivers and long term care policy), health insurance, health care technology, direct care workers, ambulatory surgical centers and the Division of Health Care Finance and Policy (DHCFP).

331 bills were *secondary referrals*. The bills had previously been acted on by the following Joint Committees:

Children and Families	30
Consumer Protection	1
Economic Development and Emerging Technologies	1
Education	8
Elder Affairs	35
Environment, Natural Resources and Agriculture	2
Financial Services	31
Judiciary	5
Labor and Workforce Development	1
Mental Health and Substance Abuse	42
Municipalities and Regional Government	2
Public Health	153
Public Safety and Homeland Security	2
Public Service	14
Revenue	1
Rules	1
Transportation	1
Veterans and Federal Affairs	1

Hearings

The Committee held nine public hearings on legislation in 2007 and one in 2008. The Committee held one informational hearing in Western Massachusetts in 2007 on the status of the primary care physician workforce.

Post-Employment Benefits Forum

In March 2007, the Committee sponsored a forum on post-employment benefits and the issues related to them for legislators and staff. Recent changes to governmental accounting standards now require governmental entities, including cities, towns and the state, to account for the future cost of benefits, including health coverage, promised to current and future retirees. This requirement has major implications for local municipal budgets, as well as for the state. The forum included presentations by the Massachusetts Comptroller, administration officials, and outside experts designed to educate legislators about the new requirements and how to address issues related to them.

Primary Care Physician Workforce Hearing in Western MA

Due to growing concerns across the commonwealth regarding primary care physician shortages, Representative Kulik and Representative Donelan hosted an informational hearing at the University of Massachusetts-Amherst in late 2007 where physicians and physician recruiters testified about the issue of primary care physician workforce shortages. Interested parties testified on bills aimed at addressing the shortage problems and were presented with H 4514 which created a primary care loan repayment program as well as a workforce council. H 4514 was based on the notion that it is imperative to keep Massachusetts-educated physicians in the commonwealth and that providing particular incentives for them to practice, especially in under-served areas, would help this cause. The workforce provisions of Chapter 305 of the Acts of 2008 were based in large part on the language from H 4514.

Currently, the Department of Public Health (DPH) is working to structure the health care workforce center created by Chapter 305, and the Governor's office is in the midst of the appointment process for the health care workforce council also created by Chapter 305. DPH is also working to establish criteria for a primary care loan repayment program which will help induce physicians and nurses to practice in underserved regions of the commonwealth.

Special Commissions

Ambulatory Surgical Centers and Medical Diagnostic Services

The Special Commission on Ambulatory Surgical Centers and Medical Diagnostic Services was created in 2006 in response to growing concerns about two separate, but related, topics: 1) ambulatory surgical centers and 2) medical diagnostic technology, specifically Magnetic Resonance Imaging (MRI) services. The Commission, established by Section 105 of Chapter 139 of the Acts of 2006 (the FY07 budget), first met on September 27th and held several subsequent meetings, informational sessions and a

public hearing. Pursuant to Section 105, the Commission submitted a report along with recommendations on June 30, 2007. Please see Appendix B for the full report.

e-Health

The Fiscal Year 2008 Budget (Chapter 130 of the Acts of 2007) created an electronic health records task force within EOHHS. The task force's mission was to provide a structure which would allow the state to take a leadership role in developing state and federal standards for the implementation of electronic health records. The task force was subsumed by the e-Health Institute created by Chapter 305 of the Acts of 2008.

Disparities

First convened in December 2007, the council is currently working to establish priorities and benchmarks for success.

Please see section on Chapter 58 legislative updates.

2007-2008 Health Care Financing Legislation Signed into Law

Acts of 2007

Chapter 1
Further Revising the Membership of the Public Health Council

This law changes the membership of the Public Health Council by decreasing the membership from 17 to 14 and requiring that 12 of the members of the council be appointees of the governor. The law also decreases the number of members who are providers of health services and clarifies that the two non-provider members who are not to be appointed by the governor are to be appointed by certain secretariats.

Chapter 142
Protecting the Confidentiality of Patient Records

This law grants a client the privilege of refusing to disclose, and of preventing a witness from disclosing, any communication between a client and a licensed mental health practitioner employed in a state, county or municipal government agency. In order to be deemed privileged, the communication must be relative to the diagnosis or treatment of the client's mental or emotional condition during a court, pursuant to certain enumerated exceptions.

Chapter 205
An Act Further Regulating Health Care Access

This law makes numerous technical corrections to health care provisions enacted as part of the 2006 Massachusetts Health Care Reform Law (see page 20 for a detailed discussion of its provisions).

Chapter 219
Investment of Reserves by Dental Service Corporations

This law modifies the prior law on reserves held by dental service corporations by deleting a section of law which restricted the amount of invested assets that could be invested in mutual funds and which allowed a corporation to deposit any amount of its funds in savings bank or savings accounts in a trust company. The law further requires that all other funds, other than the reserve funds, may only be invested as permitted by chapter 180A.

Acts of 2008

Chapter 87
Regulating Certain Insurance Benefits for Elected Officials of the Town of Easton

Clarifies that town officials who receive a stipend are *not* eligible for participation in the town's group health plan unless they pay 100% of the premium cost; grandfathers in current officials who are enrolled in the plan. Current state law dictates that city and town officials are eligible for enrollment in municipal group health plans as long as they receive any compensation; this Act allows Easton to deviate from that provision.

Chapter 116
Municipal Retiree Health Insurance in the Town of Lanesborough

Requires the Town of Lanesborough to pay 90% of the health and dental insurance premium amounts on behalf of former employees who retired prior to July 1, 1993, and on behalf of their eligible dependents.

Chapter 125
Exempting Seniors from Certain Bank Fees

This law directs bank agents to waive bank record fees for individuals who are seeking the information to verify their income for a MassHealth application. When applying for MassHealth long-term care services, elders are required to furnish bank records to demonstrate their income level and show that no assets have been transferred. Banks charge hefty fees for these records and this expense can impose an undue hardship for elders living on low, fixed-incomes.

Chapter 126
Promote the Safety of Victims of Violence

This law requires DPH to develop guidelines for the establishment of programs to protect the safety of victims of violence which coordinate services with state, community and clinical resources. The law further requires the department to establish a program to disseminate the guidelines and train health care providers on the establishment of programs under the guidelines.

Chapter 153
Retirement and Health Benefits Of Certain Elected Officials of the Town of Tyringham

Specifies that town officials who earn less than $3,000 (to be adjusted annually for inflation) are ineligible for the town's health plan; grandfathers in officials who are currently enrolled in the plan. Formerly, state law dictated that city and town officials were eligible for enrollment in municipal group health plans as long as they received any compensation. This Act allows Tyringham to deviate from that provision.

Chapter 176
Child Abuse and Neglect

The law provides a comprehensive, interagency strategy to address child abuse and neglect in the commonwealth by, *inter alia*:

- Creating Office of the Child Advocate whose duties will include reviewing and investigating critical incidents, investigating complaints and creating a 24-hour hotline for foster care children.
- Creating an advisory commission on grandparents raising grandchildren.
- Requiring instruction for municipal police officers on statewide policies and procedures for handling minors when their parents or guardians are placed in custody.
- Requiring the Executive Office of Health and Human Services (EOHHS) to assess, coordinate, and integrate responses to child abuse and neglect.
- Providing liability protections for mandated reporters who contact law enforcement.
- Requiring the Department of Children and Families (DCF) to commence investigations when a child is in immediate danger within two hours, with an interim determination within 24 hours and a final determination within five business days.

Chapter 214
Increasing Coverage of Non-Prescription Enteral Formulas

Amends prior law that required health plans to cover the cost of non-prescription enteral formulas for people with certain genetic digestive disorders. Previously, the law required coverage for formula costs up to $2,500; the new law raises that amount to $5,000.

Chapter 217
Equality in the Mass-Health Program

This law brings the MassHealth program into conformity with state law recognizing same-sex marriages by providing the same level of MassHealth benefits to all spouses of MassHealth recipients. This law will most notably affect spouses of elderly or disabled MassHealth beneficiaries who are receiving long-term care. The expense of nursing facility care can rapidly deplete a couple's financial savings and leave the spouse residing in the community without adequate financial resources to support themselves. To guard against impoverishment, MassHealth allows the spouse of an institutionalized person receiving benefits to retain a portion of the couple's assets without counting against the MassHealth eligibility of the institutionalized person.

Chapter 251
Relative to Nursing Home Transfers and Discharges

This law stipulates that when a resident who is being discharged from a nursing home requests a hearing that a "referee" determine whether the facility has provided sufficient orientation and preparation for the discharge of the resident to a safe and appropriate setting. Previously, the facility only needed to give the resident a notice of the transfer or discharge.

Chapter 256
Mental Health Parity

The law requires that health insurance companies doing business in the commonwealth to provide coverage on a nondiscriminatory basis for the diagnosis and treatment of the following four *additional* biologically-based mental disorders: eating disorders, post traumatic stress disorders, substance abuse disorders and autism. Additionally, the law requires that coverage be provided on a non-discriminatory basis for the diagnosis and medically necessary and active treatment of *any* mental disorder.

Chapter 282
To Improve the Long Term Care Career Ladder Program

This law adds long-term care labor management workforce patnerships to the list of those who may compete for career ladder program grants. The Extended Care Career Ladders Initiative (ECCLI) was established by the Legislature in 2000 in response to high turnover and vacancies among paraprofessionals in long term care institutions. These grants attempt to address high staff turnover rates by creating career ladders through approved training programs.

Chapter 305
Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care

Chapter 305 grew out of the commitment and leadership of Senate President Therese Murray to identify ways to improve quality and cost effectiveness in the delivery of health care in the commonwealth. In March 2008, Senator Murray introduced Senate Bill 2526, An Act to promote cost containment, transparency and efficiency in the delivery of quality health care. In June 2008, the House introduced a bill under the leadership of Speaker DiMasi (House Bill 4974) which was in line with the spirit and goals of the Senate President's bill, but which approached several topics and sections in a different way. After a short conference committee, the Senate and House leadership agreed on a version of the so-dubbed "cost-quality bill." This bill became Chapter 305 of the Acts of 2008 on the last day of the formal session and will pave the way for additional future cost-containment initiatives.

This law represents a commitment to contain the rising costs of health care and to improve access to quality, affordable healthcare in the commonwealth by:

- Encouraging the adoption of health information technology, including e-health records, by creating an e-health institute to provide oversight and implementation plans for a statewide interoperable electronic health records system by 2015.
- Promoting pharmaceutical reforms including implementation of an academic detailing program and a pharmaceutical manufacturer's code of conduct.
- Promote enhanced transparency and efficiency in the health care system through annual hearings at which health care providers and insurers will testify on health

care cost drivers and standardizing coding claim sets used in processing health care claims.
- Enhancing quality by requiring hospitals and clinics to report data on hospital acquired infections, serious reportable events and serious adverse drug reactions as a condition of licensure and establishing a pilot program for the use of Physician Order for Life-Sustaining Treatment (POLST).
- Promoting payment reform, including making recommendations for a common health care payment methodology for use by all payers and establishing a medical home demonstration project to provide patient-centered care coordination.
- Strengthening the health care workforce by creating loan repayment programs for doctors and nurses who commit to practicing primary care in underserved areas of the commonwealth and requiring that nurse practitioner services be covered and allowing patients to be able to choose a nurse practitioner as their primary care provider.

Chapter 321
An Act Relative to Children's Mental Health

This law enhances the early identification of children with mental health needs and expands access to mental health care by:

- Establishing a children's behavioral health advisory committee within EOHHS. The committee is responsible for advising the governor on legislative and regulatory recommendations such as best practices for children's behavioral health, issuing licensing standards for children's mental health programs and reducing racial and ethnic disparities in the delivery of care.
- Creating interagency teams to collaborate on complex cases when a child might need services from multiple state agencies.
- Directing the secretary of EOHHS to coordinate the purchase of behavioral health services for children to improve service delivery and create a comprehensive community-based behavioral health delivery system.
- Instructing the board of the Department of Early Education and Care (EEC) to train child care providers in identifying and addressing the behavioral health needs of children in their care.
- Requiring EOHHS to implement policies and procedures to ensure that children don't become "stuck" in hospitals and ensure movement into appropriate community-based settings.
- Establishing a children's behavioral health research center within the Department of Mental Health (DMH) with a mission to ensure a highly skilled children's behavioral health workforce and cost-effective and evidence-based services.
- Convening a working group under the Office of Medicaid on the early identification of children's developmental, mental health and substance abuse problems in pediatric primary care settings.

- Establishing a task force on behavioral health and public schools within EEC to build a framework to promote collaborative services and supportive school environments for children.
- Granting authority to the Division of Insurance (DOI) to regulate behavioral health manager companies.

Chapter 323
An Act Prohibiting Restrictive Covenants for Social Workers

This law renders void and unenforceable the section of any professional contract involving a social worker which restricts the right of the social worker to practice in any geographic area of the commonwealth for any period of time after the termination of the employment relationship. This law seeks to improve access to mental health services by protecting social workers and their patients from covenants not to compete; covenants which are also void and unenforceable for physicians and nurses.

Chapter 333
An Act Relative to Biomedical Research

This law differentiates between a "fetus" and a "neonate" for the purpose of determining which procedures are permissible under biomedical research. The previous law was vaguely written and was interpreted to prohibit neonatal research unless it provided a direct therapeutic benefit to the baby. Under the new law, research may be conducted that has been approved by the Institutional Review Board and satisfies existing comprehensive federal regulations on the protection of fetuses and neonates. It also specifies that diagnostic or remedial procedures to determine the life or health of the fetus/neonate or procedures to preserve such life are allowed.

In addition, the law directs the attorney general to provide a written advisory opinion concerning whether such proposed research is regulated, prohibited, or authorized by the law. Should the research be authorized under this law, the advisory opinion constitutes an affirmative defense to any criminal prosecution brought upon the medical institution.

Chapter 336
An Act relative to sudden, unexplained child deaths

This law requires that the state child fatality review team conduct a study related to training and protocol for first responders and investigators when there is a sudden and unexplained death of child less than three years of age. The law requires the team to look into the feasibility of adopting statewide protocols in these cases and requires them to look at the Center for Disease Control and Prevention's protocols as a model.

Chapter 342
An Act Relative to Blood Donations by Minors

This law allows minors ages 16 to 17 to donate blood with the consent of a parent or guardian. Previously, only minors age 17 or older were permitted to donate blood without the prior consent of a parent or guardian.

Chapter 374
Amending Certain Health Insurance Options for Municipal Retirees

This law amends the statute governing municipal and regional health insurance coverage to enable municipal and regional governments to adopt measures requiring future retirees to enroll in Medicare, while allowing current retirees to remain in non-Medicare plans. Prior to the passage of this Chapter, cities, towns, and regional governments were permitted to require Medicare enrollment, but such measures had to apply to both current and future retirees, which created obstacles to adoption on the local level.

The new law maintains current statutory guarantees that coverage for retirees enrolling in Medicare be on par with the health coverage a retiree would otherwise receive (via coverage that supplements Medicare). The Medicare enrollment requirement mirrors current practice for state employees who receive coverage through the Group Insurance Commission (GIC), and is expected to produce significant savings for local governments that adopt it.

Chapter 421
An Act Relative to the Retirement and Health Benefits of Certain Elected Officials in the Town of Hull

This law stipulates that any elected official in the Town of Hull who receives compensation of less than $10,000 per year shall not be eligible for retiree benefits and health insurance under chapters 32 and 32B of the general laws. The law makes it clear that this will not affect elected officials holding office as of January 1, 2008.

Chapter 479
An Act Providing for the Establishment of Other Post Employment Benefits Liability Trust Funds in Municipalities and Certain Other Governmental Units

This law permits towns, cities, districts and counties to establish retiree health care funding trust funds and schedules. The purpose of such a schedule is to reduce the unfunded actuarial liability of retiree benefits, such as health care, to zero, while meeting the normal cost of all future owed benefits. The schedule is to be developed by the chief executive of the governmental unit, and approved by an actuary at DOI. It is to be renewed every three years in the same manner. Governmental units are permitted to appropriate the amounts required by the schedule to the separate retiree health care liability fund. Interest and other income will be added to the fund. Amounts received as a participant in the Retiree Drug Subsidy Program created under Medicare Part D may also be added to the fund.

Chapter 511
An Act Relative to Caregiver Education and Health Care Authorization

This law permits a parent or legal guardian to authorize a designated caregiver, through an authorization affidavit, to consent to medical care, obtain health care and insurance records, and make educational decisions on behalf of a minor. The statue also extends to probate courts the exclusive jurisdiction of actions concerning the execution and validity of caregiver authorization affidavits.

Chapter 521
An Act Relative to the Uniform Probate Code

This law creates Chapter 190B, which codifies the Uniform Probate Code. The purpose of the law is to increase efficiency in the probate system and to simplify the process of settling a decedent's estate by establishing formal rules relating to intestacy situations and appointment of personal representatives, among other things. The law also provides increased protection for elderly and disabled persons by amending the current guardianship and conservatorship laws so that they focus on actual evidence of a person's functional limitation in providing for his or her needs.

Chapter 527
An Act Relative to Food Allergy Awareness in Restaurants

This law directs common victuallers and innholders that serve food to display in the staff area a poster approved by the DPH relative to food allergy awareness. Further, menus must provide notice to costumers to inform their servers of any food allergies. The statue also states that an inn's food protection manager, in order to obtain certification, must view a video concerning food allergies. All certified food protection manager examinations must also include questions concerning food allergies as they relate to food preparation. Lastly, the statue directs DPH to develop a program for restaurants to be designated "Food Allergy Friendly" and will maintain a list of restaurants receiving such designation on its website. Restaurant participation is voluntary but they must meet certain DPH determined requirements to qualify.

Chapter 528
An Act to Establish Collaborative Drug Therapy Management

This law allows registered pharmacists to work collaboratively with physicians to prescribe, monitor, and evaluate the results of drug therapies. It requires a written protocol to be developed and agreed upon by both pharmacist and supervising physician. The engagement in collaborative drug therapy agreements is restricted to certain settings including hospitals, long-term care facilities, hospice settings, retail drug outlets and ambulatory care clinics.

Chapter 529
An Act Relative to Public Health Regionalization

This law strengthens the Massachusetts public health system through amending laws regarding the establishment of regional public health districts by:

- Allowing two or more municipalities to jointly employ a health director. Previously, cities were excluded from sharing such a director. It also directs DPH to develop regulations for minimum qualifications for district health directors.
- Requiring a vote of the board of health, in addition to a vote by city council or town meeting, for a municipality to join a regional public health district and Preserving legal local authority, or home rule, for participating municipalities after a district is formed.
- Allowing the regional board of health to adopt rules and regulations for the promotion of general health and extending to the board powers such as the ability to execute contracts, receive and expend funds, and apply for grants.
- Granting DPH the power to establish a formula for the state to reimburse regional health districts for the costs of initial capital outlays and, subject to appropriation, operating expenses.
- Ensuring that employees of a regional health district may return to their former municipal positions should their municipality withdraw from the district or the district disbands.
- Directing DPH, in consultation with the Department of Environmental Protection, to establish minimum performance standards for basic programs of health administration, personal health, laboratory services, health resources and other preventative health programs to protect the public's health.

Chapter 530
An Act to Improve, Promote and Protect the Oral Health of the Commonwealth

This law acts to strengthen the state's oral health infrastructure and workforce and increase access to care by:

- Establishing statutory authority for the Office of Oral Health within DPH and directing the commissioner to appoint a dental director to oversee its operation. The office's responsibilities include providing recommendations for preventing oral disease, monitoring the oral health needs and resources of the commonwealth, expanding and evaluating oral health services in the state, and distributing information concerning oral health to the health community.
- Making the director of MassHealth's dental program a full-time position and instructing the director to work collaboratively with the director of the Office of Oral Health in order to increase MassHealth recipients' access to dental public health programs and reduce oral health disparities.
- Granting registered dental hygienists the power to practice in public health settings without the direct supervision of a dentist.

- Directing DPH to submit a report on public health dental hygienists in order to evaluate whether allowing dental hygienists to practice more independently in public health settings improves access to safe and effective dental services.

Other Significant Legislation

H 4376
An Act Relative to School Nutrition

The Committee redrafted and acted favorably upon this secondary bill from the Joint Committee on Public Health to establish nutritional standards for food and beverages sold or provided in a la carte lines in school cafeterias, school stores, school snack bars and vending machines. As redrafted by the Committee, the bill directs DPH, in consultation with the Department of Education (DOE), to establish guidelines in nutrition standards for food and beverages sold in public schools and methods for the phase-in of such standards. DPH and DOE are also enabled to make reasonable exemptions from such standards for special school events. In addition, the redraft directs the Department of Agricultural Resources (DAR) to work in consultation with DOE in studying the feasibility of developing and establishing a farm-to-school program to facilitate the purchase of local farm products by area schools and colleges. Finally, the redraft calls for the phased-out use of "fryolators" in public schools, the establishment of a Governor's Commission on Childhood Obesity, and makes other various technical changes.

[Referred to the House Committee on Ways and Means]

H 1005
An Act to Prevent the Sharing of Prescription Data

The Committee acted favorably upon this secondary bill from the Joint Committee on Financial Services to prevent sharing of prescription data, otherwise known as "data-mining". Data-mining is the process by which, through a third party, pharmaceutical companies purchase confidential prescription drug information from pharmacies for use in their physician-targeted marketing and advertising campaigns. Pharmaceutical companies are able to target those physicians who are either prescribing a lot of their product in order to encourage them to continue to do so, or not enough of it, in order to entice them to start. This kind of targeted marketing has been shown to lead to excessive prescribing of name-brand drugs which is not only expensive, but can have significant public health consequences, and is most often done without the physician's consent or even knowledge. The bill prohibits pharmacists from revealing the contents or nature of any prescription, including the name of the prescriber with any person other than the patient or his or her authorized representative. Thus, the bill seeks to prevent the kind of data-mining described above, while retaining the ability for companies to purchase the information for research and clinical trial purposes.

A version of this bill was included in House 4974 An Act to Contain Health Care Costs, Enhance Quality and Promote Transparency and Workforce Development, however, it was left out of the conference committee report, and thus was not a part of Chapter 305 of the Acts of 2008.

[Referred to the House Committee on Steering, Policy and Scheduling]

S 2775 An Act Relative to Pandemic and Disaster Preparation in the Commonwealth

The Committee redrafted and acted favorably upon S 2259 which was in turn redrafted by the Senate Committee on Ways and Means. The most significant difference between the two bills was that Senate Ways and Means removed a line item of $36.5 million which would have funded a number of measures designed to improve the commonwealth's capacity to respond to a pandemic flu.
This bill specifies certain roles and responsibilities in the event of a pandemic flu outbreak or other disaster by:

- Granting power to the commissioner of DPH and local public health authorities in a public health emergency which is declared by the Governor.
- Authorizing the Governor to enact an emergency plan and granting civil immunity to those who provide services during a public health emergency.
- Granting DPH the power to require health care providers to report diseases to DPH and local public health authorities. Requires reporting and accurate and confidential record keeping by the department and local public health authorities.
- Requiring mandated reporters to report suspected criminal causes of a public health emergency.
- Requiring DPH to establish a volunteer registry for individuals who can provide services during a public health emergency. Grants the commissioner authority to activate the volunteers during a declared emergency and to request assistance from other states if necessary.
- Authorizes the commissioner or local public health authority to issue an order requiring various safety measures if there is a threat of disease or to decrease or prevent the spread of disease.
- Defining "isolation" and "quarantine" and granting power to the commissioner and local public health authorities to isolate or quarantine individuals or domestic animals.
- Granting authority to the governor to declare, in conjunction with the attorney general and director of the office of consumer affairs and business regulation, a supply emergency as a result of specified disasters.

[Engrossed in the Senate and referred to the House Third Reading]

LEGISLATIVE CHANGES TO CHAPTER 58

During the previous (2005-06) legislative session, a major achievement of the Committee was the crafting of a comprehensive health reform law, the first of its kind in the nation. While responsibility for implementation of the new law lies primarily with the administration, the Committee continues to play an important role in that process, particularly as the need for legislative adjustments to the original, and very complex, law arises. During the 2007-08 session, the Committee took action on a number of bills that made technical and substantive changes to provisions that were included in Chapter 58. In addition, the Committee members and staff provided input and assistance as the House and Senate Committees on Ways and Means made additional adjustments within budget language. This section provides details on the changes made in 2007-08.

Chapter 1 of the Acts of 2007: An Act Further Revising the Membership of the Public Health Council

The Public Health Council was established by the legislature in the nineteenth century to advise the commissioner of DPH on policy decisions and promulgate public health regulations. Before 2006 all nine members of the council were appointed by the governor. But over time concerns arose about the politicization of the Council by governors, and the legislature wanted to assume some authority over the Council.

Both the initial House and Senate health reform proposals that ultimately resulted in Chapter 58 contained provisions (contained in MGL 17 § 3) changing the composition of the Council and the manner in which future appointments are to be made. The original law simply called for members whom were "providers" and "non-providers" on the Council, leaving wide latitude for the governor to chose who filled those roles. Both chambers' proposed versions increased the number of members and added experts from medical schools, providers, and consumer groups. Specific consumer and provider groups, such as the Massachusetts Public Health Association and the Massachusetts Medical Society, were given appointing privileges. Differences remained, however, on a few of the specific groups. In addition, the House retained four slots under the nominating power of the governor while the Senate version had no members appointed by the governor. The conference committee version, and ultimately the language that was included in Chapter 58, included the appointing privileges of medical and consumer groups and left no slots for the governor to appoint. Governor Mitt Romney vetoed this section of the bill and the legislature subsequently overrode the veto.

Governor Romney responded to the override by filing a lawsuit against the commonwealth in November of 2006. He charged that the legislature had breached the constitutional separation of powers by barring the governor from naming members to the council, an executive panel. The timing of the lawsuit was designed to allow the court to determine the constitutionality of this section prior to undergoing a transition in the membership of the Council on February 1, 2007.

In response to the Governor's lawsuit the legislature sought corrective action at the end of the 2005-2006 session in the form of an amendment to Ch. 58 (approved in

December of 2006). The amendment required non-governmental health care related groups to submit three names to the Governor who would in turn appoint one as a member of the Council. This allowed for Romney's successors to appoint 12 members but still required consultation with health care groups. Governor Romney vetoed this bill, but the legislature re-enacted the legislation at the start of the formal session in January of 2007. Newly-elected Governor Patrick signed the bill and it became Chapter 1 of the Acts of 2007.

Chapter 205 of the Acts of 2007: An Act Further Regulating Health Care Access

This chapter contains a number of important technical changes to further enable implementation of the Massachusetts Health Care Reform Law and to provide clarification where needed. The law:

- Redefines some of the responsibilities of the disparities council which was created in Chapter 58, including requiring the council to make recommendations to increase racial and ethnic diversity in the health care workforce and requiring the council to coordinate its efforts with the health care quality and cost council. Further, it adds three members to the council, including the attorney general, the Massachusetts Hospital Association and Blue Cross Blue Shield of Massachusetts. Finally, it requires that the council meet at least bimonthly.
- Corrects statutory references to the Health Safety Net Office and Trust Fund (which replaces the Uncompensated Care Pool) and adds oversight language to ensure adequate management of the new program including a requirement that DHCFP enter into a service agreement with MassHealth to develop and implement a plan to enhance oversight and improve operations of the Health Safety Net Trust Fund. That plan must include analysis of free care and emergency bad debt claims; implementation of an approach to identify all sources of third-party liability for patients receiving free care; and implementation of an on-going claims and utilization review system.
- Clarifies the definition of "dependent" related to the provisions requiring insurers to cover individuals up to age 26 or two years after the loss of their dependent status, whichever is first.
- Allows for interagency information sharing between DOR, DHCFP, MassHealth, and DOI in order to facilitate the implementation of health reform provisions, including for the purposes of establishing whether an individual has complied with the individual mandate. Because there is the potential of sensitive information being shared, this chapter also requires that such information be limited and that none of the information so shared is to be a matter of public record.
- Allows the MassHealth Wellness program created in Chapter 58 to use incentives which include premium and copayment reductions in order to incentivize compliance with wellness goals.
- Expands the age range for the Young Adult Plans so that 18 year olds are included.

- Creates a legislative commission to study the role of the Connector in providing access to health insurance products, including investigating ways to promote efficient enrollment of uninsured individuals in to health insurance.
- Exempts data provided to the Massachusetts Health Care Quality and Cost Council (QCC) from public records law except as provided in Council regulations. Further requires such regulations to consider patient privacy protections and the prevention of the release of information that could result in collusion or anti-competitive conduct.
- Clarifies what the QCC website shall consist of and sets deadlines for the operation of different components of the website.
- Tightens the time by which employers must remit "free-rider" surcharge payments from 180 days after assessment to 90 days after assessment.

Budget Changes to Chapter 58

Acts of 2007

Chapter 16 (FY07 supplemental budget, 2/07)

Section 8 authorizes the use of $3 million of the health reform implementation reserve funds allocated in Chapter 58 for the purpose of the implementation of the Fair Share assessment by the Division of Unemployment Assistance.

Chapter 42 (FY07 supplemental budget, 5/07)

This bill made changes to bring Medicaid statute (MGL 111E§23) concerning third-party liability in line with federal law. Although not technically a change to health reform provisions, the law inadvertently replaced language inserted by Chapter 58 with incorrect references; these were corrected by Chapter 205 (see below).

Chapter 61 (FY08 General Appropriations Act)

The FY08 budget included several technical changes to Chapter 58:

- **Section 15** moved the Health Safety Net Office from under the Office of Medicaid, where Chapter 58 placed it, to DHCFP; a separate section (**45**) contained language requiring DHCFP and Medicaid to coordinate oversight of the new office.
- **Section 16** amended Chapter 58 to specify that a portion of revenue from Fair Share contribution payments by employers may be used to pay for administrative costs of collecting the payments, and **section 63** allocated $1.8 million (to be transferred from the Medical Security Trust Fund) for such initial costs.

In addition, sections 55, 57and , 60 govern transfers of various funds—including allocations for Commonwealth Care, the Safety Net Trust Fund, and Essential Community Provider grants to hospitals, and section 42 amended the Chapter 58 provisions governing Pay-for-Performance and associated provider rate increases.

Chapter 122 (FY07 supplemental budget, 9/07)

This supplemental budget allocated an extra $9.5 million for Essential Community Provider Trust Fund grants (in addition $28 million allocated in the FY08 budget two months earlier).

Chapter 140 (FY07 supplemental budget & other legislation, 10/07)

Sections 57 and 57A amend FY08 budget language by further specifying the terms of various transfers of health-related funds to certain hospitals.

Chapter 194, An Act Relative to the Sharing of Information by the Division of Unemployment Insurance

This act originated in an amendment proposed by the Governor to section 17 of the FY08 budget. The final language, which reflects a further amendment by the legislature, authorizes the Division of Unemployment Insurance to share information with the Division of Health Care Finance and Policy in order to implement the Fair Share and Free Rider Surcharge provisions of the reform law.

Chapter 228 (FY08 supplemental budget, 12/07)

Section 7 contains a technical change specifying that penalties for violation of the requirement that individuals obtain health care if it is affordable are to be determined with reference to the cost of plans offered through the Connector.

Acts of 2008

Chapter 120 (FY08 supplemental budget, 5/08)

Sections 4 and 5 amend the FY08 budget to increase amounts allocated for expenditures on the Commonwealth Care health insurance program and the Safety Net Care program.

Chapter 182 (FY09 General Appropriations Act)

Section 79 specifies that $58 million of the Medicaid rate increases provided by the health reform law will be linked to hospitals meeting performance standards in FY09.

Section 88 governs transfers among funds related to the financing of health care reform programs, and provides $869.4 million for the Commonwealth Care health insurance program and just under $383 million for the Health Safety Net Fund. The section also adds new language requiring the submission of quarterly reports detailing projected and actual revenues deposited in and expenditures made from

the Commonwealth Care Trust Fund, and requires EOHHS to structure expenditures in a manner designed to produce the maximum level of federal reimbursement.

Chapter 302 (FY08 supplemental budget, 8/08)

This supplemental budget included a number of provisions designed to increase funding for health reform programs. Included are provisions to tap excess health insurer reserves via a temporary assessment (section 17), changes designed to tighten the current rules governing Fair Share assessments on certain employers who do not make a fair and reasonable contribution to employee health care and to speed up the collection of those assessments (sections 18-19), increases in allocations for Commonwealth Care and the Health Safety Net Trust Fund to cover higher-than-expected costs (sections 26-27), technical changes to pay-for-performance language (section 54), a temporary increase in the assessment that hospitals pay to the Health Safety Net Trust Fund (section 57), and a transfer from the Medical Security Trust Fund (used to pay for health coverage for low-income unemployed people) for other health care uses.

HEALTH CARE COST CONTAINMENT AND QUALITY IMPROVEMENT IN MASSACHUSETTS: THE CURRENT LANDSCAPE AND FUTURE OPTIONS

A BRIEFING PAPER FOR MEMBERS OF THE COMMITTEE ON HEALTH CARE FINANCING

MARCH 11, 2008

Prepared by the Staff of the Committee on Health Care Financing
House of Representatives
Patricia A. Walrath, Co-Chair

CONTENTS

Introduction

The passage of Chapter 58, the Massachusetts Health Reform Law, was a major step in reform of the state's health care system and thus far the state has made huge strides toward reaching the law's goal of universal health coverage. Full, or nearly full, universal coverage has the immediate benefit of providing coverage to people who didn't have it before—a social good in itself—and can also be expected to benefit the health care system by leading to more efficient use of health care and potentially lower insurance costs as risk is spread among a larger, healthier population. However, it is increasingly clear that rising health care costs pose the greatest obstacle to successful implementation of universal health coverage. Too rapid cost growth could endanger the viability of the new Commonwealth Care subsidized insurance and existing Medicaid programs. In addition, the continued trend of private insurance cost increases that substantially exceed inflation and income growth will continue to put pressure on employers and individuals, both crucial partners in health reform. At the same time, greater access to health coverage is not meaningful if the quality of the care available is not adequate, if the newly insured can't find health providers, or low quality care brings with it additional costs.

Rising health care costs pose the greatest obstacle to successful implementation of universal health coverage.

This briefing paper, prepared by Committee on Health Care Financing staff, is meant to provide relevant background as legislators and other policymakers move to address cost and quality issues. Part I of the paper provides a general overview and discusses some of the themes that have informed this discussion on a national level. Parts II and III focus more directly on Massachusetts and review existing public and private cost and quality initiatives (in Part II) and current legislative proposals and new initiatives (in Part III). A final summary section notes questions that policymakers need to consider as they consider options for future state action in this area.

I. Cost & Quality Issues Background

The cost and quality field is a broad one—in fact nearly everything that happens in the health care world has some relation to cost and quality. As concern about cost and quality issues continues to grow, so has the academic and policy research work dealing with these areas. This section attempts to put the issues in context and highlights some of the main questions and themes that have been addressed.

Why Are Costs Growing?

Experts have cited many reasons for the growth in health spending over time. In part, spending is rising because of changes in the population, changes in disease prevalence, and the fact that the population is getting older and people live longer now – all changes that we cannot prevent or control. In addition, more people have insurance than they did in the 1970s and 1980s, which leads to more use of the health care system. Some experts argue that it may also contribute to the growth in new technology.[1]

Medical technology has been considered a major driver of the growth in health care spending. The increases are related to new, more costly technology and procedures and new, less expensive technology that leads to greater use along with increasing use of older technology such as MRIs. Research has shown that changing technology in medicine accounts for 50-66% of the increase in health spending outside of inflation.[2] The benefits of new technologies are not always as marked, however. Rather, in many cases, new technologies have minimal impact but cost significantly more than more traditional medical treatments. In such cases the societal benefit is questionable. Given the rapid growth of medical technologies over the past decade, doctors face increasingly complex decisions in directing the care of various patients suffering from a host of medical conditions. Likewise, insurance companies and state governments face tough moral and political decisions related to controlling utilization, providing, or mandating coverage of these new technologies.

[1] The Henry J. Kaiser Family Foundation. Health care costs: A primer, key information on health care costs and their impact. Aug 2007.
[2] Ginsburg PB. Controlling Health Care Costs. N Engl J Med 2004 Oct 14; 351;16:1591-3.

Are Cost and Quality Related?

Good access to care has been shown to be highly correlated with quality. However, research has demonstrated that, at best, there is no relationship between the cost and quality and, at worst, increased health care spending is associated with poorer quality care. For example, personal health care spending is not correlated with mortality—in other words, spending more does not necessarily reduce mortality. Indeed, states spending the most on health care often have the lowest quality ratings, higher state Medicare spending appears associated with higher preventable hospitalizations, and states with higher concentrations of specialists receive lower quality rankings.[3] While cost and quality are inextricably, although generally conversely related, for the purposes of generating policy solutions, it is important to try to isolate cost from quality.

Do Health Spending and Quality in Massachusetts Mirror National Trends?

Nationally, there has been increasing concern about the growth in health care spending. Health expenditures have increased by nearly 60% since 1970, more than doubling their share of the GDP between 1970 (7.2%) and 2005 (16%). At the current growth rate, health expenditures are expected to be nearly 20% of the GDP by 2016.[4] In 2004, Massachusetts was the second highest in the nation in health care spending per capita at $6,683 per person, compared with $5,283 nationally.[5] From 1991-2004, our average annual growth per capita was 5.7%, slightly higher than the national trend (5.5%) and putting us 31st among other states.[6] That gap has continued to widen in the most recent period—between 2000 and 2004, the average per capita growth rate in Massachusetts was 7.4%, compared to 6.9% for the entire country.[7]

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[3] Davis K. and Schoen C. State health system performance and state health reform. Health Affairs 2007; 26(6):w664-w666; Baicker K, Chandra A. Medicare spending, the physician workforce, and beneficiaries' quality of care. Health Affairs 2004; web exclusive: w4-184-w4197.

[4] The Henry J. Kaiser Family Foundation. Health care costs: A primer, key information on health care costs and their impact. 2007 Aug; 1-15.

[5] The Henry J. Kaiser Family Foundation. State Health Facts: Health expenditures by state of residence. Accessed 2008 Feb 25. Available at: http://www.statehealthfacts.org/comparecat.jsp?cat=5

[6] The Henry J. Kaiser Family Foundation. State Health Facts: Health expenditures by state of residence. Accessed 2008 Feb 25. Available at: http://www.statehealthfacts.org/comparecat.jsp?cat=5

[7] Massachusetts Health Care Cost Trends 1991-2004. Presentation to the Health Care Quality and Cost Council by Sarah Iselin, Commissioner, Division of Health Care Finance and Policy.

The Commonwealth Fund's 2006 Health System Performance scorecard noted that the United States spends the most on health care compared with all other developed countries, while demonstrating need for improvement on several comparable indicators related to quality, access, efficiency, and equity.[8] In addition, there were significant disparities from state to state in health system performance.[9] Massachusetts ranked 8th overall in health system performance but 35th in the 'Avoidable Hospital Use and Costs' and 20th in the 'Healthy Lives' categories.[10] Furthermore, racial and ethnic disparities persist in both access to quality care and in health outcomes. Nationally, significant disparities by race in health outcomes exist including disparities in infant mortality, life expectancy, and chronic disease rates.[11] Disparities also exist in access to care including significant disparities by race in use of preventive health services.[12] As a result, addressing health disparities is a national priority; the U.S. Department of Health and Human Services' Healthy People 2010 second goal is to eliminate health disparities.[13] Massachusetts, despite its high spending on health care, also has significant racial and ethnic disparities in health access and outcomes. The Department of Public Health just released its annual birth report which demonstrated persistent disparities in birth outcomes by race and ethnicity.[14] Furthermore, the Boston Public Health Commission has reported significant disparities by race in Boston, including disparities in health insurance rates, use of preventive services, mortality, and chronic disease rates.[15]

Cost Containment Efforts Past and Present

Managed Care, PPOs, and Consumer-Directed Models:

Health care costs have been growing for more than 40 years in Massachusetts and across the United States, and efforts at cost containment have an equally lengthy history. Beginning in the 1970s and reaching their height in the 1990s, managed care organizations and health

[8] Commonwealth Fund Commission on a High Performance Health System. Why not the best? Results from a national scorecard on U.S. health system performance. The Commonwealth Fund. Sept. 2206: 1-7.
[9] Ibid..
[10] Commonwealth Fund, MA State Scorecard on Health System Performance 2007.
[11] National Center for Health Statistics. Health, United States, 2004 with Chartbook on Trends in the Health of Americans. Hyattsville, MD: 2004. Available at: http://www.cdc.gov/nchs/data/hus/hus04trend.pdf#03
[12] National Center for Health Statistics. Health, United States, 2004 with Chartbook on Trends in the Health of Americans. Hyattsville, MD: 2004. Available at: http://www.cdc.gov/nchs/data/hus/hus04trend.pdf#03
[13] To view this or other HP2010 goals, visit: http://www.healthypeople.gov/
[14] Massachusetts Department of Public Health. Massachusetts Births 2006. 2006 Feb.
[15] Boston Public Health Commission. Data report: A presentation and analysis of disparities in Boston. 2005.

maintenance organizations (HMOs) promoted comprehensive coverage at a low premium, but such benefits came at the cost of consumer choice. With HMOs, also came increasing forms of care management in the forms of utilization review (retrospective analysis of appropriateness of care received) and utilization management (prospective efforts to control care received). These efforts were implemented primarily as cost controls with hopes for improving quality, and both utilization review and management are still used today. HMOs were successful in containing costs with set payments and networks but given their restrictive nature, they ignited resistance among consumers and providers alike. In the late 1990's resistance to HMOs gave rise to Preferred Provider Organizations (PPOs), which provide beneficiaries with access to care via networks based on negotiated price discounts with providers. However, due to the nature of the product design and the fact that enrollees are allowed to go outside of established networks to receive care, PPOs were less successful in managing costs and coordinating care.

Perhaps not surprisingly health care costs, which had remained low under managed care, once again began to increase after the heyday of managed care. More recently, the backlash against managed care has given rise to a new interest in consumerism. Consumer-directed models are intended to encourage consumers to take an active role in coordinating their care, for instance through the use of Health Savings Accounts attached to high deductible, catastrophic plans. Consumer-directed health plans use high cost sharing as a means of making consumers more price-conscious and reducing unnecessary discretionary spending. The landmark RAND experiment found the action of paying for medical care out of pocket made consumers more sensitive to costs and those consumers who paid for their own medical bills spent less on health care than individuals whose medical care was financed under a health plan.[16] However, more recent information suggests that such savings may occur at the expense of foregone necessary medical care. Most notably, the high cost-sharing obligation may act as an access barrier to low-income consumers with genuine medical needs.

In addition, other significant obstacles have impeded the success of the consumer-directed model. In particular, more support needs to be provided to make this model successful. While

[16] Manning, W., et al, "Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment," *The American Economic Review*, 77(3):251277, (June 1987)

the growth of the internet and recent trends towards public reporting and transparency of health care information has made a plethora of information accessible to consumers, much of the information is difficult for consumers to interpret. Lack of available information and/or overly technical resources hinder consumers' ability to make good health decisions, especially in times of duress, such as when they are sick and need care. These concerns call the long-term usefulness of this model into question.

Other Payer Cost Control Strategies:

In addition to the insurance models discussed above, public and private insurers, often led by the federal Medicare program, have also tried several reimbursement strategies to control costs, particularly at the physician and hospital levels including:

- Changing physician payment from fee-for-service to the Medicare developed 'resource-based relative value system' (RBRVS), a system that attempts to quantify the value of the work, associated practice and malpractice costs, and the 'resources' used to provide each service.
- Moving from a retrospective hospital payment for the actual cost of providing services to the Medicare model of paying by Diagnostic Related Groups (DRG). The DRG methodology groups patients based on diagnoses that require similar hospital resources.

More recently, public and private payers alike are looking towards the use of **Pay for Performance (P4P)** with a sense of optimism. Under P4P, a portion of payment is withheld and awarded to providers based on the quality of care provided (performance). In particular, it is hoped that the use of P4P will provide a tangible incentive for providers to improve quality. However, early findings indicate that P4P may not lead to marked improvements. A study comparing the impact of a P4P in the California PacifiCare network with a similar network that had not introduced P4P found that both networks exhibited a similar degree of quality improvement.[17] Moreover, growing concern centers on the question of whether providers will focus on the processes targeted by the P4P and consequently neglect other aspects of care delivery.

[17] Rosenthal M. et al. Early Experiences with Pay-for-Performance. JAMA 2005;294:1788-1793.

New Themes in Cost Containment

Separate from strategies on the payer side, there are a growing number of proposals whose proponents claim will help contain costs, improve quality, or both.

Hospital Acquired Infections

Nosocomial infections, or hospital-acquired infections (HAIs), pose a major problem in health care facilities across Massachusetts and the United States. The federal Centers for Disease Control and Prevention (CDC) assert that HAIs are a large contributor to mortality and morbidity among patients at facilities across the nation, estimating that 1.7 million instances of HAIs occur in hospitals across the nation and claim the lives of 99,000 patients annually.[18] Such infections not only pose dangers to patients, but also add unnecessary costs to the already straining health care system. In Massachusetts alone, it has been estimated that 34,000 HAIs may occur each year, resulting in extra care costs totaling $200 to $400 million.[19] In 2004, Pennsylvania became the first state to mandate hospital reporting of HAI rates, and the results show the magnitude of the problem. According to the Pennsylvania Health Care Cost Containment Council, the group charged with oversight of the reporting requirements, HAIs are prevalent in Pennsylvania's 168 acute care hospitals and have significant cost implications with regard to extra patient days. According to a 2006 report, Pennsylvania hospitals reported a HAI rate of 12.2 per 1,000 cases, requiring additional hospitalizations that cost an estimated $3.5 billion in hospital charges.[20] Public reporting has resulted in a documented reduction in hospital mortality rates.[21] Statistics like these have made the elimination of HAIs a hot topic. Most proposals have centered on increased reporting and limits on or witholding of payments for hospitalization related to HAIs. For instance, the Center for Medicare and Medicaid Services (CMS) announced last fall that it would end Medicare reimbursements for certain hospital-acquired conditions, including some

[18] Centers for Disease Control and Prevention (2007, May 30). *Estimates of Healthcare-Associated Infections*. Retrieved November 17, 2007 from <http://www.cdc.gov>.
[19] John Snow, Inc. and Betsy Lehman Center for Patient Safety and Medical Error Reduction for DPH. Prevention and Control of Healthcare-Associated Infections In Massachusetts: Final Recommendations of the Expert Panel. January 31, 2008.
[20] PCH4 (2006)
[21] PCH4 (October 2007). "Critical Condition: The State of Health Care in Pennsylvania." Retrieved from <http://www.phc4.org/reports/sos/07/docs/sos2007report.pdf>.

infections. Other proposals would limit HAIs by focusing on behavioral changes at the service delivery level, such as hand-washing requirements or use of procedure checklists.[22]

Chronic Disease Management

Like many other countries, the United States population is aging. In 2000, the proportion of individuals age 65 and older in the U.S. was 12.5 percent and this share is projected to grow to 16.6 percent by 2020.[23] Older individuals are more likely to have one or more chronic conditions. A 2004 Commonwealth Fund survey of older adults asked respondents if a physician had told them they had any of six conditions: hypertension, heart disease, cancer, diabetes, arthritis or high cholesterol. A majority—67%—of respondents aged 50-64 cited at least one chronic condition, as did 84% of those aged 65 to 70.[24] Other studies have shown that the 20% of Medicare beneficiaries with five or more chronic conditions account for 66% of Medicare spending and they receive services from an average of almost 14 physicians in a given year.[25] The Miliken Institute recently estimated the total economic impact of chronic illness on the Commonwealth of Massachusetts at $34 billion, including both treatment expenditures and lost productivity.[26] Miliken ranked Massachusetts 40th in the nation in its burden of chronic disease, and the Commonwealth Fund's 2007 State Scorecard ranked Massachusetts 32nd in the nation for hospitalizations for diagnoses where timely and effective primary care could have prevented or reduced the risk of hospitalization.[27] In response to these data and as the cost of providing health care increases, both public and private entities have embarked on a variety of chronic care and case management initiatives. One academic medical center recently estimated that care management programs could produce total savings of $3 to $5 billion dollars over the next 15 years in Massachusetts.

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[22] Gawande, Atul. The Checklist. New Yorker Magazine, December 10, 2007.
[23] Anderson GF and Hussey PS. Population Aging: A Comparison Among Industrialized Countries. Health Affairs, May/June 2000 19(3): 191-203.
[24] Collins SR, Davis K, Shoen C, Doty MM, How SK, and Holmgren AL. *Will You Still Need Me? The Health and Financial Security of Older Americans*. New York: The Commonwealth Fund, June, 2005.
[25] Partnership for Solutions," Medicare Cost and Prevalence of Chronic Conditions," fact sheet (Johns Hopkins University and the Robert Wood Johnson Foundation, July 2002).
[26] Milliken Institute, 2007 in *Health Care Quality and Cost Council Annual Report* (Draft), February, 2008, p. 11.
[27] Commonwealth Fund State Scorecard, 2007 in *Health Care Quality and Cost Council Annual Report* (Draft), February, 2008, p. 11.

Access to Primary Care Providers and Reduction of Disparities

As thousands of new individuals are getting health insurance for the first time under the Health Reform Law, there is growing concern among advocates and policymakers about the availability of primary care services. The Massachusetts Medical Society has reported that there are severe shortages in many medical specialty areas beyond primary care. Such shortages make it difficult for patients to get cost-effective preventive care, and arguably lead to overuse of more expensive specialty care. Advocates argue that measures to address the current shortage of primary care physicians (PCPs), such as loan repayment programs, could ultimately save billions of dollars. As with increased access to PCPs, the elimination of disparities in health care access and outcomes has potential benefits in both the areas of quality and cost, and it is one of the top public health priorities at the community, state, and national level.

Pharmaceutical Costs

Concern about prescription drugs as a factor in rising health costs has prompted a variety of proposals. These tend to focus in a few areas: a) encouraging patients to use generic drugs or other cost-effective options through prior approval, preferred drug lists, and tiered co-pay schemes, b) proposals designed to encourage cost-efficient prescribing by doctors, including limits on gifts from pharmaceutical manufacturers and better education concerning drug options for patients, and c) proposals designed to promote cost-effective purchasing of pharmaceuticals, such as bulk purchasing initiatives or coordinated purchasing on the state level.

Health Information Technology and Administrative Simplification

Advocates of administrative simplification—measures to decrease the amount of paperwork and administrative burden on both providers and payers—argue that such initiatives could save millions of dollars by decreasing the portion of health care spending that goes to such activities. Likewise, many have argued that greater use of technology can enhance the delivery of health care, decrease errors and enhance quality while saving dollars. Recent proposals in this area include the adoption of standard coding and physician credentialing systems. A recent study of the use of Computerized Physician Order Entry (CPOE) systems estimated that CPOE systems could save community hospitals in Massachusetts an average of $2.7 million per hospital by the third year of implementation, with a benefit to payers of $898,515, although the cost of

implementing the systems would exceed savings for the first two years.[28] Currently only 10 of 73 hospitals in Massachusetts use CPOE. Similar to CPOE, Electronic Health Records (EHR) have been heralded as both a cost-saving and quality-enhancing development in health information technology. Such a system would create a patient database containing a complete medical history for everyone in Massachusetts that could be accessed by all providers in the state, reducing medical errors and duplication of services.

Summary

Currently there is great variation among states in addressing cost and quality in health care. Reforms have focused on building consumer awareness of health spending and quality by publicly reporting data, expanding the use of electronic technology, and controlling chronic diseases, as well as some of the other strategies identified above. The chart on pages 12-13 summarizes the common themes and initiatives that have been tried at the state-level or that are frequently discussed in the literature.

It is important to note that many of the oft-proposed strategies represent short-term solutions that may reduce average health spending but do not address the more ominous problem of cost growth over time.[29] Furthermore, strategies aimed at improving 'efficiency' in the system can be politically risky because they can result in people getting less care and because "all health care spending represents someone else's income."[30]

Many of the oft-proposed strategies represent short-term solutions that do not address cost growth over time.

On the national level, efforts are underway to address this issue. Legislation has been filed to establish a Center for Comparable Effectiveness Research and has garnered significant support. It is anticipated that such a center may be placed under the auspices of the Agency for Healthcare Research and Quality.[31] The provision of clinical effectiveness research would help to guide both provider behavior and consumer health

[28] Massachusetts Technology Collaborative and the New England Health Care Institute. Saving Lives, Saving Money: The Imperative for Computerized Physician Order Entry in Massachusetts Hospitals. February 2008, 19-26.
[29] The Henry J. Kaiser Family Foundation. Health care costs: A primer, key information on health care costs and their impact. Aug 2007.
[30] Ginsburg PB. Controlling Health Care Costs. N Engl J Med; 351;16:1591-3.
[31] Wilensky, Gail. Developing a Center for Comparable Effectiveness Information. Health Affairs. November 7, 2006.

care decisions. Other countries have already established centers for comparable effectiveness. Many European health systems base pharmaceutical coverage decisions based on comparative effectiveness data. In particular, the National Institute for Health and Clinical Excellence (NICE) in England examines medical technologies and publishes guidelines for provider and consumer use.

Cost and Quality Themes		
Proposal	**Pros**	**Cons**
Transparency and Public Reporting ➢ Make public reliable quality and cost information (such as data concerning infection rates or mortality) on health care procedures and providers ➢ Provide general cost information to illuminate health industry costs (e.g., CEO salaries, proposed premium increases)	Empowers consumers to become more active participants in health care decisions and more efficient purchasers by making them more price-conscious; provide incentives for provider to improve quality of care to remain competitive. Provide data to further discussion about cost increase factors	Lack of easy-to-understand information can prevent successful navigation of health care system. Studies show that consumers generally don't use available information. Producing meaningful data can raise privacy and anti-competitiveness issues.
New Payment Methods ➢ Use **Pay-for-Performance (P4P)** to provide incentives for quality and other improvements ➢ Institute **Tiering** of providers to determine reimbursements ➢ Use **Value-Based Purchasing** and other mechanisms to align payments and incentives (such as extra payment for chronic care management, denial of payment for preventable errors)	Provides incentives for providers to improve performance. Provides incentives for consumers to seek higher quality providers through lower out of pocket costs.	May encourage providers to focus on the processes targeted by the program or avoid high-risk patients; can be financially burdensome on individual or small-group providers Developing appropriate measurements is difficult; new payment structures may improve quality but will provide only short-term cost benefit because they do not address the growth in costs over time.
Care Management ➢ Ensure access to providers and reduce disparities in access and outcomes ➢ Expand access to preventive care such as immunizations ➢ Improve management of chronic conditions such as diabetes and heart disease	Improved access and better care can reduce costs by controlling serious medical conditions and preventing unnecessary hospitalization. Proponents claim savings from chronic care would be immediate and substantial.	May reduce average costs without addressing issue of cost increases over time.

Health Information Technology ➢ **Electronic Health Records (EHR):** A database of patient health data that can be shared by clinical staff beyond immediate provider ➢ **Computerized Physician Order Entry (CPOE):** Allows doctors to enter treatment instructions into a system that connects to a patient's EMR and flags potential issues, such drug allergies or interactions ➢ **Telemedicine:** Allows providers to monitor chronically ill patients from off-site, via telephone or the internet	Improves quality and reduces costs by reducing the possibility for medical errors, coordinating care, and reducing administrative costs. Studies suggest that CPOE systems alone would save community hospitals as much as $2.7 million annually.	It is difficult to show each stakeholder how they will benefit individually in exchange for a high initial cost of implementation; multiple systems complicate the ability to maintain a cross-provider database; providers may have a disincentive to work with their competition to implement a uniform state-wide system; some physicians and other clinical personnel are reluctant to change to a new way of doing things. A statewide EMR system is estimated to cost as much as $500 million in total.
Pharmacy Costs ➢ Use **tiered co-pay systems** or **prior authorization** to control costs at the payer level ➢ Regulate **prescription advertising** and **marketing** by pharmaceutical agents ➢ Create public **"drug detailing"** programs to provide objective guidance to physicians	Drug detailing programs that encourage greater use of generics and other alternatives could save both public and private payers millions of dollars.	Strong opposition from pharmaceutical companies; consumers may experience some reduction in choice of treatment, or information available. Public drug detailing programs require state expenditure, yet may deliver bulk of savings to private payers, unless the latter are required to pay in.
Consumer Driven Plans ➢ **Health Savings Accounts** (attached to high deductible plans) ➢ **Other flexible benefit plans** (such as plans that do not cover state-mandated benefits)	Encourage consumers to take an active role in coordinating their health care and increase price-sensitivity.	Cost savings may occur at the expense of foregone necessary and preventive medical care, especially among low-income populations.

II. The Current Cost-Quality Landscape in Massachusetts

This section aims to provide an overview of the efforts to promote cost-containment and quality improvement that are currently underway in Massachusetts on both public and private fronts. It is impossible to be entirely comprehensive here, and we do not attempt to discuss initiatives undertaken by cities, towns, and private businesses looking to reduce the cost of providing coverage to employees, but we believe this discussion provides a realistic snapshot of much of the activity today.

MASSACHUSETTS STATE GOVERNMENT INITIATIVES

In its role as a purchaser of health services, particularly through its Medicaid program and on behalf of state employees, as well as in its role as a regulator of hospitals and other providers, the Commonwealth obviously needs to grapple with issues of cost containment and quality improvement. In fact, Massachusetts had already begun to make significant strides in the areas of cost and quality long before they became the buzzwords of the day.

Health Care Quality & Cost Council

The Health Reform Law created a new section of state law (MGL 6A:16J-L) establishing the Health Care Quality and Cost Council (QCC). The QCC is responsible for establishing statewide goals for improving health care quality, containing health care costs, and reducing racial and ethnic disparities in health care. The council will then determine the steps necessary to implement these goals, with a view to both costs of implementation and expected long-term savings and quality improvement. The QCC is also charged with creating a consumer-friendly website, along with other media, to disseminate comparative health care cost, quality, and related information for consumers, health care providers, health plans, employers, policy-makers, and the general public. Insurers and health care providers are required to submit data to the council upon request.

Betsy Lehman Center

The Betsy Lehman Center for Patient Safety and Medical Error Reduction (established under MGL 6A:16E) was launched in 2004 in response to the 1999 Institute of Medicine report, "To Err is Human," which found that an estimated three to four percent of hospitalizations result in adverse events and that 44,000-98,000 of hospital patients die annually as a result of medical errors. Named for Betsy Lehman, a *Boston Globe* reporter who died as a result of a chemotherapy overdose, the Center serves as a clearinghouse for the development, evaluation and dissemination of best practices for patient safety and the reduction of medical errors. Accordingly, the Center coordinates safety efforts of state agencies with those of licensed facilities while creating ways to encourage consumer involvement. For instance, in 2004, at the instruction of then-Commissioner of the Department of Public Health, Christine Ferguson, the Center convened an expert panel to study patient safety issues related to surgical weight loss programs and procedures and make evidenced-based recommendations for improvement. The resulting report was published in *Obesity* in 2005, and has been widely disseminated among health policy professionals. After additional information was published on this topic, the Center convened a panel in 2007 to update its earlier best practice recommendations and issued a revised report. Most recently, the Center worked with the DPH and the JSI Research and Training Institute to convene a panel of experts to make evidenced-based recommendations and goals for the Commonwealth's Statewide Infection Prevention and Control Program, including methods for the prevention and control of hospital acquired/associated infections. The final report was issued in January 2008. Going forward, under new DPH regulations the Center will play a key role in reviewing hospital-reported data on hospital acquired/associated infections for quality improvement purposes (see discussion in Part III).

MassHealth Program

MassHealth is the Massachusetts Medicaid program that provides health care coverage to low-income groups, including pregnant women, children, disabled individuals and elders. The program provides health coverage for over one million people. As the primary source of long-term care coverage for impoverished elders, the program will be under increasing financial

pressure as the state population ages.[32] At the same time, while per-member costs for non-elders are generally lower, it is crucial to control costs in this area in order to ensure continued federal reimbursement and the long-term viability of the programs. Over the past decade, MassHealth has employed a number of techniques to ensure the provision of quality care and control cost growth in the program. These include:

- Use of a drug formulary program and the development and use of evidence-based clinical standards among providers. Established in 1996, the Office of Clinical Affairs oversees the creation of such standards and maintains the drug formulary. Since 2002, the use of a preferred drug list based on clinical efficacy and cost-effectiveness has significantly aided in containing costs and resulted in roughly $7 million in cost avoidance each month.[33]
- Enrollment of 356,000 beneficiaries (non-elder) in a Managed Care Organization (MCO) program.[34] MassHealth contracts with four MCOs, Cambridge Health Alliance's Network Health, Boston Medical Center's HealthNet Plan, Fallon Health Plan, and the Neighborhood Health Plan, to provide this coverage. The MCO Program develops quality improvement initiatives based on information obtained from annual contract meetings that assess MCO performance on quality improvement goals, Healthcare Effectiveness Data and Information Set (HEDIS) measures, a member satisfaction survey derived from the Consumer Assessment of Health Plan Survey (CAHPS), and an external quality review as required under the Balanced Budget Act of 1997. Under their contracts with MassHealth, the MCOs are required to include care management programs in four areas (asthma, maternal and child health, HIV/AIDS, and behavior health).
- Managed care for members over age 65 through the Senior Care Organization and Program of All-Inclusive Care for the Elderly (PACE) programs.

In the past year and a half, MassHealth has also undertaken two additional initiatives dictated by provisions in the Health Reform Law.

- Creation of a **Wellness Program** intended to provide incentives for members to engage in healthy lifestyles. In its initial phase, the Wellness Program focuses on tobacco

[32] Massachusetts Medicaid Policy Institute. The Outlook for Medicaid in Massachusetts. March 2007, 2.
[33] Office of Medicaid. Transition Report. October 2006, 15.
[34] Office of Medicaid. Transition Report. October 2006, 18.

cessation, diabetes and cancer screenings for early detection, teen pregnancy prevention, and stroke education.

- Implementation of a **Pay-for-Performance (P4P)** program within the Medicaid rate system for hospitals and physicians that ties a portion of the $90 million Medicaid rate increase promised to hospitals and physicians in the Health Reform Law to performance standards. Under the P4P plan in hospital rate year 2008 (i.e., starting in October, 2007) $20 million will be linked to performance measures in five areas: 1) Health Disparities ($4.5 million), 2) Community Acquired Pneumonia ($4.5 million, 3) Surgical Infection Prevention ($4.5 million), 4) Maternity and Neonatal Care ($4.5 million), and 5) Pediatric Asthma ($2 million). Because hospitals have not reported data on all the relevant measures in the past, the administration views 2008 as a first phase in the process towards full implementation of P4P. Under the administration's phased-in approach, hospitals can meet the P4P criteria for three measures by simply beginning to report the relevant measures. In the two areas for which prior hospital data are available (Health Disparities and Community Acquired Pneumonia), payments will be linked to a hospital's level of achievement in meeting certain benchmarks.

Group Insurance Commission

The Group Insurance Commission (GIC) administers health insurance and other benefits to the Commonwealth's employees and retirees. With an appropriation of over $1 billion, the GIC is charged with maintaining the coverage of 289,000 enrollees. In an effort to control costs, improve quality, and promote cost-efficiency through increased transparency, the GIC has implemented a Clinical Performance Improvement Initiative (CPII). The most prominent component of CPII is physician tiering. Providers are divided into Tier 1 and Tier 2 based on their track records of delivering cost-efficient, "best practice" care. Consumers are subject to a lower co-pay when they choose a Tier 1 provider. This system is somewhat controversial because the GIC rates providers individually, and critics contend that such tiering could be unreliable, leading to inappropriate results. They claim that for a provider rating to be reliable, and based on sufficient sample size, it should be done at the group level. The GIC also employs a three-tier co-payment structure for prescription drugs. Generic drugs enjoy the lowest co-pays, with preferred brand names, and non-preferred brands getting progressively more expensive.

Some GIC plans also utilize the following programs in an effort to reduce cost and improve quality:

- A step therapy program that requires the use of effective first-line drugs before more expensive, second line alternatives will be covered.
- The use of mandatory generics when available.
- Specialty drug pharmacies for certain treatments (often for ailments such as hepatitis C, rheumatoid arthritis, infertility, and multiple sclerosis) which provide 24-hour clinical support, education and side effect management.

CPII also provides financial incentives to HMO plans for increased admission to hospitals meeting national safety standards.

Department of Public Health

The Department of Public Health (DPH) oversees a vast array of public health programs, including some that give the Department a major role as an overseer of quality and cost-related issues. In particular, DPH licenses hospitals, clinics, and nursing homes; the boards of registration in a variety of health fields are located within the agency; and the Department also administers the Determination of Need program. Each of these roles involves DPH in the cost and quality arena. In particular, acting in accordance with directives contained in the Health Reform Law, DPH has developed a **Statewide Infection Prevention and Control Program**. In November 2006, DPH collaborated with the Betsy Lehman Center (BLC) and the JSI Research and Training Institute to convene a panel of experts to discuss evidenced-based recommendations and goals for the new program. As part of this program DPH released new regulations governing Hospital Acquired Infections in late 2007 (see discussion in Part III).

Under the **Determination of Need (DoN) program**, DPH approval is required for the construction of certain health care facilities, purchase of some forms of new technology, and major changes in services or ownership. Adoption of the DoN process in the early 1970s was based on a belief that market forces alone were insufficient to allocate health care resources efficiently. The original goal of the DoN program was to constrain health care costs and ensure quality by requiring health care entities proposing to build new facilities to demonstrate that

there was an unmet health care need.[35] In 1978 a new federal law, the National Health Planning and Resource Development Act, required all states to adopt a DoN process or face a cut in Medicaid revenues but this measure was reversed in the 1980s (about 36 states still have some form of process, although they vary widely in the types of facilities to which they apply). In Massachusetts the focus of DoN shifted over the years to maintaining quality of care, and today DPH describes its mission as the promotion of "availability and accessibility of cost effective quality health care."[36] In recent years, providers who wish to build Ambulatory Surgical Centers (ASCs) have complained that the DoN process limits the creation of such facilities (which they claim would increase access and provide services at a lower cost); hospitals have countered with the charge that a shift of certain well-reimbursed services to ASCs would make it impossible to maintain the hospital infrastructure on which communities depend.

Health Disparities Council

The Health Reform Law established the Health Disparities Council within the Executive Office of Health and Human Services. The intent was to make permanent the special Commission to End Racial and Ethnic Health Disparities that was established in Chapter 65 of the Acts of 2004. The Council is made up of members of the administration, legislature, outside organizations, and community members.

E-Health Task Force

The FY 2008 budget included a provision creating an electronic health records system task force to be headed up by the Executive Office of Health and Human Services (EOHHS). This group of policy makers and stakeholders is charged with developing an electronic health records (EHR) system that links multiple settings, including MassHealth, S-CHIP, and programs serving the Commonwealth Connector, that utilize health records. The system is to be consistent with requirements for community health records and electronic prescribing. The task force, which has

[35] Current regulations (105 CMR 100.533) require that facilities a) make a clear and convincing demonstration that the proposed projects are needed and do not duplicate current services and b) demonstrate the reasonableness of proposed expenditures and costs (the likely effect of the expenditure on public and third-party payer costs can be considered). Projects must also meet other criteria designed to prevent duplication of services while providing adequate access. The DoN process requires a public hearing and allows for a public comment period.

[36] Mission Statement, Massachusetts Determination of Need Program, Department of Public Health website. Note also that there is some evidence that DON programs are associated with better quality and a long-term reduction in acute care per capita spending [check: Journal of Health Politics, Policy and Law, 1998 23(3):455-481].

yet to officially convene, is to make its recommendations on the advisability and feasibility of an electronic health records system to the secretary of EOHHS by December 31, 2008.

MEDICARE

MassPro

MassPro is a federally designated Health Care Quality Improvement Organization (QIO) contracted by the Centers for Medicare and Medicaid (CMS). There is a QIO in every state and in some states, including Massachusetts, MassPro also provides utilization review services for the state Medicaid office. CMS requires QIOs to work with provider organizations at the micro-level if there are beneficiary complaints. The QIO goes out to the provider, reviews relevant information and then acts as a mediator between the provider and the beneficiary to come to a reasonable solution. At the macro-level, QIOs help providers make systems changes that lead to quality improvement. In Massachusetts, MassPro uses publicly reported, state-specific data for hospital, home-health, and hospice care for every registered Medicare and Medicaid provider. Providers can use this data to compare their performance at the individual, state, and national level. The data and comparisons are available publicly and help drive providers to produce better outcomes on standard measures. Providers participate voluntarily but MassPro works hard to recruit providers to participate.

The CMS contract dictates each QIO's work and sets specific goals for the QIO to achieve. The current contract scope (2005-2008) for MassPro includes goals related to reducing hospital readmission rates for home health patients; implementing appropriate care measures for hospitals; and reducing pressure ulcers, use of physical restraint, and better pain management in nursing homes. Performance is measured at the beginning of each cycle and again at the end, and while there are no data for the current cycle, the last cycle showed marked improvement.

PROVIDER INITIATIVES

Patients First

Patients First is an initiative of the Massachusetts Hospital Association (MHA) that was, in part, a response to a push for mandatory nurse staffing ratios, although its activities fall under the

quality improvement rubric. It is made up of hospitals, represented by the Massachusetts Hospital Association, and the Massachusetts Organization of Nurse Executives (MONE). As part of the initiative, hospitals sign a pledge to follow the group's "five-part leadership agenda," which includes commitments to 1) provide "staffing that meets patient needs" and make staffing plans available to patients and, ultimately, the state; 2) promote a safe work environment, including allowing mandatory overtime in emergencies; 3) make hospital performance measures available to the public (the Patients First website allows users to look at these measures by hospital); 4) tackle the shortage of nurses and other caregivers via, for instance, in-house education programs, career ladders, and mentoring; and 5) educate the public about hospital efforts to ensure and improve safe care. As part of the Patients First initiative hospitals report on several quality measures, and the MHA recently announced it will begin to publicly report pressure ulcer (i.e., bedsore) prevalence measures for member hospitals.

Hospital Disease Management Programs

A number of hospitals and providers have also launched disease and case management programs to address the growing concern over the prevalence and cost of chronic diseases, including:

- Telemonitoring programs for patients with diabetes mellitus, chronic heart failure (CHF), and chronic cbstructive pulmonary disease (COPD); and homecare patients with other diagnoses.
- Initiation of heart failure clinics as part of a health care system's CHF disease management program.
- Nurse Case Management programs for high-risk patients who have commercial insurance.
- Post Discharge Telephonic programs for high risk patients with high probability of readmission in collaboration with selected commercial insurers P4P plans. In one of the demonstration projects, three to four hundred patients are being followed post discharge by a case manager.
- Care management for high-priced high risk patients with chronic conditions. One organization is participating in a Center for Medicare and Medicaid (CMS) demonstration project in which 2,500 high risk high cost patients have been identified to

be followed by case managers who are imbedded in their disease specific ambulatory practices.

Coalitions/Non-Profit Organizations

Massachusetts Health Quality Partners (MHQP)

MHQP is a coalition of physicians, hospitals, health plans, consumers, and government organizations. Their mission is to improve quality in health care by promoting collaboration among stakeholders in the health care system. MHQP has three primary ongoing projects:

- Measuring and privately and publicly reporting patient experiences with their primary care doctors via patient surveys (the next survey, which is in the field, will also include: OBs, cardiologists, and orthopedists).
- Measuring and publicly and privately reporting on provider performance on clinical quality measures.
- Developing quality guidelines for providers, which currently include preventive care, immunization, perinatal care, and asthma guidelines.

MHQP is the only site in the country that has practice-specific quality information on patient experiences with their physician. California has similar data but only at the group level. The clinical quality measures are at the medical group level. They use clinical categories from claims data that are well tested and reported. In terms of consumer use of the website, MHQP has approximately 10,000 non-distinct hits upon a new public release of data. Over time, the site is accessed less frequently. MHQP would like to improve on building awareness through more frequent public releases and/or advertising. A main challenge for MHQP is collecting and posting data that is useful to consumers. They have conducted many focus groups on the usefulness and usability of their website and have found that people want more individual level data and so the organization is currently working towards a better balance of public health information and other types of data. In addition, the Massachusetts ehealth Collaborative (see description below) hired MHQP to capture the clinical data from their pilot sites, enter it into a data warehouse, analyze and privately make comparative performance reports to doctors' offices.

Massachusetts Health Data Consortium

The Massachusetts Health Data Consortium works to develop multi-stakeholder projects related to health data and health quality. They convene health plans, providers, and other public and private organizations around various projects to improve health system functioning in these areas. Some recent projects include:

- Convening health plans to develop consensus around quality improvement measures to improve data collection and reduce administrative costs.
- Convening hospitals and health plans to come to consensus around coding for the same procedures, with the aim of reducing administrative costs for hospitals.
- Convening a group on how e-health technology relates to public health from a quality and cost perspective.

The consortium, although not directly collecting or posting quality data, describes itself as an 'essential lubricant in the functioning of the system' because of its work to bring competing stakeholders together to work through specific quality or cost issues.

Massachusetts ehealth Collaborative

The Massachusetts eHealth Collaborative (MAeHC) was formed to bring together the state's major health care stakeholders for the purpose of establishing an electronic health records system (EHR). The Collaborative is working to overcome the significant barriers, including immense investments of both capital and time, which stand in the way of a working EHR system. MAeHC's 34 member organizations participate in a variety of working groups convened to make recommendations and develop standards and requirements for demonstration pilot programs. Three such programs have already been implemented in Brockton, Newburyport and North Adams. MAeHC is funded by a $50 million grant from the Blue Cross Blue Shield Foundation.

III New Initiatives and Proposals

The past several months have seen a variety of new proposals that are intended to address cost containment and quality issues. These include three omnibus cost-quality bills currently under consideration by the Committee on Health Care Financing: a) An Act Controlling Health Care Costs (S.1238/H.2197), filed on behalf of the advocacy organization Health Care for All; b) An Act to Reduce Health Care Costs and Promote High Quality Care (H.4587), filed on behalf of the Massachusetts Association of Health Plans; and c) An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care (S.2526), filed by Senate President Murray. The Committee also has before it numerous smaller bills that include various cost and quality measures. While all these proposals differ in scope and emphasis, they tend to echo at least some of the themes identified in the first section of this paper (see chart on page 12-13) and include provisions to increase transparency in the areas of both cost data and quality measures, change payment structures in order to encourage more efficient and higher quality care, reduce administrative costs, increase access to services (such as primary care physicians), and control pharmaceutical costs. Legislation aside, Government Patrick's administration has also launched some new initiatives, the Health Care Quality and Cost Council has just issued its comprehensive plan, and both payers and providers have also announced new efforts in this area. This section provides an overview of the various proposals, starting with the omnibus packages and then moving to other bills and non-legislative initiatives.

OMNIBUS PACKAGES

An Act Controlling Health Care Costs (H.2197/S.1238)

This comprehensive bill was filed by Senator Montigny and Representative Marzilli on behalf of the advocacy organization Health Care for All (HCFA), which has made cost/quality legislation a key priority during the current legislative session. The bill is based on the principle that fundamental reforms in financial incentives and care management are required to improve quality and cost, rather than the recent trend of cost shifting to patients and consumers to reduce

overall expense. The bill encompasses 17 legislative proposals outlined in a report released by the organization last fall.[37] Major elements include:

- Provisions meant to control pharmacy costs and protect consumers, including the creation of an academic "detailing" program to educate providers about generic medications and low-cost alternatives to brand-name drugs, development of common drug lists to form a basis for a statewide purchasing consortium, a ban on pharmaceutical marketing strategies such as gifts to providers, and restrictions on the sale of individual patient information to the pharmaceutical industry.
- Provisions prohibiting commercial insurers from charging co-pays for preventive care and requiring public hearings for proposed premium rate increases that are greater than seven percent.
- Establishment of common quality and payment measures for MassHealth, the Commonwealth Health Insurance Connector Authority, the Group Insurance Commission, and other public payers; the Executive Office of Health and Human Services would also develop payment methodologies that provide financial incentives for high-value health delivery, including rewards for reductions in preventable readmissions and incentives for chronic illness management.
- Creation of a chronic disease self-management program under DPH and expanded case management for seniors and the disabled through the Senior Care Options program.
- Establishment by DPH of emergency room patient flow standards for hospitals.
- Implementation of a plan to make MassHealth and the subsidized Commonwealth Care program leaders in the use of health information technology.
- Creation of a special commission to develop a statewide plan to strengthen primary care.

While the HCFA report does not estimate potential savings, it does point to five areas in which action could yield cost control: a) ambulatory visits, 2) hospital stays and peri-hospital stays, 3) year-long episodes of illness, 4) long-term care, and 5) prescription drug use.

[37] Goldfield N, Hams M, McDonough J, Miller M, Rosman B. A Consume-Driven Health Care Cost Control Agenda for Massachusetts: 17 Legislative Proposals. March 2007.

An Act to Reduce Health Care Costs and Promote High Quality Care (H.4587)

After announcing a legislative initiative to contain costs and improve health care quality last December, the Massachusetts Association of Health Plans (MAHP) submitted actual legislation, filed by Representative Spellane, in mid-February. A key feature of the bill is its requirement that the Health Care Quality and Cost Council (HCQCC) hold annual public hearings to examine both health insurance premium increases and provider side cost (e.g., labor, capital, administrative) issues and reimbursement rates. Under this provision, designed to increase transparency around the issue of rising health care cost increases, the HCQCC would have expanded powers to require testimony and define information to be provided by entities that testify. In addition, the proposed legislation contains another 16 sections that fall into several categories:

- New requirements for reporting of hospital acquired infections (HAIs), "never events", and preventable readmissions, and a prohibition on billing third party payers for services related to such incidents. Hospitals would also be required to submit written plans to DPH to a) eliminate duplication of unnecessary diagnostic services, and b) eliminate emergency room overcrowding and diversions.
- Proposals designed to streamline or strengthen existing regulatory processes, including changes that would involve the Attorney General and Inspector General in the current Determination of Need process for health facilities and that would require standardization of physician credentialing and data reporting process.
- Provisions designed to eliminate obsolete mandated benefits and create a moratorium on mandated benefits until there is no longer *any* growth in health costs. The bill also proposes to allow health plans (so-called "mandate-lite plans") that do not cover many health benefits currently mandated under state law.
- Other provisions would require the Division of Insurance to issue a report concerning duplicative regulations and to convene a commission to make recommendations concerning simplification of administrative services and practices in health care. The bill would also require the electronic transmission of health care transactions by providers and carriers.
- Creation of a pilot program of medical malpractice court committees to provide an alternative adjudication process for such claims.

- A commission to study the potential impact of reinsurance on the small group health insurance market.

Although press materials provided last December claim the bill has the potential to save "several billion dollars" no details on exactly how, or where, these savings would be realized has been provided thus far. MAHP has indicated its intent to commission a third-party study of potential savings.

An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care (H.4587)

The latest arrival on the cost-quality legislative scene is an omnibus bill filed by Senate President Murray. The bill contains over 50 sections, many of which overlap with provisions contained in bills already before the Committee on Health Care Financing or already reported by it. Major components include:

- Expansion of the Health Care Quality and Cost Council board, and additional authority and duties for the body, including the promulgation of regulations for reporting of "never events" and prohibitions on payments for these incidents.
- Creation of an academic "detailing" program to educate providers about generic medications and low-cost alternatives to brand-name drugs and a ban on pharmaceutical marketing strategies such as gifts to providers.
- Numerous provisions designed to advance health information technology, including requiring competency in the use of Computerized Physician Order Entry (CPOE) systems as a condition for physician licensure, adoption of CPOE and e-health records systems as a condition of hospital licensure, and creation of a state "e-health institute" to maintain a statewide electronic health records system.
- Provisions to expand access to primary care providers (PCPs), including the creation of a Center for Primary Care Recruitment and Placement under DPH, loan forgiveness and tuition waiver programs, and a requirement that insurers list Nurse Practitioners as PCPs.
- Language recently agreed to by insurers and providers that would require the adoption of certain standard codes (see discussion of existing bill below), and a loosening of current requirements concerning retention of medical records.

- A directive that the Division of Insurance study medical malpractice insurance costs, and changes to the Determination of Need statute that are apparently intended to make it easier for ambulatory surgical centers to become licensed.

No estimate of cost savings was provided with the bill.

OTHER LEGISLATION

In addition to the comprehensive bills and other major initiatives discussed above, a variety of currently pending bills deal with various aspects of cost and quality.

Transparency

A number of bills requiring hospitals to report data on hospital acquired infections and other incidents were filed this session, and these were recently reported by the Committee on Public Health under **S.2517, An Act Promoting Healthcare Transparency and Consumer-Provider Partnerships** The redraft, currently before the Committee on Health Care Financing, would require the Department of Public Health to promulgate regulations to reduce HAIs to zero or as close to zero as feasible. Hospitals would be required to report infection data, and would also be required to report data concerning serious reportable events, or so-called "never events." Data would be the posted on a public website; the bill also requires establishment of patient and family advisory councils at hospitals.

Care Management

S.1279, An Act to Promote A Statewide System for Chronic Care Management to Improve Health Care Quality and Contain Costs, recently reported favorably by the Committee on Public Health and currently before the Committee on Health Care Financing would authorize the development of a statewide system for chronic care and prevention, a chronic care management program for individuals enrolled in MassHealth, and the development of an implementation plan for the prevention of chronic conditions and chronic care management in the Commonwealth.

Health Information Technology

S.264 and H.1130, An Act to Reduce Administrative Burdens in the Delivery of Health Care Through the Use of New Technology, currently before the Committee on Economic

Development and Emerging Technologies, would create a new trust fund to develop a statewide Electronic Health Records (EHR) system; the fund would receive a $50 million annual appropriation from the general fund, as well as a revenue from a new assessment on hospitals and insurers. Other technology-related initiatives include **S.676, An Act Requiring Medicaid Reimbursement Payments to Health Care Providers for Electronic Consultations** and **S.680, An Act Concerning the Use of Telemedicine to Promote Efficiency in the Delivery of Health Care Services**, which would require Medicaid reimbursement for telemedicine services delivered by home health agencies. These bills both received favorable reports from the Committee on Health Care Financing; the first is currently awaiting action in the Senate, and the second is in Senate Ways & Means.

Administrative Simplification

S.697, An Act Standardizing Medical Coding and Billing Formats for Health Insurers, would require all payers and providers in Massachusetts to recognize Medicare coding and guidelines. After much debate between the various parties involved, new compromise language has been proposed as a replacement for the original bill (the language is also contained in the omnibus bill filed by the Senate President). The new proposal would require all payers and providers to recognize certain standard coding sets (International Classification of Diseases (ICD); American Medical Association's Current Procedural Terminology (CPT); and Centers for Medicare and Medicaid Services Healthcare Common Procedure Coding System (HCPCS)) by 2012 and also requires the use of standardized paper and electronic claims forms. Another measure, **H.4145, An Act Relative to the Physician Credentialing Process**, would create consistent forms and processes across all carriers for physician credentialing. The Committee on Health Care Financing reported the bill favorably last fall and it is currently awaiting a second reading in the House.

Access to Primary Care

Earlier this year, the Committee on Health Care Financing reported out a two-part bill, **H.4514, An Act Relative to Financial Incentives for Primary Care Physician Recruitment**, that would establish a primary care physician loan repayment program within the Department of Higher Education and create a permanent health care workforce council within the Office of

Labor and Workforce Development to address primary care and other workforce issues. That bill was based in part on language in **H.1162, An Act Establishing a Healthcare Workforce Council within the Office of Labor and Workforce Development**. Two other bills—**H.2164, A Resolve Relative to Primary Care Physician Recruitment and Retention**, currently before the Committee on Health Care Financing, and **S.1078, An Act Creating a Special Task Force to Make an Investigation and Study on Issues Related to the Healthcare Workforce**, currently before the Committee on Labor and Workforce Development—establish special commissions to research and make recommendations on health care workforce issues. **S.731, An Act Establishing a Loan Repayment Programs for Physicians**, currently before the Committeee on Higher Education, would do what its title suggests, while another bill before the Committee on Health Care Financing, **S.682, An Act Providing for a Commonwealth Care Medical Home Demonstration** would advance a new model intended to reward primary care providers.

Health Care Disparities

A number of bills designed to eliminate health disparities were filed this session, including **H.2161, An Act Relative to the Elimination of Racial and Ethnic Health Disparities**, currently before the Committee on Public Health, which would require the Secretary of Health and Human Services (EOHHS) to evaluate the extent of health disparities and promulgate regulations to reduce them, and **H.1149, An Act Relative to the Commission for the Elimination of Health Disparities**, which would establish a permanent disparities commission within the (EOHHS); the latter bill is currently before the Committee on Health Care Financing. A more expansive bill, **H.2234, An Act to Eliminate Racial and Ethnic Health Disparities in the Commonwealth**, also before the Committee on Public Health, would establish an Office of Health Equity within EOHHS; the office would be responsible for coordinating all state activities to eliminate racial and ethnic disparities, including educating other agencies, collection of relevant data, and administration of a health worker training program. Finally, the FY09 Governor's budget includes a new line item (4000-0622) to establish an Office of Health Equity within EOHHS with an appropriation of $1 million.

Determination of Need (DoN)

As in past sessions, a number of bills related to the Determination of Need process have been filed, some that would loosen existing requirements and other intended to protect hospitals from competition by ambulatory surgical centers (ASCs). Among the proposals are **H.2006, An Act Requiring Annual Licensure, Determination of Need and Parity in Uncompensated Care Pool/Safety Net Trust Fund Participation for Freestanding Ambulatory Surgical Centers Providing Advanced Surgical Services** and **H. 2063, An Act Relative to Determination of Need**. Both of these bills, which are currently before the Committee on Public Health, would make all ambulatory surgical centers subject to DoN, including those operating under the physician office exemption (and not currently required to undergo the DoN process) and would also require ambulatory surgical centers to pay a free care assessment, as hospitals do**. H.2078, An Act Relative to Ambulatory Surgical Centers**, also before the Committee on Public Health, requires that ASCs (whether licensed or unlicensed) be included in Medicaid program, as does **H.1150**, currently before the Committee on Health Care Financing.

OTHER MAJOR INITIATIVES

Health Care Quality & Cost Council

The Health Care Quality & Cost Council has taken a wide view of the cost quality landscape in developing its goals which are intended to lower or contain the growth in health care costs, improve quality of care, and reduce racial and ethnic health disparities. The council intends to consider any and all potential cost-saving initiatives that have been discussed, including rate setting, changes to the DoN program, increased cost-sharing measures, and malpractice reform. Once all options have been thoroughly studied, the council intends to develop legislative and regulatory recommendations to control health care costs.

The Council has developed the following six specific 2008 goals and related strategies to achieve these goals:[38]

1. **Reduce the cost of health care by reducing the annual rise in health care costs to no more than the unadjusted growth in GDP by 2012.** Key strategies are the development of a website providing comparative cost information and preventing the need for avoidable

[38] Health care Quality and Cost Council Annual Report (Draft) February, 2008, p 3-21

hospital stays; the Council intends to have the web site available in June 2008. In addition, the Council will contract with independent experts to analyze causes of increases and decreases in health care costs, adopt a standard of measurement for total annual Massachusetts health care spending and develop legislative, regulatory, and other recommendations to control health care costs. Finally, the Council will create a Massachusetts Global Health Cost Indicator that will allow it to track changes in health care costs, both as a whole, and in specific sectors.

2. **Ensure patient safety and effectiveness of care by eliminating hospital associated infections by 2012 and eliminating "Serious Reportable Events" (so-called "never events").** The Council recommended that hospitals implement the Endorsed Safe Practices for Better Health Care from the NQF and the Betsy Lehman Center Expert Panel for the Prevention and Control of Healthcare-Associated Infections recommendations, and encouraged public and private health plans to align financial incentives with this goal.
3. **Improve chronic and preventive care for conditions such as diabetes mellitus, chronic heart failure, and asthma; and reduce complication rates, readmission rates and avoidable hospitalizations**. The Council recommends that the Executive Office of Health and Human Services (EOHHS) convene a working group to develop a blueprint for the development of a statewide model system of care that improves the health status of people with, or at risk for, chronic conditions to achieve this goal.
4. **Develop processes and measures of health care quality in areas where current data are inadequate.** The focus of this goal will be on developing processes and measures to improve adherence to patients' wishes in providing care at the end of life and increasing access to high-quality, coordinated hospice and palliative care. Strategies to achieve this goal include an EOHHS-sponsored public health educational campaign, and the implementation and evaluation of a pilot program similar to the Physician Order for Life Sustaining Treatment processes currently used in other states.
5. **Reduce and eliminate racial and ethnic disparities in health access and outcomes.** Specific areas for action identified are hospital associated infections, serious reportable events, disease complication rates, readmission rates, avoidable hospitalizations, and screening and management of chronic illnesses. The strategy for achieving this goal involves incorporating racial and ethnic disparities in each quality improvement effort rather than

through a separate effort. Race and ethnicity will be included as data elements for collecting hospital associated infection rates and serious reportable events. In addition, the Division of Health Care Finance and Policy added race and ethnicity data to its hospital discharge dataset in January 2007.

6. **Promote quality improvement through transparency by the development of a publicly available website.** Quality measures for the website will be determined using nationally accepted standard measure sets that are meaningful to providers and patients, and evidence-based measures from reliable and stable data sources with sufficient sample sizes for accurate reporting. The Council will seek to use measures that are representative of a significant proportion of the provider's practice, to inform providers about the development and validation of the measures and to give them an opportunity to view their own performance.

Department of Public Health (DPH) Hospital Acquired Infection (HAI) Regulations

Building on the Statewide Infection Prevention and Control Program (discussed above in Part II),DPH has established a strategic plan that, among other things, would require hospitals to report on their HAI rates as well as their prevention and control processes. Accordingly, DPH proposed amendments to existing regulations governing hospital licensure (105 CMR 130.000) in November 2007, and these were approved by the Public Health Council in February 2008. The new regulations would initially target eight HAIs, including three central venous catheter-associated blood stream infections (CVC-BSI), four variations of surgical site infections (SSI), and ventilator-associated pneumonia (VAP). Under the regulations, hospitals are directed to report data to DPH and the BLC via participation in the Center for Disease Control's National Healthcare Safety Network (NHSN). Data collected via NHSN will be reported to a) DPH for review and preparation for reporting to the public, b) BLC for monitoring and quality improvement purposes, and c) internally within the facility to aid in performance and quality improvement efforts. DPH asserts that once data have been received and assessed, consumer-friendly statewide and hospital-specific reports will be created for public use. DPH intends to work with the existing Health Care Quality and Cost Council to establish website links to encourage public access to such information. Hospitals must register for NHSN by April 1st and begin collecting and submitting infection data by July 1st of this year. DPH intends to create more specific programmatic and administrative guidelines that will be developed by a broadly

representative Technical Advisory Group. Compliance will be a condition of hospital licensure and that adherence will be enforced.[39]

MassHealth Cost Control & Quality Improvement Initiatives

House 2, the Governor's proposed FY09 budget proposes a variety of Medicaid cost-containment initiatives. The measures are intended to enable MassHealth to realize total savings of $303 million in total spending, and include the elimination of special rate earmarks and institution of value and cost-based purchasing (these payment methodology changes account for two-thirds of the projected savings), as well as care management initiatives, more efficient drug utilization, and other administrative savings. Since a portion of all Medicaid spending comes from federal reimbursements, the lower spending would result in lower federal reimbursements, and thus the actual net savings to state revenue are estimated at $168 million. In addition, the administration will be procuring contracts with the MCOs that serve a large portion of the MassHealth population and plans to "attach significant financial incentives" to specific quality measures.[40]

Healthy Massachusetts Compact

Launched by the Secretary of Health and Human Services last December, this new initiative essentially consists of a commitment (incorporated in a signed Memorandum of Understanding) by various state secretariats as well as the Group Insurance Commission, Attorney General, Commonwealth Health Insurance Connector Authority, and Health and Educational Facilities Authority to work together on a number of fronts, including:

- Coordination of purchasing (including using payment systems to encourage cost-efficient care and disease prevention/management).
- Use of electronic health records and other shared processes.
- Promotion of transparency, support of the Health Care Quality and Cost Council, elimination of disparities, encouragement of new technologies, achievement of high quality health care standards.

[39] DPH, Final Promulgation of Proposed Amendments to 105 CMR 130.000 Memo, February 13, 2008.
[40] MassHealth. Section 1115 Demonstration Project Extension Request: Health Care Reform Sustainability. December 21, 2007.

- Partnerships with cities and towns to reduce health care costs and support community health and wellness work.
- The initiative is to be coordinated by the EOHHS secretary, who will conduct regular meetings; reports on its progress are semi-annually.

Since the inception of this initiative some initial steps have been taken, according to informal reports; the administration did not respond to our request for additional details.

Other Payer and Provider Initiatives

In recent months, hospitals, payers, and other interested parties have all jumped into the cost and quality fray with a variety of proposals and request, among them:

- The Massachusetts Hospital Association announced that its member hospitals have agreed not to charge patients or third-party payers for nine "never events", including surgery on the wrong body part or wrong patient, use of the wrong surgical procedure, or foreign objects left inside a patient, and serious disability or death due to a medication error, air embolism, or administration of incompatible blood. The agreement is similar to one implemented by Minnesota hospitals.
- This past February, the Massachusetts Technology Collaborative and New England Healthcare Institute released a report showing that ten percent of patients admitted to six Massachusetts community hospitals suffered serious medication mistakes. The two groups argue that these mistakes could have been avoided by use of a Computerized Physician Order Entry (CPOE) system for prescriptions, testing, and other medical procedures. The groups, along with other advocates—particularly community hospitals—have called on the state to provide funding to allow statewide adoption of such systems.
- Last January, Blue Cross Blue Shield of Massachusetts announced a proposal to change the way it reimburses doctors and hospitals, moving from per-visit or treatment payments to a system of flat sums per patient that would be supplemented by bonuses for improved care, in the hope of achieving changes in care delivery, such as quicker access to doctors by phone and home visits to the chronically ill. The insurer has also committed $50 million to maintain three Electronic Health Record pilot programs in the state (the program is set to expire in July, 2008), and announced that, beginning in 2012, hospitals

will have to employ CPOE in order to participate in an incentive program that currently pays over $100 million to them annually.

Summary

While the need for work to contain health care costs and improve quality is clear, it may be far more difficult to achieve meaningful success than in the case of The Health Reform Law's expansion of access to health coverage. Effectively addressing issues of cost and quality will require serious challenges to existing structures and ways of doing business. Some changes may be more appropriately left to regulation, or even to private initiatives or market forces. Simply coordinating the plethora of organizations, coalitions, and other entities that have launched initiatives in this area within Massachusetts in order to avoid unnecessary duplication of efforts, will be a challenge. As legislators work to craft legislation in this area, we recommend they keep the following points and questions in mind.

- It is crucial to consider which proposals will be truly effective in achieving the goals of cost containment, rather than adopting measures based on simple political appeal. As Stuart Altman, Dean and Sol C. Chaikin Professor of national health policy of the Heller School of Social Policy and Management, has shown in a widely disseminated chart, the measures with the greatest potential for limiting health spending growth are not necessarily the most palatable ones (e.g., restrictions on services and rate-setting). [41]

  It is crucial to consider which proposals will be truly effective in achieving cost containment.

  Many strategies may seem like common sense, but careful evaluation of proposals is needed to understand their cost and impact. Furthermore, it is important to distinguish between measures that will reduce costs on a one-time basis, and those that will reduce cost *growth* over time.
- It is easier to talk about quality than cost, and improving quality does not necessarily contain costs; in fact it can cost more in at least the short run.
- While greater transparency, such as required reporting of infections and other data, is attractive it can be difficult to establish meaningful measures and quickly adopt the

[41] Altman S. Growing Healthcare Spending: Can or Should it Be Controlled to Prevent a Health System "Meltdown". Presentation at Health Care Cost Management in Massachusetts Series. November 27, 2007.

technology necessary for the reporting. Such measures also risk providing perverse incentives for providers to avoid high-risk patients. Similar issues pose a challenge to the adoption of Pay-for-Performance and other incentive payment methodologies.

- What is the appropriate role for state government in this arena? What responsibility should the state take for funding programs such as chronic disease management, technology expansions (such as funding for CPOE) and drug detailing programs to educate doctors about cost-efficient prescribing, particularly in light of the fact that many of the benefits will accrue to providers and private payers?
- How do we avoid duplication of efforts and multiple or inconsistent messaging and use of data? The Health Care Quality and Cost Council may be a good first start at getting the right mix of stakeholders at the table. However, it is important that everyone focus and hopefully come to consensus on what exactly we are trying to do. For instance, the HCQCC spent a great deal of money on getting claims data from health plans when Massachusetts Health Quality Partners (for a description of this organization, see Part II) already had this data. Likewise, experts have noted that while care appears to be improving, it is difficult to assess exactly why that is so, because there are so many initiatives from different organizations occurring simultaneously.

As policy makers across the state work to control health care costs and improve quality, it is crucial that we establish clear goals, that we carefully consider what initiatives and proposals—legislative and otherwise—will really work to achieve them, and that we coordinate efforts across the legislature, state and local governments, providers, payers and employers in order to avoid inefficient and potentially expensive duplication of efforts.

Report of the Special Commission on

Ambulatory Surgical Centers & Medical Diagnostic Services

July 1, 2007

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Appendices

- Thomas Crane
- Jean Mitchell
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4) Other written testimony
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   - Carol A. Straney, Area Center manager, MRI of Dedham
   - Jeffery Levin-Scherz, MD, CMO, Atrius Health
   - Darlene Marini, Vice President, Massachusetts Association of Ambulatory Surgery Centers
   - Massachusetts Hospital Association
   - Andrew Whitman, Vice President, Medical Imaging and Technology Alliance
   - Peggi Keegan, BSN, RN
   - Kreg Palko, East Bay Surgery Center
   - Hoagland Rosania, MD
   - Theodore A. Calianos II MD FACS
   - Richard M. Bargar, MD
   - Peter E. Bentivegna, MD FACS
   - George Picard, Greater New Bedford Surgicenter
   - Dr. George Violin, MD
   - Dr. Kevin Mitts, Berkshire Orthopaedic Associates

5) Other Submissions
   - Accreditation Association for Ambulatory Health Care, Inc., Physical Environment Checklist
   - Accreditation Association for Ambulatory Health Care, Inc., Accreditation Handbook 2005
   - JACHO Comprehensive Accreditation Manual for Ambulatory Care 2005-2006
   - Massachusetts Medical Society, Physician Workforce Study, June 2006
   - Jean M. Mitchell, *The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging*
   - *People of the State of Illinois vs. Midi LLC, et al*, Complaint
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D. Additional Comment from Commission Members

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2) Massachusetts Medical Society
3) Massachusetts Association of Ambulatory Surgery Centers
4) Fallon Clinic

I. STATUTORY MANDATE

The Special Commission on Ambulatory Surgical Centers & Medical Diagnostic Services was established by Section 105 of Chapter 139 of the Acts of 2006 (the FY2007 budget). The authorizing language follows.

SECTION 105. Notwithstanding any general or special laws to the contrary, there shall be a special commission to make an investigation and study of the impact of 1) single- and multi-specialty ambulatory surgical centers and 2) medical diagnostic or therapeutic services rendered in conjunction with innovative services and new technology as defined by the department of public health, on the health care delivery system, cost of health insurance, Medicaid costs, and uncompensated care, provided that the study shall consider a range of such facilities and services, including hospital-owned, physician-owned, and investor-owned. The study shall include a cost-benefit analysis, and shall also examine the effect of such facilities on access to health services, and the impact on the provision of hospital-based services.

The commission shall consist of 16 members, 1 of whom shall be the secretary of health and human services or his designee, 1 of whom shall be the commissioner of the department of public health or his designee, 1 of whom shall be the director of the office of Medicaid or his designee, 1 of whom shall be the senate chair of the joint committee on health care financing, 1 of whom shall be the house chair of the joint committee on health care financing, 1 representative from the Massachusetts Hospital Association, 1 representative from the Massachusetts Association (sic) of Community Hospitals, 1 representative from the Massachusetts Medical Society, 1 representative from the Massachusetts Radiological Society, 1 representative of the Massachusetts Association of Ambulatory Surgical Centers, 1 of whom shall represent Fallon Clinic, 1 of whom shall represent Harvard Vanguard Medical Associates, 1 representative from the Massachusetts Association of Health Plans, 1 representative from Blue Cross Blue Shield of Massachusetts, a health care economist appointed by the speaker of the house of

representatives and a health care economist appointed by the president of the senate. The commission shall be co-chaired by the senate and house chairpersons of the joint committee on health care financing.

The commission shall meet no later than October 1, 2006, and file a report, with recommended legislation, with the clerks of the senate and the house of representatives no later than July 1, 2007 .

II. MEMBERSHIP

Senate Chair	Senator Richard T. Moore
House Chair	Representative Patricia A. Walrath
Executive Office of Health and Human Services	Paul Dreyer, Director of Health Quality
Department of Public Health	Ed Kiely, Chief of Staff
Office of Medicaid	Phyllis Peters, Deputy Assistant Secretary for the Office of Acute and Ambulatory Care
Massachusetts Hospital Association	Timothy F. Gens, Senior Vice President, Policy and Regulation General Counsel
Massachusetts Council of Community Hospitals	Linda Shyavitz, President & CEO, Sturdy Memorial Hospital
Massachusetts Medical Society	Dr. Thomas Hutchinson
Massachusetts Radiological Society	Dr. John Dubrow
Massachusetts Association of Ambulatory Surgical Centers	Dr. Jerry M. Schreibstein
Fallon Clinic	Dr. Stephen Pezzella, President & CEO
Harvard Vanguard Medical Associates	Gene Wallace, Executive Vice President & CEO
Massachusetts Association of Health Plans	Dr. Marylou Buyse, Executive Director
Blue Cross Blue Shield of Massachusetts	Steven Fox, Senior Director of Provider Relations (replaced Sarah Iselin)
Health Care Economist (Senate)	Dr. Jean Mitchell, Professor of Public Policy, Georgetown Public Policy Institute, Georgetown University
Health Care Economist (House)	Dr. Haiden Huskamp, Associate Professor of Health Economics, Harvard Medical School

III. COMMISSION PROCESS

The Special Commission held a variety of meetings during which members attempted to further define and clarify, within the broad scope of the legislative mandate, specific and pertinent issues that could reasonably be addressed by the Commission in the time allowed for its work. These sessions were followed by a public hearing at which testimony (including solicited testimony on questions and issues that had been identified in previous meetings) was heard. The Commission then met on June 12th to discuss a final set of recommendations.

The following is a list of Commission meetings (all held at the State House).

September 27, 2006 **Organization meeting**
Introduction of Commission members and preliminary identification of issues.

October 23, 2006 **Educational Session**
Stark Law presentations by panel consisting of:

- Thomas Crane, Health Law Attorney, Mintz Levin
- David Levin, Professor and Chairman Emeritus of the Department of Radiology, Jefferson Medical College and Thomas Jefferson University Hospital
- Wes Cleveland, Health Law Legal Counsel, Departments of Private Sector Advocacy and State Legislation, American Medical Association
- Colin Zick, Health Law Attorney, Foley Hoag
- Dr. Thomas Parker, Bay State Medical Center

November 28, 2006 **Educational Session**
Determination of Need (DoN) Briefing by Paul Dreyer (Special Commission member; Director, Bureau of Quality Assurance and Control, Massachusetts Department of Public Health).

January 16, 2007 **Meeting**
Discussion of next steps, preliminary identification of pertinent issues and questions. Following this meeting legislative staff compiled a list of questions raised, which was circulated by e-mail for further additions and comment.

February 13, 2007 **Meeting**

Further discussion of pertinent issues and questions; plan for hearing and solicitation of expert witnesses.

March 21, 2007 **Public Hearing**

Invited Testimony:

- Tom Crane, Health Care Attorney, Mintz Levin
- Jean Mitchell, Professor of Public Policy, Georgetown Public Policy Institute
- John Blair, Chief of Staff, Connecticut Office of Health Care Access
- Joan Gorga, Director of DoN Program, Massachusetts Department of Public Health
- Gail Palmeri, Director of Hospital Licensing Program, Massachusetts Department of Publich Health
- Dr. David Shapiro, physician/ASC community

For a list of all people testifying, see Appendix C

June 12, 2007 **Final Meeting**

Discussion of final recommendations.

IV. BACKGROUND

Introduction

The Special Commission was created in 2006 in response to growing concerns about two separate, but related, topics: 1) ambulatory surgical centers and 2) medical diagnostic technology, specifically Magnetic Resonance Imaging (MRI) services.[1] While the two topics raise some similar questions about quality, access to health services, and cost, several Commission members noted early on that the operational and regulatory issues surrounding each area are actually rather different and Commission discussions tended to focus on each separately. Thus, for purposes of simplification, this report separates discussion of the two types of services. This section provides brief background on each area, and also notes some of the particular concerns that were identified in initial Commission meetings as members sought to further define and clarify the scope of the Commission's work within the fairly broad mandate provided by the Legislature (see Section I above for the statutory language that set up the Commission).

Ambulatory Surgical Centers

Ambulatory Surgical Centers (ASCs) are facilities that perform outpatient surgical procedures that do not require an inpatient overnight hospital stay. ASCs can be (1) freestanding clinics that are licensed by the Massachusetts Department of Public Health (DPH) and go through a Determination of Need (Don) review; (2) owned and operated by a hospital as a separate outpatient department also subject to DoN and Licensure review; (3) operated as a joint venture between a hospital and physician office; or (4) operated as part of a physician office/clinic under what is known as the "physician office exemption" from licensure and DoN review. Despite the different operational categories, the services

[1] Throughout the Commission's proceedings, consideration of medical diagnostic technology focused almost exclusively on MRI issues, and the two terms ("medical diagnostic technology" and "MRIs") are used interchangeably in this report.

provided at the four types of entities are the same; however, Massachusetts law and practice affect the four types of ASCs very differently.

Statutory & Regulatory Background:

One of the most significant areas of state regulation that affects ASCs has to do with the DoN law, which is intended to ensure that there is equitable access to health care services, help maintain standards of quality, and constrain overall health care costs by eliminating duplication of expensive technologies, facilities and services. All hospital-associated ASCs must be operated under a hospital facility license and are subject to DoN review on the same basis as other hospital facilities and services. All clinic-type ASCs are subject to DoN review and require state licensure. Under the DoN law and related regulations someone wishing to open a freestanding ASC and be licensed by DPH must go through the DoN process. In contrast, a DoN review is not required for a physician-owned ASC that relies upon the physician office exemption (the DoN law and related regulation is discussed further in the next section).

ASC Issues:

In its initial meeting and subsequent discussion, Commission members identified a number of issues related to ASCs. These included ASCs' role in providing expanded access to medical services, as well as the possibility that ASCs' operational costs might be lower for private payer, self-insured, or MassHealth patients. At the same time however, concerns were raised about the potential for increased costs to the private and MassHealth market related to duplication of services in a given geographic area, the impact on the current health delivery infrastructure and the ability of hospitals, particularly community hospitals, to maintain their crucial role in that infrastructure, including their emergency departments. Further concerns and questions arose around the issues of quality and safety, including the question of whether current rules and regulations are adequate to ensure safety at ASCs. Questions were also raised concerning the adequacy of current legal and regulatory frameworks to address these concerns. Finally, another relevant issue concerns the use of referrals of patients for ASC services. Physicians who have an ownership stake in freestanding ASCs or in clinics providing

ASC services face a potential conflict-of-interest when referring their patients to use those services. A January 2007 McKinsey Global Institute report found that the reimbursement system creates a strong incentive to self-refer cases—physicians who own equipment and ASCs refer between two and eight times more patients than their peers without equity interest. Because physicians have self-referred many of the less complex procedures out of the hospital setting, hospitals have been left with a highly-acute hospital case-mix, which directly results in increased costs for other services.

Medical Diagnostic Services

The term "medical diagnostic services" refers to the various forms of imaging technology that are used by radiologists in determining a patient's diagnosis. Of principal concern to the Commission were those services that constitute "new technology" or "innovative services" as defined in section 25B of chapter 111 of the Massachusetts General Laws (MGL). Such services include, but are not limited to, magnetic resonance imaging (MRI); computed tomography (CT scan); linear accelerators, lithotripters and positron imaging technology (PET scan). Most imaging services require a large initial capital expenditure for equipment. Services are administered either in freestanding offices that specialize in diagnostic imaging, or in hospitals or group practices that have the equipment on site.

Statutory & Regulatory Background:

State law requires that any provider who wishes to offer a "new technology" must first obtain a DoN from the Department of Public Health (DHP).[2] "New technology" is defined as equipment including but not limited to magnetic resonance imagers, lithotrypters, and linear accelerators, as defined by the department, or a service, as defined by the department, primarily intended for use in the provision of medical or surgical services, whether for diagnostic or treatment purposes, which has received approval from the U.S. Food and Drug Administration or which has been placed in "Approvable Status" by the U.S. Food and Drug Administration, or which has been

[2] MGL 111§25C

authorized for physician use by appropriate professional societies, but which is not in general use for patient care by physicians qualified to operate the equipment or provide the service."[3]

Prior to 1991, practicing physicians were generally exempt from DoN requirements under the physician practice exemption. In 1991 an amendment to the general laws added language (MGL 111, §25C) requiring a DoN review for any provider, physician or other entity that intended to offer MRI services. In 1993 the Legislature expanded the requirement to "the use of innovative services and new technologies." The 1993 amendment grandfathered in equipment acquired before December 31, 1991. It also permitted the filing of a notice of intent (before December 29, 1993) to acquire medical, diagnostic or therapeutic equipment used to provide an innovative service or which is a new technology.[4] Those who filed the notice were issued a Physician Letter of Exemption from the new DoN requirements.

A second area of relevant law has to do with the issue of referrals of patients for MRI services. Physicians who have an ownership stake in medical diagnostic services face a potential conflict of interest when referring their patients to use those services. Self-referral arrangements tend to result in increased utilization of services, some of which may not be medically necessary. This is a significant concern because increased utilization is a major driver of escalating health insurance premiums and rising health care expenditures. To combat this potential problem the federal government enacted the so-called Stark Law,[5] which prohibits Medicare payments for services that result from self-referrals. In addition, 36 states have applied these prohibitions to state, and in some cases private, payers. Massachusetts does not have a set of safeguards similar to the federal rules or these other states.

[3] MGL 111, §25B
[4] See Section 6 of Chapter 350 of the Acts of 1993.
[5] Named after its original sponsor, Pete Stark (D-CA), the "Stark Law" is actually formed by three separate statutes: the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239); the Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66); and the Social Security Act Amendments of 1994 (P.L. 103-432).

MRI Issues:

In its initial meeting and subsequent discussions, Commission members identified a number of issues related to MRIs. These included the fate of physician letters of exemption, the potential for over-utilization of services and for abuse in referrals, as well as issues of safety, and access to services (waiting times in some areas, etc).

V. QUESTIONS AND DISCUSSION

Introduction

In two meetings (January 16th and February 13th, 2007) that followed the Commission's initial educational sessions, members sought to further define the scope of the Commission's work and identified a series of questions that needed additional discussion and research before final recommendations could be made. These questions were the focus of the public hearing held on March 21, 2007. Several experts identified by Commission members were invited to testify and asked to address these questions in their presentations; at the same hearing other interested parties also provided testimony that addressed the questions, which had been circulated in advance of the hearing. The remainder of this section contains a discussion of each question that is based on both hearing testimony and additional research by Commission staff. As in the previous section, discussion is divided into two sections, the first dealing with ASC issues, the second with MRI issues.

ASC Questions and Discussion

Questions concerning ASC issues fell into three categories, a) current regulations and experience, b) issues of cost & access, and c) quality issues.

A) Current ASC Regulations and Experience

1) How does the DoN process work in Massachusetts, how does it differ from processes in other states, and should it be changed?

Massachusetts established its Determination of Need (DoN) program in the early 1970s as a means of constraining the growth of health care costs by requiring health care facilities proposing to build new facilities to demonstrate that there was an unmet health care need. Adoption of the DoN process was based on a belief that market forces alone were insufficient to allocate health care resources efficiently, along with a belief that constraining utilization was one way to control costs. Encouragement for development of

DoN processes was offered by federal law (the National Health Planning and Resource Development Act of 1974), which threatened a decrease in federal Medicaid funding to those states that did not implement DoN programs by 1978. However, during the 1980s a new emphasis on market solutions for controlling health care costs led to a repeal of many of the federal provisions related to DoN, and by the late 1990s the DoN process had shifted to a focus on maintaining quality. Today, the Department of Public Health (DPH) describes its mission as the promotion of "availability and accessibility of cost effective quality health care," noting that the program was originally created to "encourage equitable geographic and socioeconomic access to health care services, help maintain standards of quality, and constrain overall health care costs by eliminating duplication of expensive technologies."[6]

The DoN process is governed primarily by MGL 111§ 25C as well as by DPH regulations. Under the statute, a DoN is required in order to make "a substantial capital expenditure for construction of a health care facility or a substantial change in service of any such facility" and compliance with the DoN process is a condition of licensure for these facilities. The term "substantial capital expenditure" is further defined in both statute and regulations; currently a DoN is required for capital expenditures worth more than $13.6 million by acute care facilities and for capital expenditures of more than $1.4 million by clinics. The term "facility" to which the DoN requirements apply is further defined in MGL 111 § 25B and encompasses clinics, including those providing ambulatory surgical services, as defined in MGL 111 § 52. However, that definition of clinic was amended in 1979 to exclude "a medical office building, or one or more practitioners engaged in a solo or group practice...so long as such practice is wholly owned and controlled by one or more of the practitioners so associated or, in the case of a not for profit organization, its only members are one or more of the practitioners so associated."

While this so-called "physician office exemption" was originally intended to protect traditional physician practices from sweeping regulatory changes, it has allowed certain

[6] Mission Statement, Massachusetts Determination of Need Program, Department of Public Health website.

ASCs to operate without going through the DoN process or undergoing associated regulatory oversight by the state, although ASCs that want to receive Medicare reimbursement must meet separate accreditation standards (see additional discussion in question #2 below). Whether they go through the DoN process or operate under the physician office exemption, facilities must go through a DoN process if they wish to add, expand, or develop an innovative service or new technology, such as Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), or others. Finally, ASCs created under a hospital license (i.e., they are a part of the hospital, even if they are physically separate) are not required to go through the DoN process, unless the cost of developing such a service exceeds a certain capital expenditure threshold.

DPH regulations (105 CMR 100.533) set out application and DoN approval processes, and include requirements that facilities make a clear and convincing demonstration that proposed projects are needed and do not duplicate current services, that they demonstrate the reasonableness of proposed expenditures and costs (for instance, the likely effect of the expenditure on public and third-party payer costs can be considered in the DoN approval process), and that they show the primary and preventive health services they will provide, as well as their current contributions to the community. Projects must also meet various criteria designed to prevent duplication of services while providing adequate access. The DoN process requires a public hearing and allows for a public comment period.

Thanks to the federal law and incentives described above, nearly every state created some sort of Certificate of Need (CoN) program during the 1970s. While the relevant federal provisions were repealed in 1987, today about 36 states still have some type of Certificate of Need (CoN) [7] program, although many have made additional changes to the original program. States that do have CoN programs vary rather widely in respect to what services are required to undergo a CoN process—for instance, Oregon's CoN process applies to only two services, while Connecticut and Vermont require a CoN for 28 and 27

[7] "Certificate of Need: State Health Laws and Programs" NCSL website (updated April, 2007). CoN and DoN programs are essentially the same, and the terms are treated synonymously in this report.

different services, respectively (including ASCs). Of the states with a CoN process, 27 include a review of ASCs (including all New England states and New York). There does appear to be an association between the existence of a CoN program and number of ASCs in a state. For instance, when the Pennsylvania CoN statute expired in 1996, the number of ASCs increased by 55%. Likewise, in 2000 there were 44 freestanding ASCs in Missouri before the legislature raised the minimum capital expenditure level subject to CoN review. This relaxation of the CoN law led to a doubling of the number of freestanding ASCs in the state by 2005.[8]

Under the Massachusetts DoN guidelines, DPH stopped accepting applications for multi-specialty ASCs in 1995 and currently runs DoN processes for single-specialty surgery centers only. Since 1992, nineteen DoN applications for ASCs have been reviewed; fourteen were approved, four were denied, and one was withdrawn.

Opinions as to whether the current DoN statute and program in Massachusetts should be changed vary widely. Some Commission members felt that all providers of ambulatory surgical services should be held to the same state standards of licensing, quality and safety review, and DoN requirements without exception. Other Commission members argued that an overly stringent DoN process is stifling the ability of ASCs to provide greater access to ambulatory surgical services, and a lower cost for those services. One member noted that DoN programs were designed before the emergence of current health care trends that involve a shift from in-patient to out-patient care and include the growth of ASCs. At the same time, another member noted that the physician office exemption was also created before the emergence of this trend, suggesting that it was never intended to exclude oversight of office-based ambulatory surgery.

2) What is the state of current regulation and licensure of ASCs (both free standing and those that are part of a physician office) & hospitals and should it be changed?

[8] Written communication, Missouri Certificate of Need Program

As noted above in #1, compliance with the DoN approval process is a condition of licensure by DPH for hospitals and ASCs. However, as is also noted above, current Massachusetts law provides an exemption for certain ASCs under the physician practice exemption.[9] Since the creation of this exemption, multi-specialty practices that are much more advanced and complex than the more conventional physician practices, including ASCs, have emerged and have also been grouped under it, with the result that those ASCs operating under the exemption are not subject to the regulatory oversight that is associated with licensure by DPH.[10] However, in order to receive Medicare reimbursement (without which most ASCs could not survive), an ASC must be certified and must be found to meet the Medicare conditions of participation. The required survey can be conducted by Health Care Quality or by a third-party accrediting agency approved by the Centers for Medicare and Medicaid Services (CMS). Under current law, only if an ASC chooses to be licensed by DPH as a clinic is it required to submit to state licensure requirements and the state healthcare planning process incorporated in the DoN law. Likewise, Medicare certification (or other scrutiny) may be required for private third-party reimbursement. According to DPH, there are currently 55 free-standing ASCs operating in the Commonwealth. Of these, 45 are unlicensed but are Medicare-certified, while ten are both licensed and Medicare-certified. One Commission member claimed that these numbers do not represent all of the ASCs operating in the state, since ASCs that operate under the physician office exemption and choose not to receive Medicare reimbursement would not be included in this count.

Some Commission members argued that Medicare certification is evidence that ASCs meet appropriate quality and safety standards, and pointed out that all physicians practicing in any setting must meet Board of Registration Guidelines. However, other members point out that a 2002 report by the federal Office of the Inspector General found

[9] The impetus behind this exemption was to prevent services and equipment that were typically associated with traditional physician practices from being swept up into the regulatory process. While the exemption was intended to apply only to traditional physician group practices, the emergence of more complex and multi-specialty practices, and the growth of entrepreneurial medicine resulted in a need to redefine its scope. In a 1990 opinion issued by DPH's General Counsel, which relied on the Attorney General's 1982 Opinion, the Department determined that a practice under question was not entitled to the exemption.
[10] Such regulatory oversight includes DoN, DPH 1994 DoN Guidelines for Freestanding Ambulatory Surgery Centers, and DPH regulations for the Licensure of Clinics 105 CMR 140.00.

flaws in the Medicare system of oversight,[11] and argue that greater oversight of ASCs is needed, including an accurate count of *all* entities providing ambulatory surgical services in the state is needed.

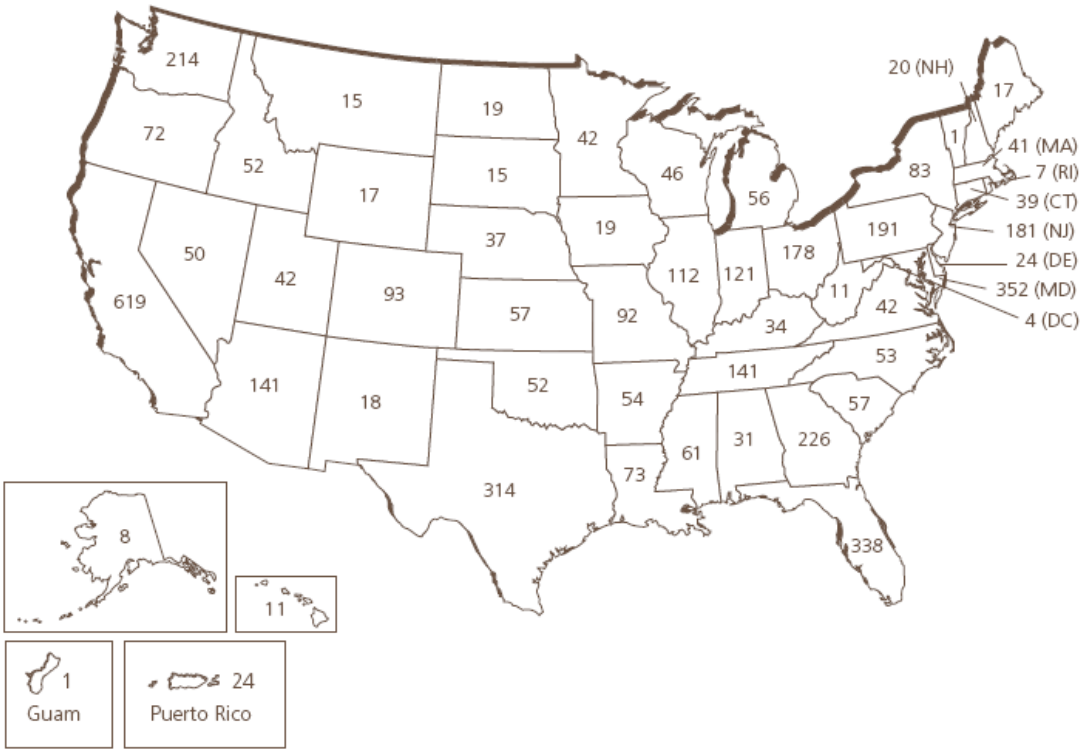
3) What are the numbers and types of ASCs in Massachusetts vs. other states?

As noted above, there are a total of 55 Medicare-certified ASCs in Massachusetts, including 10 ASCs that are also state-licensed; in theory there could be other entities providing surgical services under the physician office exemption that are not Medicare-certified or licensed, and hospital out-patient departments also provide ambulatory surgical services. There are currently about 4,700 Medicare-certified ASCs across the country, with 30% of all ASCs located in California, Texas, and Florida. In contrast to Massachusetts, New Jersey (with a population of 8.7 million) has 192 certified ASCs, while Pennsylvania, with a population roughly double that of Massachusetts, has four times as many certified ASCs (201). Neither of these states has a DoN process for ASCs. By contrast, the state of New York, which does have a DoN process for ASCs, has 83 such facilities (New York's population is slightly more than three times that of Massachusetts). Nationally, ASCs tend to be for-profit entities in contrast to hospitals, which tend to be non-profit (nearly all hospitals in Massachusetts are non-profits, and there is little penetration, thus far, by for-profit ASC chains). Of course, any physician-owned ASC may operate on a for-profit basis; however, the Commission received no authoritative information on the numbers of each type (for-profit vs. non-profit).

The chart below (from FASA, an advocacy organization associated with the Foundation for Ambulatory Surgery) provides a rough picture of the numbers of Medicare-certified ASCs around the country (it is based on older data; hence the discrepancy between the numbers reported on the map and those above).

[11] Janet Rehnquist, Inspector General, *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*, OEI-01-00-00450 (Feb. 2002).

Number of Medicare-certified Ambulatory Surgical Centers by State, 2006



FASA analysis of 2006 Medicare data.

4) **What are current reimbursement methods and how do they differ among ASCs and other types of providers, particularly hospitals?**

The main sources of reimbursement for medical services are commercial insurers, Medicare, and Medicaid. In addition, some individuals pay for their own care (self-payers), while the Uncompensated Care Pool reimburses acute hospitals and Community Health Centers for a portion of the cost of providing care to uninsured residents of Massachusetts. There are differences in the way payers reimburses similar services provided at ASCs and hospitals.

Medicare has separate reimbursement systems for ambulatory surgical procedures performed in a free-standing ASC versus those performed in hospital outpatient departments. Services provided in hospital out-patient departments (HOPDs) are

reimbursed under an Outpatient Prospective Payment System (OPPS) that groups services, based on clinical and cost similarities, into Ambulatory Payment Classifications (APCs). This system is meant to cover the hospital operating and capital costs for the services bundled within each APC, with separate payment for professional services (e.g., physicians' fees).[12]

In contrast, Medicare provides reimbursements for surgical services in free-standing ASCs using individual surgical procedures as the unit of payment. Over 2,000 procedures are grouped into nine payment categories and reimbursed using a fee schedule that ranges from $333 to $1,339 (with adjustments for geographical factors). Physician services are reimbursed separately under a physician fee schedule. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed CMS to implement a revised ASC payment system by January 2008 and this revised system will likely be based on the OPPS groups used to determine hospital payments.[13]

In Massachusetts, Medicaid provides reimbursements to freestanding, multi-specialty ASCs; currently five ASCs are approved by MassHealth (the Massachusetts Medicaid program) for reimbursement. The rates paid are those set by Medicare, and are paid for the facility component of the service only, with separate reimbursements for physicians (similar to Medicare). Medicaid reimburses hospitals for outpatient services using the PAPE (Payment Amount per Episode) methodology developed as part of the annual MassHealth Acute Hospital RFA (request for application). The PAPE system consolidates all out-patient services (surgeries, clinic visits, ancillary services, etc. except laboratory) provided to a single patient in a single day into one PAPE. A case mix factor, which measures the level of services provided at a hospital, is applied to the statewide average rate; these factors are reviewed annually. The PAPE method thus does not reflect the exact costs for services provided during the day; rather it is an average of low and high-cost procedures typically provided by a hospital. Currently average PAPE

[12] MedPAC fact sheet: (http://www.medpac.gov/publications/other_reports/Sept06_MedPAC_Payment_Basics_OPD.pdf)
[13] Med PAC fact sheet: (http://www.medpac.gov/publications/other_reports/Sept06_MedPAC_Payment_Basics_ASC.pdf)

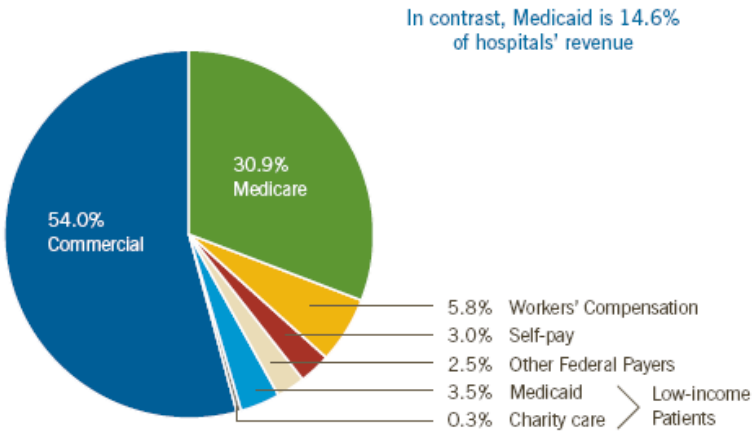
payment range from $124 to $1,500 depending on hospital case mix (with a state average of about $138).

The Commission received very little information concerning the reimbursement practices of private payers. However, in a discussion at one Commission meeting, a member noted that commercial insurance companies structure their reimbursements for hospitals to essentially "lock in" at an aggregate amount they want to pay, and then negotiate how that amount is distributed. In the same conversation, another member noted that there is "tremendous" variation in payments across different types of hospitals, and attributed differences in payments between ASCs and hospitals to an understanding, on the part of payers, that hospitals and ASCs have very different cost structures. One large insurer has described ASCs as a "cost-saving alternative" to traditional hospital care, suggesting that they reimburse ASCs at a lower rate; any such lower rates would, of course, be a consequence of the fact that hospital reimbursements reflect the aggregate costs of providing a full range of hospital care (including costs for unprofitable services).

5) Are there payer mix differences between ASCs and hospitals?

The chart below shows the breakdown of payer types for ASCs nationally, and notes the contrast in regard to the proportion of revenue accounted for by Medicaid reimbursements at hospitals (14.6%) and ASCs (3.5%). Although reliable Massachusetts-specific data for ASCs is not available, due to the lack of state regulation of centers that are not licensed by DPH, given the low number of ASCs that are eligible to receive Medicaid reimbursement in Massachusetts the proportion for ASCs in this state may be different than that shown here.

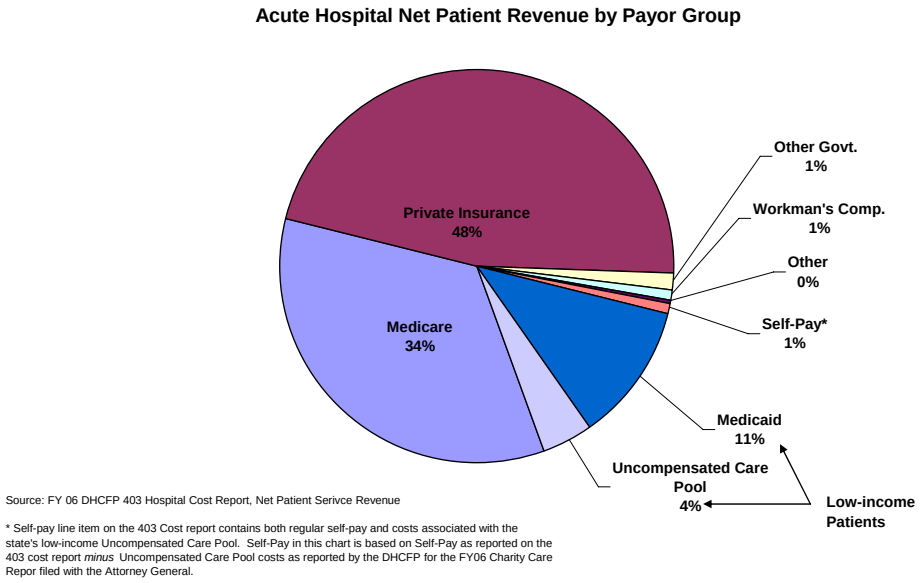
Ambulatory Surgical Center Payer Types Nationally, 2004



Source: Medical Group Management Association (MGMA), *Ambulatory Surgery Center Performance Survey*, 2005 Report, and AHA Annual Survey.

State-level data is available for hospitals, and shows that Medicaid and Uncompensated Care Pool reimbursements account for 15% of the hospital payer mix,[14] although the proportions vary substantially across hospitals and may be lower at community hospitals. The proportion of revenue accounted for by Uncompensated Care Pool reimbursements does not, however, represent the actual level of charity care provided, as these reimbursements cover only a portion of the costs related to providing this form of care. However, it is important to note that hospitals are eligible for reimbursement from the Uncompensated Care Pool for a portion of these costs, while ASCs cannot receive such reimbursement. Note also that the available data likely do not capture unlicensed ASCs operating under the physician practice exemption.

[14] Note that the hospital data include all hospital revenue, not just the portion related to ambulatory surgical services.

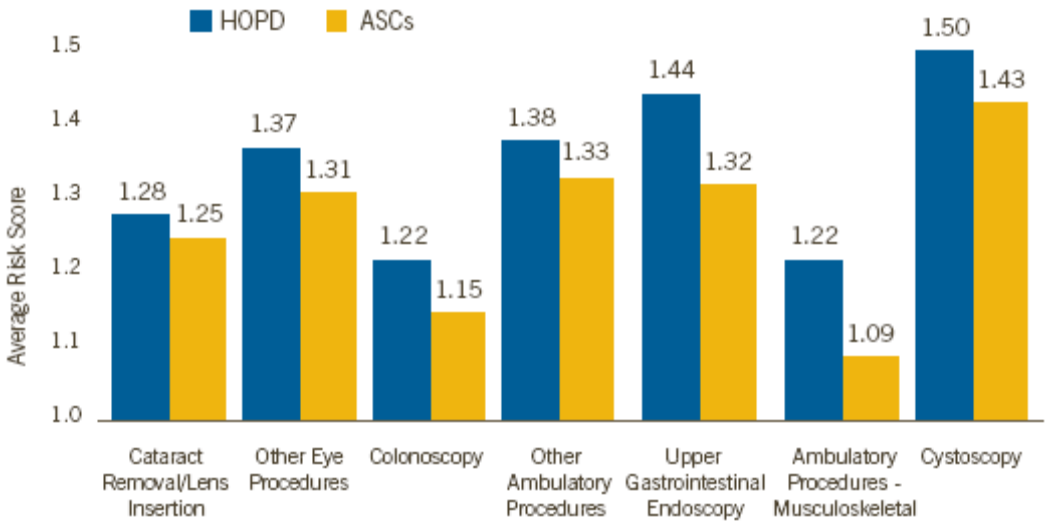


6) Are there case mix differences between ASCs and community hospitals (or other types of hospitals)?

The chart below shows the average patient risk scores (for Medicaid patients in 1999) for services performed in hospital out-patient departments (HOPDs) versus scores for the same services performed in ASCs, and suggests that hospitals are generally treating a higher proportion of patients with potential complications or other health risks. Other studies support this picture. A 2004 Rand Corporation study found that, for cataract and colonoscopy procedures, a larger share of patients treated in HOPDs tended to have hypertension and/or a diabetes diagnosis.[15] Similarly, a 2003 article published in *Health Affairs* found that hospital outpatient surgery departments tend to treat more medically complex Medicare patients than do ASCs.[16] While there are not reliable state-level data to answer this question for Massachusetts specifically, there is no reason to believe that experience should vary in this state.

[15] Wynn, Barbara et al. *Services Provided in Multiple Ambulatory Settings: A Comparison of Selected Procedures* (Rand Health Working Papers), November, 2004, No. 04-3.
[16] Winter, Ariel. *Comparing the Mix of Patients in Various Outpatient Surgery Settings,* Health Affairs 22, no.6 (2003): 68-75.

Average Patient Risk Scores for Medicaid Patients in Ambulatory Surgical Centers (ASCs) vs. Hospital Outpatient Departments (HOPD), 1999



Source: Winter, A, (2003), "Comparing the Mix of Patients in Various Outpatient Surgery Settings," *Health Affairs*, 22: 68-75.

B) Cost & Access Issues

1) How is patient cost-sharing typically structured at ASCs? Are there differences between ASCs (both free standing and physician office based) and hospitals in respects to costs and cost-sharing?

The Commission was able to obtain little information on this topic. A 2004 MedPAC report shows that co-insurance rates for Medicare patients are between 11% and 61% lower (depending on the procedure) at ASCs than at hospitals; however the same report notes that co-insurance rates at hospitals are due to decline over time to a level more similar to ASCs.[17] In fact, given potential changes to Medicare's reimbursement system (see #4 in section A, above), both payments and cost-sharing arrangements at each type of facility could become more similar.

[17] MedPAC March 2004 Report, p.187.

2) Would expanded contracting with ASCs by MassHealth (the state's Medicaid program) affect state Medicaid expenditures (for instance, might savings result?). What are the arguments for and against Medicaid adopting Medicare standards of reimbursement for ASCs?

Note that Medicaid reimbursement practices are discussed above (section A, #4). While makes sense that shifting services to a lower cost setting could lower expenditures for those services, one Commission member noted that higher utilization costs that could occur as a result of physician ownership of (and self-referral to) ASCs might lead to higher reimbursement levels. The Commission received no specific projections of potential savings for the MassHealth program.

3) What would be the impact of expanding ASCs on availability and access to medical services in Massachusetts? In particular, what impact do ASCs and clinics providing ambulatory services pose to the continued viability of (and hence access to) hospital services in Massachusetts?

Discussion of this topic tended to be subjective and based on anecdote. There is little data available to answer this question with any certainty. It might make intuitive sense that expansion of ASCs would allow greater access to the types of medical services they provide, but while such access is certainly desirable, the potential long-term effects of such an expansion are far from clear. MedPAC and CMS have made it clear that there is adequate access to ASCs on a nationwide level; however, this assessment may reflect, in part, the more rapid growth of ASCs in other states and could be less true for Massachusetts.

Hospitals have persistently argued that their services are reflective of the communities in which they operate, and that in order to be responsive to community needs they must offer a wide range of services, some of which are more profitable than others. If an expansion of ASCs means that profitable services are shifted to ASC facilities, it could increase pressure on hospitals to eliminate or restrict services for which they are reimbursed less than the cost of care, and such a shift could ultimately result in reduced access to critical services. At the same time, information provided by DPH indicates that the expansion of ASCs would likely not reduce emergency room crowding, because that

phenomenon results from insufficient staffing of in-patient beds and would not be significantly reduced by the expansion of ASCs.

4) Do ASCs and hospitals provide equal access?

Again there is little hard data to answer this question, although information discussed above indicates that patients at ASCs are less likely to be low-income or high risk. However, any such difference could well be the result of the way the system is currently structured, as well as a need for patients to receive care in a suitable setting. In other words, if ASCs are not eligible for Medicaid or Uncompensated Care Pool reimbursements, it is hardly surprising that they are less likely to see low-income patients. At the same time, it may be desirable for higher risk patients to receive ambulatory surgical services in a hospital out-patient setting where potential complications can be treated more efficiently, and it may likewise be desirable to maintain the viability of hospital infrastructure to provide such care.

C) ASC Quality Issues

1. What are the requirements and current practices concerning safety measures at hospitals and ASCs (both free standing and physician office based)?

Hospitals and different types of ambulatory surgical centers are subject to different sets of standards and regulations concerning the safety.

Hospitals that provide ambulatory surgical services in a hospital-affiliated ASC (or out-patient department) under the hospital's license must adhere to conditions of that licensure. These include allowing the Department of Public Health (DPH) the right to inspect the facility, staff, activities and records with no prior notice, submission of corrections plans if DPH finds deficiencies during inspections, and establishment of a serious complaint procedure. ASCs provide services in facilities specifically designed to perform selected outpatient surgical services. There are essentially three sets of standards that potentially apply to free-standing ASCs: a) Medicare requirements, b) state licensure,

and c) voluntary accreditation.

All ASCs serving Medicare beneficiaries must be certified by the Medicare program. In order to be certified, an ASC must comply with federal safety standards; in addition, federal regulations also limit the scope of surgical procedures reimbursed in ASCs. Generally, services are limited to elective procedures with short anesthesia and operating times not requiring an overnight stay. Under Medicare guidelines, ASCs must maintain complete, comprehensive and accurate medical records, and patients must receive pre- and post-operative examinations to evaluate risks and recovery associated with anesthesia. CMS also requires ASCs to take measures to ensure patients do not acquire infections during their care at these facilities, including active surveillance and prevention techniques. A registered nurse trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever a patient is in the ASC, and ASCs are also required to have an effective means of transferring patients to a hospital for additional care in the event an emergency occurs (in Massachusetts, an ASC must have a written transfer agreement with a local hospital, or all physicians performing surgery in the ASC must have admitting privileges at the designated hospital).

In Massachusetts there are ten free-standing ASCs that are licensed by DPH, in addition to being Medicare-certified, and which are thus subject to further regulation by DPH. This regulation includes a requirement that licensed ASCs grant DPH the right to inspect the facility with no prior notice (similar to hospitals), and a requirement that ASCs are subject to annual State Drug Control registration and periodic on-site surveys and complaint investigations, including requirements for drug storage, preparation and administration, and recordkeeping. At certified-only ASCs, the individual physician must renew State Drug Control registration every 3 years, but there is no consistent oversight of unlicensed ASCs to ensure that they are meeting criteria concerning drug storage, preparation, and administration. Likewise, while DPH-licensed ASCs are required to report to DPH all incidents occurring on their premises that seriously affect the health and safety of patients, ASCs that are only Medicare-certified are not subject to such reporting requirements.

In addition to meeting Medicare certification requirements, many ASCs choose to go through voluntary accreditation by an independent accrediting organization. Accrediting organizations for ASCs include the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for the Accreditation of Ambulatory Surgery Facilities (AAAASF) and the American Osteopathic Association (AOA). ASCs must meet specific standards during on-site inspections by these organizations in order to be accredited. All accrediting organizations require an ASC to engage in external benchmarking, which allows the facility to compare its performance to the performance of other ASCs.

Finally, ASCs that are not licensed by DPH and are not Medicare-certified are not subject to any of these requirements, although they might follow the Massachusetts Medical Society's Office Based Surgery Guidelines (but are not required to do so).

2. What are the current quality and safety reporting requirements for these facilities? What are differences between them?

ASCs must undergo an evaluation of quality standards in accordance with federal law.[18] They must engage in an ongoing assessment of the quality of care they provide, as well as the medical necessity of procedures. However, for unlicensed ASCs there is no state or federal process for ensuring that the clinic is meeting these standards.

Massachusetts requires that all complications and pre/post-operation services and procedures be reviewed internally by staff and the clinic. Licensed centers are required to report incidents occurring on the premises which seriously affect the health and safety of patients.[19] However, unlicensed and Medicare-certified only ASCs are not required to report such incidents to either CMS or DPH.

[18] CFR 426.43
[19] 105 CMR 140.307

A hospital-affiliated ASC operated under the hospital's license must adhere to conditions of that licensure, including, but not limited to:

- participating in the Board of Registration in Medicine risk management program set out in M.G.L. c. 111, §203(d) and 243 CMR 3.00, *et seq;*
- granting DPH the right to inspect, unannounced, the facility, staff, activities and records;
- submitting a plan of corrections in response to DPH statement of deficiencies found on inspection;
- establishing serious complaint procedure and reporting to DPH.

A clinic-type ASC operated under a clinic license must adhere to licensure conditions including, but not limited to:

- participating in a limited Qualified Patient Care Assessment Program;
- granting DPH the right to inspect, unannounced, the facility, staff, activities and records;
- submitting a plan of corrections in response to DPH statement of deficiencies found on inspection;
- establishing a serious complaint procedure and reporting to DPH;
- adhering to the staffing and procedure requirements for clinics providing surgical services set out in 105 CMR 140.600 subpart F.

Physician-owned ASCs have no similar requirements, although the Board of Registration in Medicine encourages, but does not require, its licensees to follow the Massachusetts Medical Society's Office Based Surgery Guidelines.

3. What is the state of current research concerning quality, safety and medical error rates at ASCs vs. hospitals, and what differences (if any) does it show?

Some research indicates that there are no significant differences in quality between ASCs and hospitals. A 1993 study from the University of Toronto examined the overall and complication related readmission rates within 30 days of surgery at an ASC. Very low readmission rates were observed, with only 1.1 % of the patients readmitted, and only .15% as a direct result of surgical complications. It is important to note, however, that the study does not provide any detail on the patient mix or the care provided to medically complex or low income patients. Unfortunately, due to the lack of reporting for any adverse incidents, utilization or discharge data, the Commonwealth cannot get a full

accounting of the quality, safety, and medical error rates associated with surgery performed in entities operating under the physician office exemption.

More recently, a 2004 study suggests that Medicare beneficiaries treated in freestanding ASCs fare as well as those who undergo surgery at hospitals. The authors analyzed claims data of 564,267 Medicare beneficiaries, of which 175,288 were treated at ASC's. The remaining patients were treated in office surgical and outpatient hospital settings. Ultimately, the study found that adverse events for patients in the ASC setting were among the lowest of all three sites of care, even after controlling for factors associated with higher patient risk. However, the authors noted that during the study period they "observed an increased risk-adjusted rate of inpatient hospital admission or death within 7 days of surgery for procedures initially performed in a physician's office compared with an outpatient hospital, suggesting the need for continued surveillance." It is important to note that the authors of this study specifically indicated that results are limited to the Medicare population and cannot be generalized to a younger population or procedures not covered by Medicare. As a result, there is no discussion of the low income populations that tend to include more medically complex patients. Further, the authors note one study limitation is that there is clear selection bias because certain types of patients are more appropriately treated in certain care locations.

4. What is the correct configuration of oversight, rules, etc. in regard to ASCs and hospitals?

In 2002 the Office of the Inspector General of the U.S. Department of Health and Human Services issued a report entitled *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*.[20] The report found that Medicare's system of quality oversight is not up to the task, and lacks accountability. It recommended that CMS determine an appropriate minimum cycle for surveying ASCs certified by state agencies. It also stated that the Medicare Conditions of Participation for ASCs should be updated to address patient rights and continuous quality improvement. The Inspector General stressed that

[20] Janet Rehnquist, Inspector General, *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*, OEI-01-00-00450 (Feb. 2002).

state agency certification must strike an appropriate balance between compliance and continuous quality improvement, rather than focusing exclusively on one or the other. The Federal Department of Health and Human Services has responded by launching a "Quality Initiative" under which members of the ASC industry, along with associations and related organizations with a focus on health care quality and safety, are working to identify specific measures for quality appropriate to ASCs.

5. How does the growth of ASCs affect utilization rates?

According to a March 2003 Medicare Payment Advisory Commission (MedPAC) report to Congress, the number of Medicare certified ASCs has more than doubled between 1991 and 2001. The volume of procedures provided to beneficiaries at ASCs increased by 60% between 1997 and 2001. Medicare payments to ASCs, including program spending and beneficiary cost sharing, increased by almost 17% in 2002 and more than tripled between 1992 and 2002.

MedPAC offers a number of reasons for the rapid increase in ASC spending. ASCs may offer patients more convenient locations, the ability to schedule surgery more quickly, and shorter waiting times than hospital outpatient departments. Medicare beneficiaries' coinsurance is generally lower in ASCs than in outpatient departments. Physicians may be able to perform surgeries more efficiently in ASCs because they often have customized surgical environments and specialized staffing. Changes in clinical practice and health care technology have expanded the provision of surgical procedures in ambulatory settings. Additionally, Medicare began covering colonoscopies for colorectal cancer screening in 1998. Finally, physicians who invest in ASCs can increase their practice revenue by receiving ASC facility payments. The federal anti-referral law does not apply to surgery services provided in ASCs, making it possible for physicians to own and provide care in these facilities.

MRI Questions and Discussion:

1. **What are the current safety requirements concerning imaging and diagnostic services?**

According to a presentation to the Commission by Gail Palmeri of the DPH Department of Healthcare Quality, MRIs located in licensed facilities are subject to compliance with American Institute of Architects Guidelines for Construction through an architectural plan review and approval for MRI. There are no specific state licensing/registration and only voluntary accreditation. Centers should conduct equipment monitoring in accordance with Manufacturer's Guidelines and staff training by general standards of practice.

2. **What reliable evidence is there concerning trends in utilization of imaging and other diagnostic services in Massachusetts?**

A growing body of national level data indicates that the volume of services being provided to consumers is increasing sharply. Testimony to the House Ways and Means Committee in 2005 from the executive director of MedPAC, Mark Miller, indicated that during the period between 1999 and 2003, the volume and complexity of imaging services grew by 45%. This is a rate that is double the growth of all other physicians' services (22%). Miller also pointed out that there are more MRI scanners in the Pittsburgh area than in all of Canada. In 2003, there were over 13 CT scans provided for every 100 members of the largest health plan in that area.

Medicare spending on these services grew over 60% from 1999 to 2003. According to the 2006 New England Journal Health Policy Report, insurers are continuing to ask whether this rise in use/spending of imaging services is directly related to improved patient outcomes. The author opines that the rapid growth in utilization of these services has been driven by medical technology advancements, but also by "physicians who have an interest in supplementing their professional fee with revenues from ancillary services."

A recent study using billing data from a large California insurer showed that in 2004 self-referring physicians accounted for 33% of MRIs, 22% of CT scans, and 17% of PET scans.[21] No similar data exist for imaging performed in Massachusetts. Studies consistently show that physicians who are not radiologists operating their own imaging equipment with the opportunity for self-referral have substantially higher utilization than physicians who refer patients to radiologists.[22]

3. What types of physician self-referral prohibitions/notifications are appropriate to guard against potential abuse in Massachusetts?

The federal Stark law generally prohibits physicians from referring Medicare patients to imaging facilities in which they hold an ownership stake. However, the law provides for a number of exceptions. Physicians who are hospital-based employees or members of a non-profit group practice are not subject to the Stark prohibitions.

The In-Office Ancillary Services Exception allows for self-referral if the service is provided as part of the physician's practice. This loophole can potentially be exploited through business models in which doctors ostensibly lease the equipment and employees of an imaging center at the time of service, thus holding no technical ownership in the practice. There is evidence of such leasing arrangements in Massachusetts.

The federal anti-kickback statute[23] makes it illegal for doctors to accept bribes or other compensation in return for generating Medicare, Medicaid or other federal healthcare program business. Also, a physician cannot offer anything of value to induce federal healthcare program business. The statute includes more than 20 permitted "safe harbors", such as investments in group practices.

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[21] Jean M. Mitchell, *The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging*, Health Affairs 26, no. 3 (2007): w415–w424.
[22] David C. Levin, Vijay M. Rao, *Turf Wars in radiology: The Overutilization of Imaging Resulting from Self-Referral*, J Am Coll Radiol 2004;1:169-172.
[23] 42 USC 1320a-7b.

4. What is the current status of physician exemption letters?

The Physician Letter of Exemption was intended to safeguard physician-owned and controlled acquisitions from the DoN process if the acquisitions were made or a notice of intent were filed by a specific date. While the letters did not include an expiration date, their transitional nature is evidenced by the fact that the "grandfathering" provisions of the amendments were never codified in law. Grandfather clauses are used only to apply to existing situations, and to ease the transition of eventually applying to all future situations. However, a lack of regulation of these exemption letters has enabled their use as freely transferable personal exemptions. Individuals have purchased these letters for prices upwards of $300,000. This includes some who have come in from out of state many years after the deadline to file a notice of intent. In 2001, legislation was passed prohibiting further use of physician exemption letters in Berkshire County.[24]

According to Joan Gorga, director of the Determination of Need Program at DPH, the department issued 24 exemption letters for MRIs, 14 letters for radiation therapy, and 16 letters for Positron Emission Tomography (PET). It is unclear exactly how many letters are currently in use, and in what capacity.

5. Should diagnostic MRI and CT services be subject to Federal or state regulatory oversight?

While the Stark law and anti-kickback statute do not apply to patients with private health insurance, private payers employ extensive utilization review procedures to ensure that ordered tests are medically necessary.[25] Despite this market safeguard, 36 states have passed additional anti-self-referral laws that apply Stark-like regulation to patients with private insurance. The Commission received no testimony from the private insurance industry regarding a perceived need for additional measures.

[24] Chapter 203 of the Acts of 2001, §18.
[25] Krasner, Jeffrey, "Blue Cross to require preapproval for scans", *Boston Globe*, Sept. 6, 2005

Phase III of the Stark regulations were expected in March 2007. It was anticipated that the law would be changed to address improper lease arrangements and other potential loopholes. However, CMS sought a delay and the timeline for publication was pushed back until March 26, 2008.

At the Commission hearing, Thomas S. Crane, an attorney with Mintz, Levni, Cohn, Ferris, Glovsky & Popeo, P.C., suggested that the Legislature wait to see what was in the new regulations before acting on the self-referral issue. He also suggested the possibility of applying the Stark and anti-kickback provisions to all payers in Massachusetts.

VI. Recommendations

At this time the Commission makes the following recommendations:

Ambulatory Surgical Centers:

1. Medicaid/Free Care Reimbursement

Ambulatory Surgical Centers (ASCs) that are certified by Medicare should be eligible for Medicaid and the Health Safety Net Care Fund (i.e., Uncompensated Care Pool) reimbursement, provided that potential cost-savings from such a change can be demonstrated. The goal of expanded eligibility should be achieved by creating a special accreditation process for the purpose of Medicaid and Health Safety Net Care Fund reimbursements with oversight and transparency requirements, to be overseen by the Office of Medicaid in consultation with the Department of Public Health (DPH). The current assessment paid by hospitals to the Uncompensated Care Pool and the successor Health Safety Net Fund should extended in an equitable fashion to ASCs that receive such reimbursement (with a corresponding decrease in assessments on hospitals). The Office of Medicaid and the Division of Health Care Finance and Policy should take steps to ensure that ASCs that are eligible for Medicaid and Health Safety Net reimbursements do not limit access to patients whose care is reimbursable from these sources.

2. DoN Process & Licensure

The state should revisit statutory definitions related to clinics and the physician office exemption and consider creating a separate definition and set of regulations for ASCs, including those currently operating under the physician office exemption. In addition, the Commission recommends that ASCs wishing to become specialty hospitals be required to go through the full DoN process.

3. Safety & Transparency

All ASCs should have a written agreement with an acute care hospital concerning emergency situations. The DPH should promulgate regulations setting reporting requirements that are consistent for hospitals and ASCs (both licensed and Medicare-

certified). Such reporting requirements should be consistent across facilities for each service or procedure subject to reporting. The Quality and Cost Council should have access to data reported under these requirements. In addition, the Commission recommends that DPH monitor the numbers and types of ambulatory surgical services performed at hospitals and freestanding ASCs, in order to analyze any potential detrimental impact on hospital finances. Such data should include the location of ASCs and a breakdown of types of cases treated and types of payers (Medicaid, Medicare, private, HMOs, Health Safety Net Fund), along with information concerning ownership.

4. Additional Concerns

While it was not a primary focus of the Commission's deliberations, some members expressed serious concerns about cases of existing hospitals expanding ambulatory and other services under their current license in to new geographic areas, particularly those areas where other hospitals currently exist. We believe this issue merits further attention.

Medical Diagnostic Technology

1. Registration and Sunset of Physician Letters of Exemption

DPH should establish a registry of physician letters of exemption in order to determine who currently owns the 54 letters that were issued, and whether each letter has been implemented. All letters should be registered with DPH by January 1, 2008. The registry should include the current owner of the letter, as well as the status of the project and its location. After that time all unregistered letters should be considered null and void. Once registered, letters should be considered non-transferable.

Registered exemption letters should be implemented by January 1, 2009, at which time the rights conferred by unimplemented letters will sunset. Registered letter holders should be able to appeal for an extension with the Public Health Council until July 1, 2009. Registered physician letters of exemption that are not in use as of January 1, 2008 should be subject to a DoN with an expedited review process to be set up by DPH, at

which time section 18 of Chapter 203 of the Acts of 2001 should be repealed. Letters in use before that date should be grandfathered in with no DoN required.

2. MRI Technology, Maintenance and Staff Requirements

Medical diagnostic equipment should be required to meet current technology standards and maintenance requirements. DPH should draft regulations that will provide for the credentialing of those who calibrate and maintain such equipment. The Board of Registration in Medicine should draft regulations that will provide for the credentialing for those who read and interpret such results. In addition, MGL 111, §5Q(b), which currently regulates mammography facilities, should be amended to apply to all imaging technology, including but not limited to MRI, CT and PET.

3. Piggybacking Stark and Anti-Kickback in state law

The legislature should act to address potential self-referral issues with respect to state payers (MassHealth, Commonwealth Care, and the Group Insurance Commission). The best way to accomplish this is to piggyback the provisions of both the Stark law and the anti-kickback statute, including all exceptions and safe harbors, in state law. The attorney general should be charged with enforcement of these provisions.

This will allow the state provisions to stay flexible, and will not require frequent amendments as these laws are changed at the federal level. However, with CMS delaying the publication of its new regulations on the subject, the Commission feels that the potential problem of improper leasing arrangements should be immediately addressed by the state. Therefore, the legislature should apply all self-referral preclusions to physician leased, as well as physician owned facilities.

4. Licensing of Health Screening Providers

Legislation should be passed to require that anyone advertising or offering so-called preventative health screenings using ultrasound technology be licensed by the Commonwealth as a physician, nurse, or allied health professional. Those who operate and calibrate ultrasound equipment should be certified by either Cardiovascular Credentialing International, or the American Registry of Diagnostic Medical

Sonographers. Results should only be interpreted by a person who is board certified by the American Board of Radiology or the American College of Cardiology. These providers should be subject to further oversight by DPH and the Board of Registration in Medicine.

APPENDIX A

Stark Law Information session

1) "Stark Law Historical Perspective and Special Considerations" (presentation by Thomas Crane, Mintz Levin)
2) "General Court's Commission on Ambulatory Surgical Centers and Medical Diagnostic Services" (presentation by Dr. David Levin, Department of Radiology, Jefferson Medical College and Thomas Jefferson University Hospital)
3) Presentation by Wes Cleveland, American Medical Association

APPENDIX B

Determination of Need Information Session

1) "The Determination of Need Program" (presentation by Paul Dreyer, Bureau of Quality Assurance and Control, Massachusetts Department of Public Health)

APPENDIX C

Public Hearing Testimony

1) Agenda
2) List of witnesses (as signed in)
3) Invited testimony
   - Thomas Crane
   - Jean Mitchell
   - John Blair
   - Joan Gorga
   - Gail Palmeri
   - David Shapiro
4) Other written testimony
   - Mark Taylor, CEO, New England PET Imaging System/Merrimack Valley MRI
   - Carol A. Straney, Area Center manager, MRI of Dedham
   - Jeffery Levin-Scherz, MD, CMO, Atrius Health
   - Darlene Marini, Vice President, Massachusetts Association of Ambulatory Surgery Centers
   - Massachusetts Hospital Association
   - Andrew Whitman, Vice President, Medical Imaging and Technology Alliance
   - Peggi Keegan, BSN, RN
   - Kreg Palko, East Bay Surgery Center
   - Hoagland Rosania, MD
   - Theodore A. Calianos II MD FACS
   - Richard M. Bargar, MD
   - Peter E. Bentivegna, MD FACS
   - George Picard, Greater New Bedford Surgicenter
   - Dr. George Violin, MD
   - Dr. Kevin Mitts, Berkshire Orthopaedic Associates
5) Other Submissions
   - Accreditation Association for Ambulatory Health Care, Inc., Physical Environment Checklist
   - Accreditation Association for Ambulatory Health Care, Inc., Accreditation Handbook 2005
   - JACHO Comprehensive Accreditation Manual for Ambulatory Care 2005-2006
   - Massachusetts Medical Society, Physician Workforce Study, June 2006
   - Jean M. Mitchell, *The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging*
   - *People of the State of Illinois vs. Midi LLC, et al*, Complaint
   - Siemens Medical, *Imaging Opportunities for ENT Physician Practices*

APPENDIX D

D. Additional Comment from Commission Members

1) Massachusetts Hospital Association
2) Massachusetts Medical Society
3) Massachusetts Association of Ambulatory Surgery Centers
4) Fallon Clinic