# SB 2863: Sweeping Changes to Health Care Law in Massachusetts

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## Agenda

- Introduction (Mark Waxman)
- Gift ban legislation Ch. 111N (Lawrence Vernaglia & Mark Waxman)
- Quality and cost counsel and e-health institute (Lawrence Litwak)
- DPH requirements (Alan Einhorn)
- Family council & rapid response teams (Alpana Kumar)
- Insurance provisions (Michael Blau)

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# Chapter 111N: The Massachusetts Gift Ban Law

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## What We Will Cover

- The Background
- The New Law – The Debate Points
- Steps To Implementation
  - Regulations
  - January 1, 2009
- The Key Provisions
  - Who's Covered
  - What's Covered
  - The Requirements
  - Enforcement



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# The New Law

- The Background
  - Large Pharma and Device Settlements
    - False Claims Act Recoveries
    - Off-Label Marketing Schemes
    - Kick-Back Claims
  - Adverse Publicity and Public Suspicions
    - Conflicts of Interest
    - Over prescribing and over utilization
    - JAMA Articles
  - Industry's Own Positive Changes
    - PhRMA
    - AdvaMed
    - ACCME
  - Congressional Interest, Inquiries And Interactions



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# Why the Law is Important?

- Applies to practices conducted in Mass – regardless where manufacturer is headquartered
- Regulates marketing practices that are not otherwise illegal
- Requires disclosure of confidential business information
- Establishes reporting regime
- Mandates compliance programs
- Limitations on continuing education and other academic/professional presentations
- Financial penalties



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# The New Law

- The Debate Points
  - In Favor –
    Governor Patrick – "...help insure... choices about prescription drugs and medical devices [are] based on therapeutic benefits and cost- effectiveness..."
    - Curb the influence of inappropriate marketing
  - Against–
    - Too strict prohibitions will be roadblocks to medical research
    - Endangers level of clinical trial activity (5,673 trials in Mass.)
    - Forces disclosure of trade secret information
    - A threat to "academic scientists"



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# What the Law Requires

*Applicable to*:

- "Pharmaceutical or medical device manufacturing company" (PMDMCs)
- PMDMC "agents"
- PMDMC "marketers"
- Physicians and other prescribers
- Hospitals, nursing homes, pharmacists, and health benefit plan administrators



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## Mandatory Marketing Code of Conduct

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- Mass. DPH to adopt
- "based on" "applicable legal standards and incorporate principles of health care"
- Shall be "no less restrictive" than PhRMA and AdvaMed Codes.



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## Mandatory Marketing Code of Conduct (cont'd)

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Code "shall not allow"

- Payment for meals for practitioners that are
  - (a) part of entertainment or recreational event;
  - (b) offered without an informational presentation made by "pharmaceutical marketing agent" or without the agent being present;
  - (c) outside health care practitioner's office or hospital setting; or
  - (d) provided to practitioner's spouse or other guest



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# Mandatory Marketing Code of Conduct (cont'd)



Code "shall not allow"

- Entertainment or recreational items of any value (e.g. tickets to theater/sporting events, sporting equipment, or leisure or vacation trips, to any health care practitioner who is not a salaried employee of the company;
- Sponsorship or payment for CME that doesn't meet ACCME Standards For Commercial Support, or directly to a health care practitioner



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# Mandatory Marketing Code of Conduct (cont'd)



Code "shall not allow"

- Cost of travel, lodging, other personal expenses of non-faculty practitioners attending CME, third-party scientific or educational conference, or professional meetings, directly "or indirectly to the event's sponsor"
- funding to compensate for the time of practitioners participating in CME, third-party scientific or educational conferences, or professional mtg



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## Mandatory Marketing Code of Conduct (cont'd)



Code "shall not allow"

- Payment for meals directly at CME, third-party scientific or educational conferences, or professional meetings
- payments in cash or cash equivalents to practitioners "either directly or indirectly, except as compensation for *bona fide* services"



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## Mandatory Marketing Code of Conduct (cont'd)



Code "shall not allow"

- grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to practitioner
  - in exchange for prescribing prescription drugs
  - or using medical devices or commitment to continue prescribing or using



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# Mandatory Marketing Code of Conduct (cont'd)



## Code "shall allow"

- the provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information
- Advertising in journals
- Prescription drug samples for patients
- Comp for "substantial professional or consulting services" of practitioner in connection with genuine research project or clinical trial;
- Reasonable expenses for technical training on medical device if part of vendor's purchase contract for device



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# Mandatory Compliance Program



## PMDMC that employs a person to sell or market in MA must:

- Adopt/comply with the Code
- Training program for all sales and marketing staff on (w/o lim) the Code
- Annual audits to monitor compliance with the Code
- Adopt policies/procedures for investigating noncompliance with Code; take corrective action
- Mandatory reporting of noncompliance to "the appropriate state authorities"
- Identify compliance officer for operating and monitoring the Code



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# Section 5 Reports (Structural)

PMDMC that employs a person to sell/market "prescription drugs or medical devices" in MA annually submit to DPH:

- Description of its training program
- Description of its investigation policies
- Compliance officer contact info
- Certification that it has conducted its annual audit and is in compliance with the marketing code of conduct



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# Section 6 Reports (Substantive)

- PMDMC that employs a person to sell/market "a drug, medicine, chemical, device or appliance" in Mass shall disclose to DPH:
  - the value,
  - nature,
  - purpose and
  - particular recipient
- of any fee, payment, subsidy or other economic benefit with a value of at least $50, which the company provides, directly or through its agents,
- to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or other person in the commonwealth authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the commonwealth



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## Section 6 Reports (Substantive) (cont'd)

- Note different scope of Section 5 and Section 6 reporters
- Note breadth of fees to be disclosed
  - Regulations may provide guidance



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## Section 6 Reports (Substantive) (cont'd)

- "All disclosed data" (likely from Section 6 Reports not Section 5 Reports)
  - publicly available and
  - easily searchable on its website.



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## Enforcement

- No PMDMC or agent may "knowingly and willfully" violate the Code
- $5,000 fine for each transaction, occurrence or event in viol of Ch. 111N
  - Collateral consequences of violations?
- Enforced by DPH, AG, DAs
  - DPH to report to AG any payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value provided in violation of the market [sic.] code of conduct



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## Areas of Uncertainty

- Who's really covered?
  - Different sections of 111N apply to different types of industry players
  - Application to multi-corporate entities?
    - Separate R&D vs. sales entities
  - Marketer "or any other person". . .
- Medical Device Companies
  - Software?



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## Areas of Uncertainty (cont'd)

- Purchase of assets or licensing (patents or other IP?)
- Will regs distinguish commercial rebates/discounts, etc. from disclosable fees?
- What types of sponsorships are acceptable in Mass?
  - Conference where meals/reception paid for by other vendors?



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## Areas of Uncertainty (cont'd)

- What about ed programs that can't be done in the office/hospital? (medical device training facilities – Philips, Hologic, Smith & Nephew Endo)
- Travel and lodging for bona fide employees or consultants?
- What is minimum level of detail in Section 6 Reports?
- What protections for trade secrets other confidential information?



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## PhRMA-Pharmaceutical Research and Manufacturers of America

- Code of Interactions with HealthCare Professionals
- Updated Code takes effect January, 2009
- The operative principle: "...a healthcare professional's care of patients should be based, and should be perceived as being based, solely as each patient's medical needs and the healthcare professional's medical knowledge and experience"



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## Key Provisions

- Informational Presentations
- Prohibition on Entertainment and Recreation
- Support of CME
- Consultants
- Speaker Programs and Training Meetings
- Formulary or Clinical Practice Guideline Committees
- Scholarships and Educational Funds
- Prohibition on Non-Educational and Practice-Related Items
- Educational Items
- Prescriber Data
- Independence and Decision Making
- Training and Conduct of Company Representatives



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## PhRMA vs. Mass. Law

- Meals
- Sponsorship of programs not meeting ACCME standards



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## AdvaMed-Advanced Medical Technology Association

- Code of Ethics Adopted effective January 1, 2004
- Added FAQ's: April 15, 2005
- "[T]o facilitate Members' ethical interactions with those individuals or entities that purchase, lease, recommend use, arrange for purchase or lease of, or prescribe Members' medical technology products in the United States."



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## Areas Covered

- Member-Sponsored Product Training and Education
- Supporting Third party Educational Conferences
- Sales and Promotional Meetings
- Arrangements With Consultants
- Gifts
- Provision of Reimbursement and Other Economic Information
- Grants and Other Charitable Donations



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## AdvaMed vs. Mass. Law

- "Healthcare practitioner"(§1) vs. "Healthcare professionals" (FAQ 2)
  - "recommend"
  - "arrange" for purchase or lease
- Gifts
- Reimbursement Support Programs
  - No Mass. Law analogy



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# ACCME Standards for Commercial Support



- Independence
- Resolution of Personal Conflicts of Interest
- Appropriate Use of Commercial Support
- Appropriate Management of Associated Commercial Promotion
- Content and Format Without Commercial Bias
- Disclosures Relevant to Potential Commercial Bias



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# What's Next?

- Physician Payments Sunshine Act (S. 2029)(Grassley)
  - Pending in the Senate
  - Reporting of Payments or Other Transfer of Value
  - Scope: Manufacturer of a covered drug, device or medical supply
    - To a physician, or physician's employer, or has tenure with, or an ownership interest in
  - Coverage: Payments or other transfers of value directly or indirectly or through an agent, subsidiary or other third party



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# PPSA Continued

- Disclose to Secretary
  - Physician's office address
  - Affiliated facilities
  - Value
  - Date
  - Nature of transfer or payment
- Definitions:
  - Manufacturer – Gross revenues >$100 million
  - Payment or transfer of value >$25
- Exclusions:
  - Product samples
  - Clinical trial funding
  - When physician is a patient



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# What's Next?

- State by state effort vs. National reporting?
- Other provider relationships?



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# Health Care Quality and Cost Control

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## Health Care Quality and Cost Control Council (G.L.C. 6A, Section 16k)



- Purposes/Objectives of Council
  - Promote Transparency of quality and cost of health care
  - Improve health care quality
  - Reduce racial and ethnic health disparities
  - Contain health care costs



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# Structure of Quality and Cost Control Council

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- "Within but not subject to control of [EOHHS]"
- Organization of Council
  - 16 members: 9 ex-officio government and public agency officials; 7 health care related NGO representatives appointed by governor
  - Council may appoint executive director, and adopt Bylaws and regulations, employ staff and consultants



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# Structure of Quality and Cost Control Council (cont'd)

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- Advisory Committee (G.L.C. 6A, Section 16L)
  - Composed of 29 members appointed by governor
    - 21 represent specific agencies or healthcare organizations
    - 8 represent general healthcare interests
  - Council required to consult with Advisory Committee before setting goals, standards, benchmarks or filing any reports
- Data collected by Council not public records unless otherwise provided by Council



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# Functions/Activities of Quality and Cost Control Council

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- Collect and disseminate quality and cost data via website
- Establish quality improvement and cost containment goals
- Establish standard performance measures; quality performance benchmarks; statewide health information technology goals



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# Data Collection

- Use existing public and private data sources and agency processes for data collection, analysis and technical assistance
- Providers, insurers, TPAs must submit data in accordance with Council's regulations
- May contract with other agencies as well as independent organizations for data collection, analyses and technical assistance
- Penalty for failure to submit required data:
  - $1000 for each week of delay
  - $50,000 annual maximum



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## Dissemination of Data on Website

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- Council must establish consumer health information website in friendly format
- Website will have Cost and quality comparisons including (if available) comparative quality information by facility, clinician or group practice for:
  - Each service category for which comparative cost information is provided; and
  - Non-service specific information (e.g., patient safety and satisfaction)



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## Dissemination of Data on Website (cont'd)

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- Website to contain data concerning health care-acquired infections and services reportable events reported under c. 111, Section 51H
- Website to contain other general health care information



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# Annual Reporting Plan

- Council will prepare annual reporting plan in collaboration with state and federal agencies that develop, collect and report healthcare quality and cost measures
- Plan will specify quality and cost measures for use on website and security measures to preserve confidentiality and integrity of data
- Council adopts or rejects Plan after public hearing



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# Access to and Use of Data

- Council sets conditions for access to and use of data: which
  - Protect patient privacy
  - Prevent collusion or anti-competitive conduct
  - Prevent release of data that may be expected to increase cost of healthcare
- Council will provide providers their de-identified data, including, quality and cost comparisons with other providers
- Council may allow other agencies to use data (e.g. DHCFP) to evaluate mandated benefits



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## Development of Annual Quality and Cost Containment Goals

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- Council must develop annual healthcare quality improvement and cost containment goals designed to:
  - Promote high quality, safe effective, equitable, patient centered healthcare
  - Reduce racial and ethnic healthcare disparities
  - Incorporate recommendations of health disparities council and office of health equity
- For each goal Council must:
  - Identify steps to achieve goal
  - Estimate cost of implementation
  - Project anticipated financial savings
  - Estimate improvements in health of consumers



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## Development of Annual Performance and Quality Measures

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- Council, in consultation as the Advisory Committee, state agencies and private healthcare organizations will develop and annually publish:
  - Standard performance measures (including consistent reporting of measures used for P4P)
  - Quality performance benchmarks for providers and insurers that:
    - Are clinically important, evidence-based, standardized and timely
    - Include outcome and process measures;
    - Encourage improvement in health care quality
    - Are based on work of national organizations
  - Goals for statewide adoption of health information technology



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# Annual Progress Report

- Council files report (at least annually) with house and senate committees on its progress in achieving goals for improving quality and containing or reducing healthcare costs



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# Massachusetts E-Health Institute

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## Massachusetts E-Health Institute (G.L.C. 40J, Section 2)

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- Massachusetts E-Health Institute established to "be an institute for healthcare innovation, technology and competitiveness" and "advance dissemination of health information technology (HIT)...including the deployment of electronic health records (EHR) systems in all health care provider settings that are networked through a statewide information exchange"



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## Relationship to MassTechnology Park Corporation

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- Corporation's Executive Director appoints Director of Institute
- Corporation employs Director of Institute
- Corporation maintains E-Health Institute Fund
- Executive Director administers Fund
- Health information technology council is "within Corporation"
- Director recommends and Exec. Director and Council approve all grants and contracts with implementing organizations



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## Specific Objections of Institute/ Council

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- Facilitating implementation and use of EHR systems to improve delivery of care, reduce unwarranted treatment, eliminate waste, facilitate chronic disease management initiatives and establish transparency
- Facilitating statewide interoperable EHR network to permit providers to exchange patient health information with other providers
- Identify and promote accelerated dissemination of emerging HIT developed and employed elsewhere but not yet widely implemented in Mass.



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## Health Information Technology Council

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- Council advises Institute and approves Institute's decisions/actions
- Council: 9 members (4 ex-officio from public agencies and 5 having specific expertise appointed by Governor)
- Council and Corporation make all final decisions; statute does not establish structure, form or composition of Institute



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# Statewide EHR Plan

- Institute prepares, council and "board" approve statewide electronic health records plan that will be annually updated
- EHR Plan will include:
  - Budget for use of E-Health Institute Fund
  - Community-based component plans that assess readiness of cities, towns or region for implementation and use of EHR systems and interoperable EHR network



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# Community-Based Implementation Plan

- Each Community-based Implementation Plan expected to
  - (i) create seamless, secure electronic exchange of information among authorized providers users
  - (ii) provide consumers secure electronic access to own health information
  - (iii) meet applicable privacy and security requirements
  - (iv) give patients options to allow only designated providers ability to disseminate patient's identifiable information
  - (v) provide public health reporting capability
  - (vi) meet interoperability standards
  - (vii) allow legally required reporting of de-identified information



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## Implementation Plan Requirements

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- Allow patients to opt-in and opt-out at any time
- Maintain identifiable information in secure environment
- Provide list of anyone who accesses identifiable patient information



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## Grant Program

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Institute and Council expected to develop grant program (and other mechanisms) to assist providers with costs of implementing HIT

Grant recipients must:

- Capture and report quality improvement data
- Implement the EHR system fully, including all clinical features, "not later than the second year of grant, and
- make use of the system's full range of features



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# E-Health Institute Fund

- Fund pays for Institute's/Council's activities, services provided under contracts with implementing organizations and grants
- No specific appropriation or funding mechanism
- Director expected to solicit gifts, grants and donations from private sources to "maximum extent possible"
- Director to work with Medicaid to maximize FFP
- Fund administered by Executive Director contracts with implementing organizations and grants require approval of institute, Executive Director and Council



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# Annual Progress Report

- Institute must file annual report to legislative committees by Jan 30
- Report to cover general activities of Council, progress in implementing statewide EHR, and any recommended legislation



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# DPH Requirements

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## DoN Law Changes

- "New" definition of "expenditure minimum" for "substantial capital expenditures"
  - Indicates that
    - Expenditure minimum for acute care hospitals and comprehensive cancer centers is $7.5 million (rather than current $14.2 million), and
    - Expenditure minimum for other facilities is $800,000 (rather than current $1.5 million)
  - But, this "new" definition only changes the outpatient services limit
  - Acute and non-acute limits may not change



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# DoN Law Changes

- Expenditures and acquisitions concerned solely with outpatient services, other than ambulatory surgery, not otherwise defined as "new technology" or "innovative services," shall not require a DoN, and shall not be included in the calculation of the expenditure minimum,
  - UNLESS the expenditures and acquisitions are at least $25 million, in which case a DoN is required
  - Includes projects seeking written approval of final architectural plans 6 months or more after the effective date – i.e., February 10, 2009



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# Ambulatory Surgery Center Licensure

- Any entity that is certified, or seeking certification, as an ambulatory surgical center by CMS for participation in the Medicare program shall be a clinic for the purpose of licensure under MGL c. 111, Section 51
  - ASCs shall be deemed to comply with the conditions for licensure under Section 51 if they are accredited to provide ambulatory surgery services by
    - Accreditation Association for Ambulatory Health Care
    - Joint Commission on Accreditation of Ambulatory Surgery Facilities
    - Other national accrediting body acceptable to Department



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## Ambulatory Surgery Center Licensure/DoN

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- No original license shall be issued to establish an ambulatory surgical clinic unless there is a DoN for such facility
- HOWEVER, any entity providing ambulatory surgical centers services which is
  - in operation, or
  - under construction (as determined by DPH)
  - On the effective date of the Act (August 10, 2008) is exempt from this DoN requirement, and is eligible to make application for a clinic license for up to 6 months after the effective date of regulations adopted by DPH



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## DPH Reports: Healthcare Associated Infections and Serious Reportable Events

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- A "facility" (includes hospitals and clinics providing ambulatory surgery) shall report data information about "healthcare associated infections" and "serious reportable events"
- "Serious reportable events" shall be reported by a facility no later than 15 working days after their discovery. (Not clear how this requirement relates to DPH's current serious incident reporting requirements)
- No time-frame stated for reporting of "healthcare associated infections"



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## DPH Reports: Healthcare Associated Infections and Serious Reportable Events (cont'd)

- "Healthcare-associated infections" are localized or systemic conditions that result from an adverse reaction to the presence of an infectious agent or its toxins that:
  - Occur in a patient in a facility;
  - Were not present or incubating at the time of the admission during which the reaction occurs; and
  - If occurring in a hospital, meet the criteria for specific infection site as defined by the CDC and its national safety network
- "Serious reportable event" is an event that results in a serious adverse patient outcome that is clearly identifiable and measurable, reasonably preventable, and that meets any other criteria established by DPH in regulations



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## DPH Reports: Healthcare Associated Infections and Serious Reportable Events (cont'd)

- As of October 1, 2012, facilities are required to report "serious adverse drug events"
- "Serious adverse drug events" are preventable events that cause inappropriate medication use in a hospital or ambulatory surgical center that lead to harm to a patient, as further defined in regulations
- Question as to whether these events are already reportable



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## DPH Reports: Healthcare Associated Infections and Serious Reportable Events (cont'd)

- DPH may require facilities to register in and report to nationally recognized quality and safety organizations
- DPH shall transmit data collected from the reports to the Betsy Lehman Center for patient safety and to the health care quality and cost council for publication on its website
- A facility which fails to comply with the reporting requirements may
  - Be fined up to $1,000 per day
  - Have its license revoked or suspended
  - Both of the above
- DPH is charged to promulgate regulations prohibiting a facility from charging or seeking reimbursement for services provided as a result of a serious reportable event that was
  - preventable
  - within the facility's control, and
  - unambiguously the result of a system failure



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## Hospital/Clinic Records Law

- Amends existing law to specifically allow for the maintenance of record in electronic digital media, and the conversion of records to electronic digital media
  - Also states that
    - DPH will establish an appropriate notification process (to DPH) when records will be destroyed
    - Hospitals and clinics must provide information regarding this provision of the law in their Notices of Privacy Practices and in their records termination policies



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# Healthcare Workforce Center

- A Healthcare Workforce Center shall be established within DPH to, in consultation with the Healthcare Workforce Advisory Council:
  - Coordinate DPH's health care workforce activities with other agencies and public and private entities involved in healthcare workforce training, recruitment and retention;
  - Monitor trends in access to primary care providers, nurse practitioners, and other physician and nursing providers
  - Establish criteria to identify underserved areas in the Commonwealth for administering the Health Care Workforce Loan Repayment Program and determining statewide target areas for provider placement
  - Address health care workforce shortages through various activities



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# Health Care Workforce Advisory Council

- A Health Care Workforce Advisory Council shall be formed to advise the Health Care Workforce Advisory Center on
  - Trends in access to primary care
  - The development and administration of the Health Care Workforce Loan Repayment Program
  - Solutions to address identified health care workforce shortages
  - The Center's annual report



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# Health Care Workforce Loan Repayment Program



- There shall be a Health Care Workforce Loan Repayment Program, administered by the Health Care Workforce Center, which shall provide repayment assistance, for medical school loans, to participants who:
  - are graduates of medical or nursing schools
  - specialize in primary care
  - demonstrate competence in health information technology
  - satisfy other criteria to be determined
- Each recipient of assistance must enter into an agreement with the Commonwealth which obligates the recipient to perform a term of service of not less than 2 years in medically underserved areas as determined by the Center



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# Family Council and Rapid Response Teams

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## Patient and Family Advisory Councils

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- Every hospital in the Commonwealth will be required to establish a 'patient and family advisory council' to advise the hospital on:
  - Patient and provider relationships
  - Institutional Review Boards
  - Quality improvement initiatives
  - Patient education on safety and quality matters



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## Patient and Family Advisory Councils (cont'd)

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- Council members may:
  - Act as reviewers of publicly reported quality information;
  - Be members of task forces;
  - Be members of awards committees for patient safety activities;
  - Be members of advisory boards;
  - Participate on search committees and in the hiring of new staff;
  - Act as co-trainers for clinical and non-clinical staff



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## Rapid Response Teams

- Acute care hospitals will be required to have a 'suitable method' for staff members, patients, and families to request 'additional assistance' from 'a specially trained individual' if a patient's condition appears to be deteriorating
- Must have an 'early recognition and response method' available 24/7

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# Insurance Provisions

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# Insurance Provisions

- Nurse Practitioner Coverage/Parity
- Payor Data Collection and Analysis
  - Health Care Quality and Cost Council (HCQCC)
  - Division of Insurance (DOI)
  - Division of Health Care Finance and Policy (DHCFP)
  - Attorney General Role
- Uniformity and Consistency of Reporting Patient Care Information



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# Nurse Practitioner Coverage

- Consumer Choice of Nurse Practitioner Services (Chapter 176R)
  - All carriers are required to recognize nurse practitioners as participating providers and shall ***include coverage on a nondiscriminatory basis*** for care provided by nurse practitioners for the purposes of health maintenance, diagnosis and treatment
  - "Nondiscriminatory basis" means that the plan does not contain ***any lesser annual or lifetime dollar or unit of service limitation*** than imposed for the same services by other participating providers
  - Coverage includes ***benefits in all settings*** (including retail settings, like CVS) when rendered by a participating nurse practitioner to the extent that the policy currently provides benefits for identical services rendered by another licensed health care provider



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## Nurse Practitioner Coverage (cont'd)

- NP as Designated PCP—A carrier that requires the designation of a PCP shall provide its insureds with an ***opportunity to select or change to a participating nurse practitioner as their primary care provider***
  - Participating NPs must be ***included by carriers on provider directory lists***
  - Major change for primary care gatekeeper products
  - May raise questions about relative qualifications for prescribing, determining medical necessity, prior certification and referral management



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## Nurse Practitioner Coverage (cont'd)

- Issues
  - Applicable only to NPs (not other nurses practicing in an extended role)
  - Not applicable to self-funded plans (ERISA preemption)
  - Does not technically mandate that NPs be given staff privileges on a non-discriminatory basis (unlike podiatrists)
  - Does not mandate that NPs be paid at same rates as primary care physicians
  - Scope of NP practice subject to collaboration agreement and approved guidelines
    - Not all NPs have prescribing privileges
  - Relative liability risks for RN, supervising MD or institution



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# Payor Data Collection and Analysis

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- Data submission to HCQCC, DOI and DHCFP
- Health Care Quality and Cost Council
  - Insurers and TPAs submit unspecified data to the Council (or designee) or DHCFP
  - Not a public record
  - Penalties for non-compliance of $1000 per week, up to $50,000/year



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# Payor Data Collection and Analysis (cont'd)

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- Division of Insurance – – duty to (i) collect, analyze and publish data concerning the cost of health insurance and the health status of individuals, (ii) hold annual hearings concerning provider and payor cost trends and (iii) make recommendations to promote efficient health care delivery
  - DOI may publish regulations for uniform reporting of information from private and public health care payors to enable DOI to analyze and compare among plans:
    - Changes over time in health insurance premium levels
    - Changes in benefit and cost-sharing designs offered by payors
    - Changes in measures of plan cost and utilization
- DOI Report–annual report to legislature concerning spending trends and underlying factors, with recommendations to increase efficiency



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# Payor Data Collection and Analysis (cont'd)



- Payors must submit to DOI:
  - Average annual premium rates for health insurance plans offered (including most popular private plans for a representative range of group sizes, and lowest cost plan in each group size)
  - Actuarial assumptions that underlie the premiums for each plan
  - Average annual pmpm for enrollees in MassHealth PCC and fee for service programs
  - Summaries of plan designs for each plan or program
  - Information concerning the medical and administrative expenses, including medical loss ratio for each plan
  - Information concerning the payor's current levels of reserves and surpluses
  - Information on provider payment levels and methods (including for public payors, the 25 most common procedures provided to enrollees in those programs in a format that permits payment comparison of Medicaid FFS and Medicaid managed care organizations)
- Much of the data required to be submitted is proprietary and competitively sensitive. Not clear what data will/can be maintained in confidence by DOI



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# Payor Data Collection and Analysis (cont'd)



- DOI Public Hearings–Private and public payor witnesses may be required to provide testimony under oath concerning:
  - Factors underlying premium cost and rate increases
  - The relation of reserves to premium costs, the payer's efforts to develop benefit design and payment policies that enhance product affordability and encourage efficient use of health resources and technology
  - Efforts by the payer to increase consumer access to health care information
  - Efforts by the payer to promote the standardization of administrative practices
  - Other matters as determined by the DOI



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# Payor Data Collection and Analysis (cont'd)



- Attorney General Role–AG may review and analyze information submitted to DOI
  - AG may intervene in DOI hearings
  - AG may require ***any provider or payor*** to produce documents and testimony under oath related to health care costs and cost trends, factors that contribute to cost growth, or the relationship between provider costs and payor premium rates
  - Information produced is confidential and not a public record; except if used by the AG in a public hearing, a rate hearing before the DOI or in a case brought by the AG
  - Cold comfort?



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# DHCFP Study of Surplus/ Reserves



- DHCFP to conduct a study of options available to provide regulation, oversight and disposition of the reserves, endowments and surpluses of heath care ***insurers and hospitals***
  - Report due to legislature by July 1, 2009



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# Uniformity and Consistency in Reporting

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- Uniformity and Consistency in Reporting of Patient Care Information (G.L. c. 118E, § 55;176O, § 5A)–for data collection, comparison and analysis purposes
  - EOHHS and carriers (and their subcontractors) shall, ***without local customization:***
    - Accept and recognize patient diagnostic information and patient care service and procedure information submitted in compliance with HIPAA code set standards using IDCN, CPT and HCPCS codes
    - Use standard claim formats for processing claims adopted by the National Uniform Claim Committee (UB-82)
  - EOHS and private payors (and their subcontractors) shall accept and recognize at least 85% of all compliant claims submitted by health care providers
    - Does this just mean confirm receipt?
    - Elsewhere in the statue it says the carrier must accept and recognize "*all* compliant claims"
  - Monitored and enforced against private carriers by Bureau of Managed Care in DOI



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# Uniformity and Consistency in Reporting (cont'd)

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- Other Issues
  - No/limitations on local codes?
  - Less flexibility in recognizing NOC procedures and experimenting with new payment paradigms?
  - Implications for code "bundles" and episodes of care coding?
  - Does not preclude the payor from adjudicating a claim pursuant to its billing guidelines, payment policies or provider contracts



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## SB 2863: Sweeping Changes to Health Care Law in Massachusetts

# Questions & Answers

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