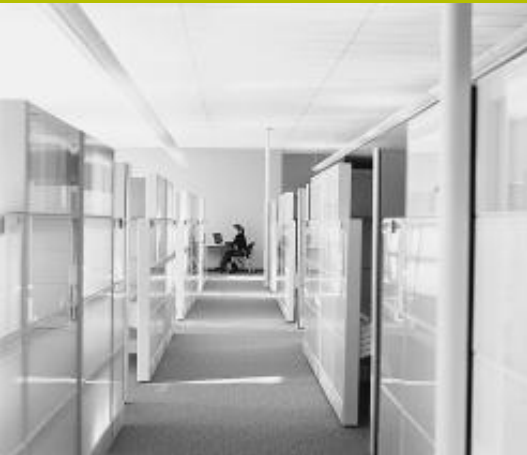




ACI's Physician Payments Disclosure and Aggregate Spend Conference:



A “Modest” Proposal: Massachusetts’s New Emergency Regulations and Their Implications

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Massachusetts: A Challenging Regulatory Environment

- The Massachusetts “gift ban” rules went into effect July 1, 2009, pursuant to Mass. Gen. L. ch. 111N and 105 Code of Massachusetts Regulations 970.
- Massachusetts has probably been the *second* most challenging regulatory environment in the U.S. (second to Vermont) in this regard, because:
 - Massachusetts has a significant number of physician who practice in key product markets and are opinion leaders.
 - Massachusetts’ rules were so strict:
 - one of the broader definitions of “sales and marketing” of any state;
 - Massachusetts prohibits certain payments to providers by pharmaceutical and medical device manufacturers; and
 - Massachusetts is one of the few states to make disclosure of data part of the public record.

Refresher: Who Are Covered “Health Care Practitioners” under Massachusetts law?

- Health Care Practitioners (HCPs) covered by the regulations include those who:
 - Prescribe prescription drugs for any person; and
 - Are licensed to provide health care in Massachusetts (also partnerships or corporations comprised of such persons or their agents).
- Does not include full-time company employees or board members who are not HCPs.
- Does not include hospitals.

Massachusetts Code of Conduct – What It Allowed In Its Prior Form and Is Unchanged

- Provision of peer reviewed academic, scientific or clinical information
- Advertising in peer reviewed academic, scientific or clinical journals
- Limited free use of devices for use by and education of patients
- Compensation for professional consulting services in connection with research and clinical trials
- Price concessions, including rebates and discounts

Massachusetts Code of Conduct – Prior Rules for Meals and Gifts

- Prohibited payments to HCPs for meals that are:
 - Part of an entertainment event
 - Offered without an informational presentation made by a marketing agent, or without the agent being present
 - Outside of the HCP’s office or “hospital setting”
 - Hospital, academic medical center, or “specialized training facility”
 - Provided to the HCP’s spouse or other guest
- Prohibited gifts to HCPs including:
 - Providing or paying for entertainment or recreation items of any value to any nonemployee HCP
 - Payments in cash or cash equivalents except as compensation for services
 - Expressly prohibits “complimentary items” such as pens, coffee mugs, gift cards, etc.
 - Grants, scholarships, contracts or practice items in exchange for prescribing drugs or using medical devices

Massachusetts Prior Disclosure Requirements

- Requires covered companies employing marketers to disclose annually the:
 - Value, Nature, Purpose, and Recipient
 - of any fee, payment, subsidy, or other economic benefit with a value of at least \$50 which a manufacturer provides, directly or through its agents
 - to any “covered recipient”
 - Broader than just HCPs: person authorized to prescribe, dispense or purchase prescription drugs or medical devices in the Commonwealth, including a hospital, nursing home, pharmacist, health benefit plan administrator, or a health care practitioner
 - Employees are excluded
 - in connection with “sales and marketing activities”

New Developments in Massachusetts

- In July 2012, the Massachusetts legislature enacted several statutory amendments to ch. 111N.
- One of the recent statutory amendments now permits manufacturers to pay for:
 - “modest meals and refreshments”
 - “in connection with non-CME educational presentations”
 - “for the purpose of educating and informing healthcare practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information”
 - “provided that such presentations occur in a venue and matter conducive to information communication”.
- The statutory amendment expressly required the Massachusetts Department of Public Health (DPH) to define “modest meals and refreshments” by regulation.

The New Regulations: A “Modest” Proposal

- At a hearing of the Public Health Council on September 19, 2012, DPH presented emergency regulatory amendments.
- These emergency regulatory amendments define “modest” meals and refreshments as:
 - “food and/or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner”
 - “that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense”.
- At the hearing, DPH stated that this definition was based in part on guidance for health care practitioners published by the American Medical Association

More Changes Under The New Regulations: Training Expenses

- The emergency regulatory amendments confirm, as required by the recent statutory amendments to Chapter 111N, that medical device companies can reimburse health care practitioners for:
 - reasonable expenses necessary for technical training on the use of a medical device,
 - regardless of whether such payments are permitted under a contract to purchase.

More Changes Under The New Regulations: Reporting

- The emergency regulatory amendments also relieve companies from any disclosure of expense reports (and the payment of accompanying reporting fees to DPH) for all calendar years after 2012, with one exception:
 - companies reporting marketing expenses under the federal Sunshine Act (42 U.S.C. § 1320a-7h) to the U.S. Department of Health and Human Services need to provide quarterly reports to DPH of the estimated amount expended on meals per participant at education programs held outside of the hospital setting.

Questions Left Unanswered By the Massachusetts Regulatory Process

- Are these emergency regulations currently in effect?
- How can we objectively determine what is “modest”?
 - Will what is “modest” vary between primary care physicians at community health centers and orthopedic surgeons at Mass. General because of where they regularly dine?
- What are the limits on a “venue ... conducive to information communication”?

Next Steps in the Regulatory Process

- The Massachusetts DPH will hold a public hearing on the emergency regulatory amendments on Friday, October 19, 2012 at 10:00 a.m.
- Written comments on the emergency regulations must be submitted by October 26, 2012.
- After comment, the regulations may be revised; any revisions will be voted on by the Massachusetts Public Health Council on November 14, 2012 and such revisions would become effective on December 7, 2012.



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