


 Council on Licensure, Enforcement and Regulation


2010 Annual Educational Conference - September 23-25

Surveying the Landscape – Legal Trends in Regulatory Practice


Presenters: Richard Steinecke
Steinecke Maciura LeBlanc

Promoting Regulatory Excellence

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Thoughts on Regulation


- "All professions are conspiracies against the laity." George Bernard Shaw
- "If you have ten thousand regulations you destroy all respect for the law." Winston Churchill
- "Regulations grow at the same rate as weeds." Norman R. Augustine


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Thoughts on Regulation

- "Virtue is more to be feared than vice, because its excesses are not subject to the regulation of conscience." Adam Smith
- "In today's regulatory environment, it's virtually impossible to violate rules." Bernard Madoff


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<h3>Overview</h3> <ul style="list-style-type: none">• Concept of self-regulation• Regulatory activities• Recent pressures and trends• What works and what doesn't		


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<h3>Concept of Self-Regulation</h3> <ul style="list-style-type: none">• Social contract<ul style="list-style-type: none">- Monopoly, title and status- If one effectively regulates in public interest• Typically under a statute which sets out mandate and powers• Majority of governing body selected by the profession• Typically regulation funded by the profession through fees		

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<h3>Concept of Self-Regulation</h3> <ul style="list-style-type: none">• Generally, but not always, a separation of regulator and self-interest body• Increasingly safeguards are being introduced to ensure that the public interest is promoted• Names vary: College, Board, Council, Association, Institute		

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<h3>Reasons for Self-Regulation</h3> <ul style="list-style-type: none">• Expertise<ul style="list-style-type: none">- Understands the issues and the constraints- Can see through the smoke• Buy-in<ul style="list-style-type: none">- The power of peers- Desire to conform to the community- The benefits of belonging		

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<h3>Mandate of the Regulator</h3> <ul style="list-style-type: none">• Regulating members transparently• Developing standards• Ensuring quality of practice• Enhancing equity• Promoting interprofessional collaboration• Facilitating change• Providing human resource data		


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<h3>Accountability</h3> <ul style="list-style-type: none">• Minister• Courts• HPARB / LAT / CRC• Advisory bodies• OFC• HRT• Profession• Public / Stakeholders / Media / Legislature		


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<h3>How Regulation is to Be Done</h3> <ul style="list-style-type: none">• Within legal jurisdiction• With procedural fairness• With transparency• Fiduciary obligations• Fair registration practices• Subject to human rights• Consistent with equity		


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<h3>What Kinds of Regulation are Involved</h3> <ul style="list-style-type: none">• Restrictive regulation<ul style="list-style-type: none">- Registration, holding out injunctions• Reactive regulation<ul style="list-style-type: none">- Complaints, discipline, fitness to practise• Proactive regulation<ul style="list-style-type: none">- Quality assurance, patient relations• Transparent regulation<ul style="list-style-type: none">- Open meetings / hearings, public register		

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<h3>Restrictive Regulation</h3> <ul style="list-style-type: none">• Example:<ul style="list-style-type: none">- Registration• Main Issue:<ul style="list-style-type: none">- Should an exemption be given?• Competing Pressures:<ul style="list-style-type: none">- TOIF, mobility,• Key to Success:<ul style="list-style-type: none">- Focusing on competency		

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Reactive Regulation		
<ul style="list-style-type: none">• Example:<ul style="list-style-type: none">- Complaints and discipline• Main Issue:<ul style="list-style-type: none">- Does concern warrant action?• Competing Pressures:<ul style="list-style-type: none">- Procedural fairness• Key to Success:<ul style="list-style-type: none">- Articulating reasons for decision		

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Proactive Regulation		
<ul style="list-style-type: none">• Example:<ul style="list-style-type: none">- QA• Main Issue:<ul style="list-style-type: none">- How to promote excellence• Competing Pressures:<ul style="list-style-type: none">- Legalism, shifting to reaction mode• Key to Success:<ul style="list-style-type: none">- Obtaining professional buy-in		

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Transparent Regulation		
<ul style="list-style-type: none">• Example:<ul style="list-style-type: none">- Public register on website• Main Issue:<ul style="list-style-type: none">- What info should public know about members• Competing Pressures:<ul style="list-style-type: none">- Privacy / confidentiality, misuse of info• Key to Success:<ul style="list-style-type: none">- Communication with profession		

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Recent Pressures & Trends
Legalization of regulatory processes

- Criminalization of discipline - battle is lost
 - "Penalties" language
 - Disclosure - could not say no
 - Constriction on complaints - Katzman
 - Defining the scope of the complaint
 - Other examples of similar conduct
 - Referral to another panel for new issues is reviewable

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Recent Pressures & Trends
Now moving to quality assurance process


- Chong case
 - Procedural fairness
 - Appearance of bias
 - Blinding the assessment tool
 - Prevents tailoring of tool?
 - Beyond the assessors, to staff and Committee?
 - Disclosure of tool details and results
 - Implications for registration

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Recent Pressures & Trends
Political involvement


- Always there for regulations, etc.
- Now to achieve other political goals
 - Specifying content of regulations
 - Reviewing Council actions
 - Operational audits
 - Minister can appoint supervisors
 - Mobility push
- Ministry staff as public members is next?


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<h3>Recent Pressures & Trends</h3> <p>Increased calls for transparency</p> <ul style="list-style-type: none">• 1980's <i>Charter</i> opened up hearings• Open Council / Board meetings• Increased disclosure in processes• Fifth Estate / prior history requirements• Enhanced register (e.g., professional negligence)		


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<h3>Recent Pressures & Trends</h3> <p>Professional direction to Colleges</p> <ul style="list-style-type: none">• Always an issue, especially where professional society / union is strong• Mandatory consultation - which is good• Seeing increased use of slate of candidates• Even seeing lobbying of Board members• Especially when a hot issue arises		


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<h3>Recent Pressures & Trends</h3> <p>General regulatory creep</p> <ul style="list-style-type: none">• Apology Act• Privacy legislation• Occupational Health• Accessibility• Not-for-Profit corporate law reform• Case law developments (e.g., disclosure, reason writing, judicial review)		

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<h3>Threats to Self-Regulation</h3> <ul style="list-style-type: none">• Declining model in the world• Commonwealth examples• Triggers:<ul style="list-style-type: none">- Scandal- Audits- Government perception• Cost• Paralysis creep		

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<h3>Recap on Pressures</h3> <ul style="list-style-type: none">• Regulator is constantly under microscope• Need to be TOIF (transparent, objective, impartial and fair)<ul style="list-style-type: none">- And be seen to be TOIF• And have one's own house in order<ul style="list-style-type: none">- i.e., governance		

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<h3>Successes</h3> <ul style="list-style-type: none">• Public access to process and information• Public appointees• External review and accountability		

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<h3>What Doesn't Work</h3> <ul style="list-style-type: none">• Duplicative external oversight<ul style="list-style-type: none">- Need regular cost-benefit analysis• Entrenched external oversight• Lack of boundaries in the political oversight• Any stakeholder that becomes too dominant		

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<h3>Conclusion</h3> <ul style="list-style-type: none">• Self-regulation is the best model in the world when it works• It can also be one of the worst when it fails		

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<h3>Speaker Contact Information</h3> <p>Richard Steinecke Steinecke Maciura LeBlanc Barristers & Solicitors 401 Bay Street Suite 2308, P.O. Box 23 Toronto, ON M5H 2Y4 rsteinecke@sml-law.com (416) 626-6897</p>		


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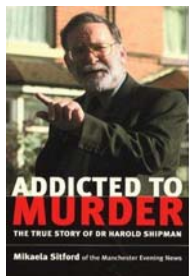
Surveying the
Landscape - Legal
Trends in Regulatory
Practice

Presenters: Jonathan Bracken
UK Health Professions Council


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The "Law and Order" Years



Harold Shipman
Beverley Allitt
William Kerr
Michael Haslam
Clifford Ayling
Richard Neale
Rodney Ledward

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Causal Factors

- poor clinical governance
- ineffective disciplinary processes
- weak/opaque regulatory procedures
- lack of support mechanisms for patients
- loyalty/belief that colleagues "do no harm"
- tolerance of sexualised behaviour
- unwillingness to act on rumours
- concerns at being a whistleblower

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The Solution? Regulation

Regulate the delivery of care

- improved clinical governance
- new 'care regulators' (NICE, CQC)

Regulate the professions

- independent regulators
- increased public involvement
- rigorous and consistent public protection
- fair and effective 'fitness to practise' processes

Regulate the regulators

- Council for Healthcare Regulatory Excellence

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The Government's Approach


"The overriding interest is the safety and quality of care that patients receive from health professionals

Regulatory bodies need to be independent of

- Government,
- Professionals and
- all other interest groups

Equally important, regulators must be seen to be independent and demonstrably impartial"

*Trust, Assurance and Safety:
Regulation of Health Professionals in the 21st Century.*


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Fitness to Practise

"We need a system that understands the pressures and strains under which professionals operate and shows understanding, compassion and support where these are appropriate.

It means a system that is better able to identify people early on who are struggling, showing the same care to them that they have shown to their patients..."


*Trust, Assurance and Safety:
Regulation of Health Professionals in the 21st Century*

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It's not about punishment...

"...the purpose of FTP procedures is not to punish the practitioner for past misdoings but to protect the public against the acts and omissions of those who are not fit to practise. The Panel thus looks forward not back. However, in order to form a view as to the fitness of a person to practise today, it is evident that it will have to take account of the way in which the person concerned has acted or failed to act in the past".


General Medical Council v Meadow [2006] EWCA Civ 1319

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Or is it?...

"The Panel is concerned with the issue of whether ... fitness... to practise has been impaired taking account of the critically important public policy issues,... [which include]... the need to protect the individual patient and the collective need to maintain confidence in the profession as well as declaring and upholding proper standards of conduct and behaviour which the public expect".


Cohen v General Medical Council [2008] EWHC 581 (Admin)

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Better Regulation Executive


Five principles of good regulation:

- transparent
- accountable
- proportionate
- consistent
- targeted

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The Hampton Principles

- risk assessment should focus resources on areas of need
- regulators should be independent decision makers but accountable for their efficiency and effectiveness
- no inspection should take place without a reason
- no one should be asked for unnecessary information
- persistent offenders should be dealt with quickly
- regulators should provide clear advice easily and cheaply
- a regulator should not be created if an existing one can do the job
- regulators should encourage economic progress, only intervening when there is a clear case for doing so

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But the Axeman Cometh....

GENERAL TEACHING COUNCIL TO BE SCRAPPED

OFFICE OF THE HEALTH PROFESSIONS ADJUDICATOR NOT NEEDED	GENERAL SOCIAL CARE COUNCIL TO BE ABOLISHED
END FOR QUALIFICATIONS AND CURRICULUM DEVELOPMENT AGENCY	HEARING AID COUNCIL TO CLOSE ITS DOORS
STANDARDS BOARD SET TO GO	

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Presenters: Catherine Dower, JD
Center for the Health Professions
University of California, San
Francisco

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Professional Regulation in the US

- State based, "self-regulation"
- Licensure tied to legal scope of practice
- Composite of legislative, administrative and judicial decisions

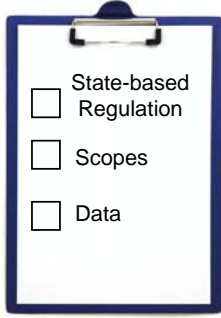
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Implications & Challenges

- Variability across states & by professions
- Early licensure = Exclusive scope
- Reactionary decisions based on minimal data and evidence base

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Explore with me how three regulatory challenges impede health care and how they are being improved.




- State-based Regulation
- Scopes
- Data

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Three Challenges


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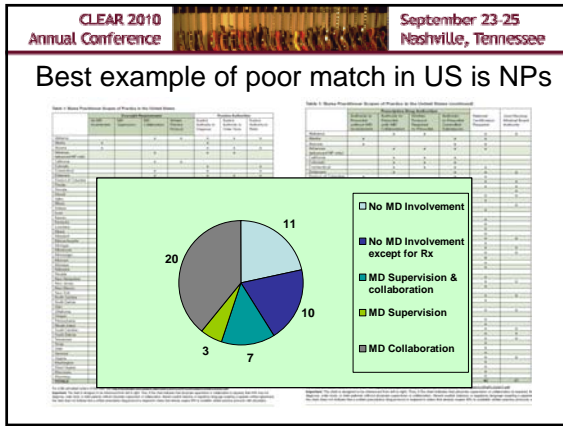
1. Scope of practice laws are state-based and politically driven...

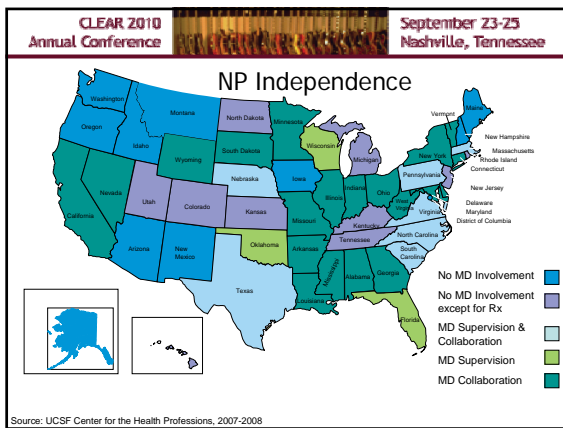


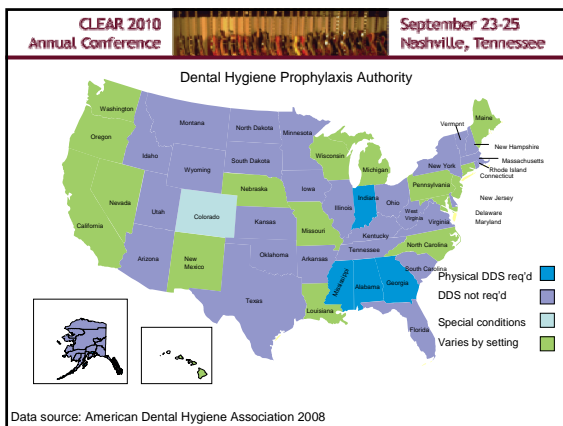
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...resulting in state variability and unnecessary limitations on professional practice.









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2. Exclusive scopes of practice exacerbate conflicts of interest.



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Citizen Advocacy Center
2nd Quarter 2010

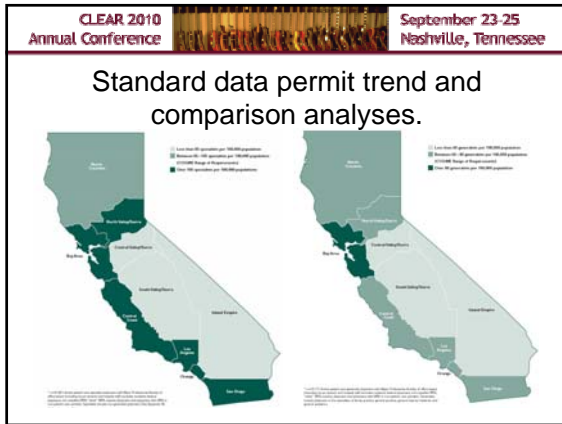
Federal Trade Commission Complaint Charges Conspiracy to Thwart Competition in Teeth-Whitening Services

June 17, 2010, the Federal Trade Commission announced that it had issued a complaint charging the North Carolina dental board with improperly excluding non-dentists from providing teeth-whitening services. The FTC's press release is www.cacenter.org

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3. Health workforce data collection and evidence-based decision-making are limited to non-existent





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Promising Examples

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1 Promising Directions for Interstate Variability


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...Towards harmonization

- Model practice acts
- Interstate compacts
- Federally-funded research
- Federally-funded demonstration projects and initiatives

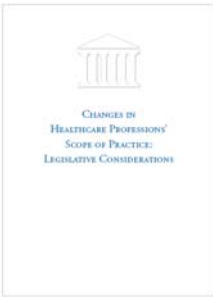


2 Promising Directions for Overlapping Scopes


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...Towards non-exclusivity

"Overlap among professions is necessary."




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Promising Directions for Data Collection and Evidence-Based Decisions


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Some states link short surveys to re-licensure...



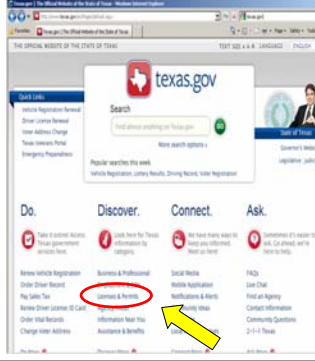
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... encouraging focus on key data points.



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Some states collect and manage the data electronically.



The screenshot shows the Texas.gov homepage with a search bar and several service categories: Do, Discover, Connect, and Ask. A red circle highlights the 'Business & Professions' link, and a yellow arrow points to it.

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Controlled studies find no quality compromises.




The image shows a close-up of a silver stethoscope with a white rubber bulb, resting on a document with printed text, likely a medical chart or research paper.

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Several states are experimenting with new ways to help decide scope issues.



The map shows the United States with several states in the central and southern regions highlighted in orange. Small lightbulb icons are placed over these highlighted states, symbolizing experimentation or innovation.

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California uses a waiver process to test new scopes of practice

A Review of California Office of Statewide Health Planning and Development, Health Workforce Pilot Projects Program 1973-2007

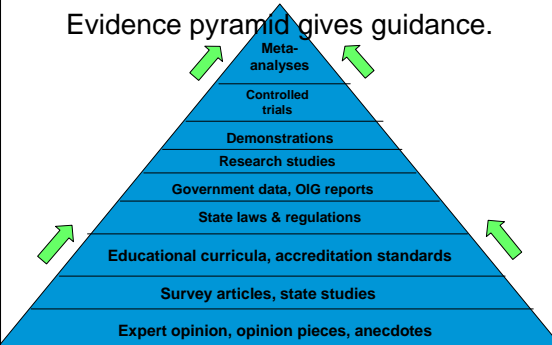
Table 8. Pilot Program Outcomes Category C: Pilots Resulting in a Regulatory Change

Regulation or Legislative Change	Number of pilots	% of all apps submitted
Nurse Practice Act (NPA) update of 1975	40	23.40%
Dental Practice Act (DPA) update of 1975	8	4.70%
Certified Nurse Midwives SB 1332 (Bakerson) 1974	3	1.75%
Emergency Services Act SB 125 (Garamendi) 1980	4	2.30%
PA Drug Dispensing, Section 1399.5417(f), Title 16, California Code of Regulations, 1983	2	1.20%
Pharmacy Drug Dispensing AB 502 (Maddox) 1983	2	1.20%
NP Drug Dispensing 1986 AB 4372 (Isenberg) 1986	7	4.10%
RCHAP, Statutes of 1991, Chapter 753	1	0.60%
Other regulatory change	8	4.6%
Total	78	44%

Source: Center for the Health Professions, UCSF 2010

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Evidence pyramid gives guidance.



© 2008 UCSF Center for the Health Professions

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Three regulatory changes could improve health care.



- State-based regulation
- Scopes
- Data

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Health Care in the News, 2009-2010

- Celebrity deaths
- Octomom
- Swine flu



Salmonella outbreaks

Acetaminophen trouble

Mammogram guidelines




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House passes health care bill on 219-212 vote
March 21, 2010

Doctors Not Reporting Impaired Colleagues, Survey Finds
July 28, 2010



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