You Have The Right To: Independent Appeals, Off-Label Drugs, Prompt Payment, & Clinical Trials

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The politics of rights and responsibilities

"Every right implies a responsibility; every opportunity, an obligation; every possession, a duty."

John D. Rockefeller, 1941

Vik's public policy principles

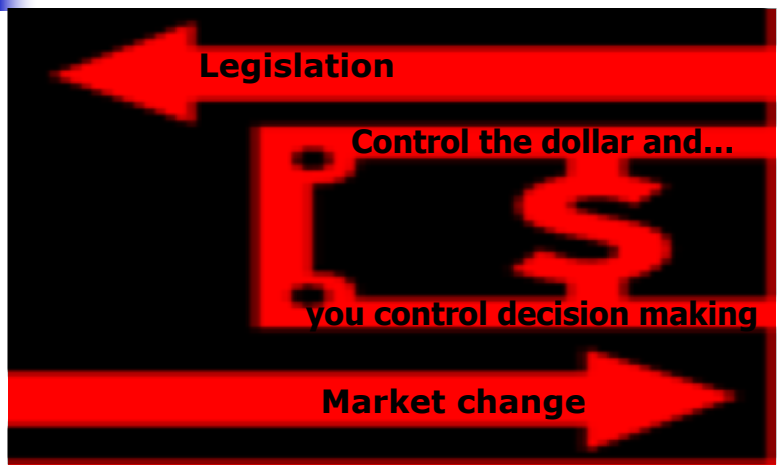
- No satisfaction without action
- Progress is a process, not a destination
- Compromise is a virtue
- Change is inevitable

Overview

- Background
- The four laws:
  - Off-label drugs
  - Prompt pay
  - Independent appeals
  - Clinical trials
- Political communication
- Conclusions

•Statutory goals
•Key elements
•Operational issues
•Quirks in the law
•Potential future fixes
•Enforcement and assistance

Battle for control in health care politics



States are legislative market makers

Marketplace: managed care organizations (MCOs)

Creative state legislation fosters change

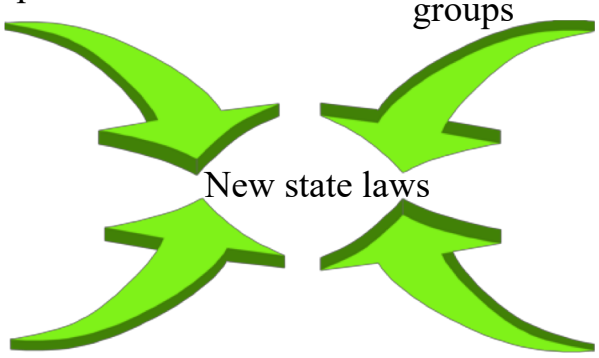
U.S. Congress

Other states

State lawmakers hear their constituents

Health plans

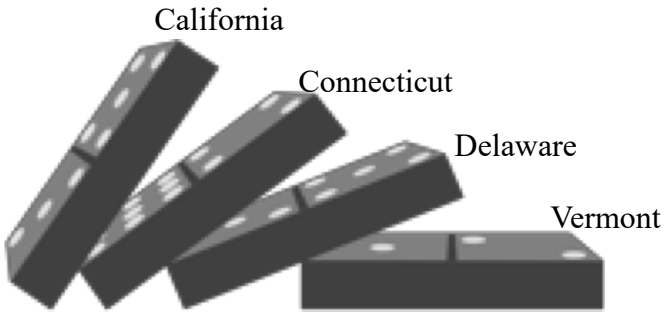
Employers/business groups



Health care providers

Individuals & groups

States often play follow the leader



States continue to build momentum in 2001 for covering care in clinical trials

Legislation is imperfect…

Over-done	*Under-done*	*Not done enough*
Diagnosis-, procedure-, or body part-specific laws	Non-binding independent appeal or prompt pay laws	Report cards/quality reports on health plans and providers

…so, condition your expectations

Goals for the four laws

- Provide regulatory structure to a specific market dynamic
- Modify a financial or administrative obstacle to care or reimbursement
- Create mechanisms for redress
- Encourage dialogue

Off label law

Statutory goal

- Compels health plans to cover and reimburse an FDA-approved drug that is used for for a purpose other than its labeled indication*

* With appropriate supporting data

Essential elements

- Applies to all health plans that cover prescription drugs
- Establishes data-driven coverage criteria
- Allows for appeal of denials by health plan enrollees
- Coincides with FDA policy on off-label use of prescription drugs

Your responsibilities

- Ensure that:
  - A licensed professional prescribes the drug
  - The patient has a life-threatening condition, or
  - A chronic or seriously debilitating condition
  - The drug is medically necessary and is on the plan's formulary

Your responsibilities (cont'd)

- Support the proposed use with
  - Two citations in the reference compendia (United State Pharmacopeia, American Hospital Formulary Service Drug Information, AMA Drug Evaluations), OR
  - Two articles from major peer-revised medical journals documenting safety and effectiveness
- Submit these data with your coverage request, IF the plan asks for them

Health plans' responsibilities

- Cover supported off-label uses (on formulary)
- Allow appeal of denials when plan decides off-label use is experimental
  - Patient can appeal this denial under the independent appeal law

Getting coverage for non-formulary drugs

- Plans maintain unique internal review processes
  - Filed with DMHC
- Denials must show specific clinical reasons
  - Inform patient of right to file an internal grievance
- Physicians may also appeal denials to DMHC
- Plans may not limit or deny drugs previously approved for a patient, but now off formulary

Off-label law quirks

- Statutory notes
  - Off-label use is legal when it is consistent with standard of care
  - Off-label use of prescribed drugs may be appropriate therapy for persons with serious illnesses
  - It is not FDA's intent to formally approve all appropriate uses of a drug…too costly

The off-label law does not…

- Prohibit health plans from having:
  - Formularies
  - Technology assessment processes
  - Other means of controlling drug utilization

Potential fixes

- Expanded right to appeal disputes over potential off-label uses
- Remove on-formulary/off-formulary distinction
- Establish penalties for non-compliance

Enforcement & assistance

Dept. of Managed Health Care
980 Ninth St.
Sacramento, CA 95814
888-466-2219
Helpline@dmhc.ca.gov

Dept. of Insurance
300 South Spring St.
South Tower
Los Angeles, CA 90013
213-897-8921
927help@insurance.ca.gov

Prompt pay law

Statutory goal

- Ensure that health plans reimburse correct claims in a specific period and pay interest when they do not*

* And pay you a $10 administrative fee

Essential elements

- Applies to all health plans, including HMOs
- Defines a clean claim that is eligible for payment by a health plan
- Establishes a payment timetable and interest penalties

Your responsibilities…

- Ensure that you submit clean claims
  - Complete and contains all the information necessary to determine payer liability, or
  - Provide reasonable access to information concerning the provider services rendered
- Send paper claims by verifiable service

Health plans' responsibilities

- Pay claims as soon as practical, but no later than…
  - 30 days (health service plan)
  - 45 days (HMO)
- Pay interest on clean claims not reimbursed within these time limits
  - 15 percent annual rate
- Include the interest payment with the claim

Health plans' responsibilities (cont'd)

- Contest claims within 30 or 45 days
- Notify providers about contested claims
  - Identify potential problems with claim and specify reasons for contesting it
- Pay a $10 fee to any provider when it fails to pay the interest with the claim
  - May not require providers to submit requests for interest payments

Prompt pay law quirks

- Reasons plans may contest claims…
  - Fraud or misrepresentation
  - Consents or releases from patients
  - Claims on appeal
  - Other issues necessary to determine medical necessity for the service
- Law applies when plans delegate payment responsibility to contracted entities

Potential fixes

- Enhanced penalties for not paying interest with claims
- Civil penalties levied by the state for noncompliance by health plans (overall performance)
  - Indiana penalties: $10,000 to $200,000

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Independent appeals

Statutory goal

- Provides health plan members with the right to have an independent entity review certain denials of care*

* If you can figure out all the rules

Independent appeals are possible when…

- A health plan denies care as
  - Medically unnecessary
  - Experimental or investigational
  - Emergency or urgent care that was medically unnecessary
- The appeal is requested within six months of the denial by the health plan

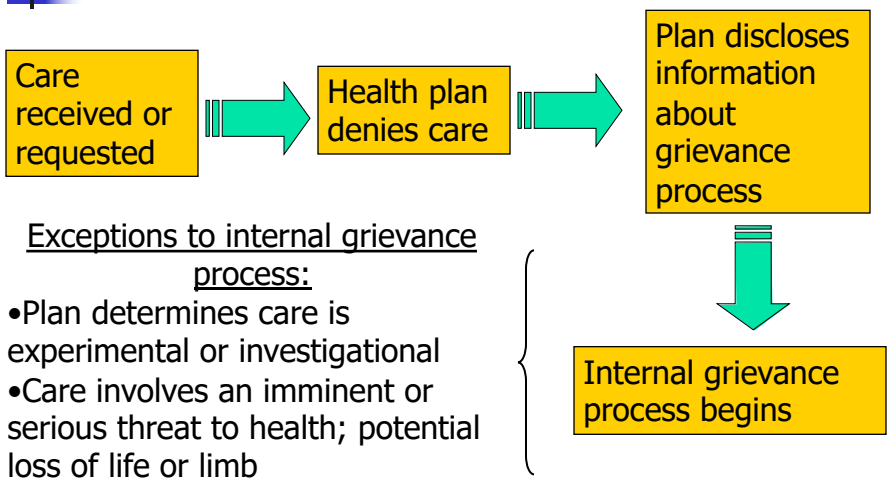
California's multi-part approach

Coverage decisions:
- Urgent cases: 72 hours
- Other care: 5 days
- Retrospective reviews: 30 days
- Time to communicate: 24 hours

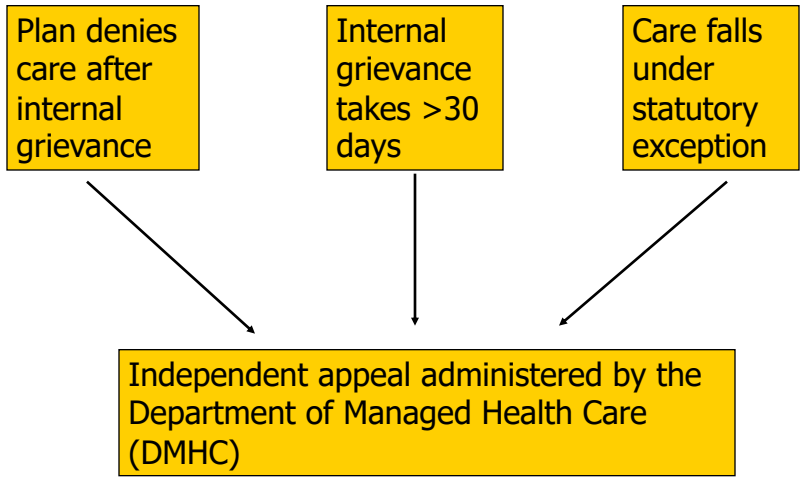
Internal grievance system:
- DMHC approved
- 30 days to resolve grievances
- Mandatory reporting of aging grievances
- Voluntary mediation

Independent appeals:
- DMHC-selected independent review organizations (IROs)
- Accelerated timeline for urgent cases

Getting to an independent appeal



Getting to an independent appeal (cont'd)



Experimental or investigational care

- Decide cases in 5 business days
- Provide a denial statement with
  - Scientific/medical rationale
  - Alternative treatments or services covered by the plan
  - Copies of the plan grievance form
- Offer patients a conference
  - 5 or 30 days, depending on circumstances

Health plan review of contested issues

- Medical director or other licensed professional
  - Clinically competent to review the contested issue
  - Education, training, and relevant experience
- An appropriate specialist, at the plan's discretion

Health plans' responsibilities

- Request only information that is reasonably necessary to complete internal grievance reviews
- Complete reviews within statutory timeframes
- Communicate grievance decisions in a timely manner
  - Within 24 to 48 hours

Health plans' responsibilities (cont'd)

- Communicate decisions by telephone and in writing
- Include a clear and concise explanation of the plan's reasoning
  - Criteria or guidelines used
  - Clinical reasons for denying medical necessity

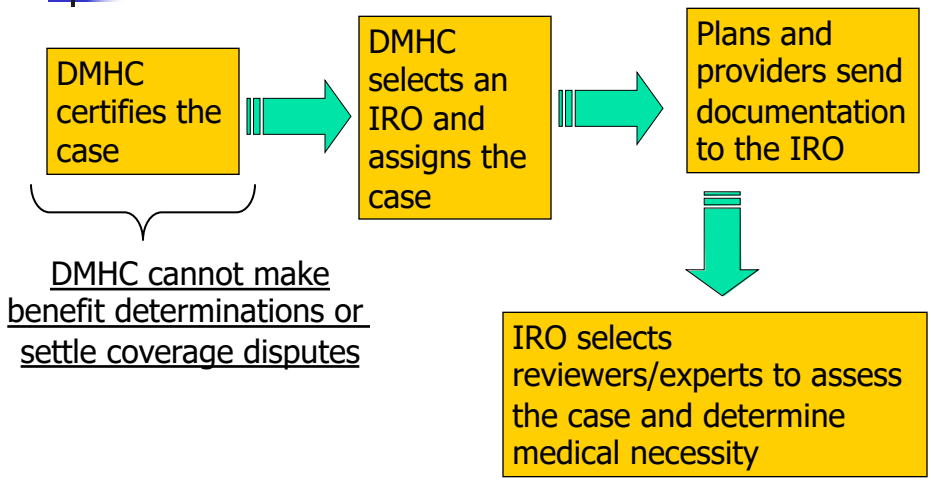
The independent appeal process

- Administered by DMHC
  - Initial screener
  - Final decision maker on claim eligibility for an independent appeal
- Must begin with six months of health plan's care denial
- Relies upon an independent medical review organizations (IROs)

The independent appeal process (cont'd)

- Has specific deadlines
  - 30 days for nonurgent cases
  - 3 days or less for urgent cases
- Governed by strict conflict of interest rules

The independent appeal process (cont'd)



Your responsibilities

- Document thoroughly the medical necessity of the disputed care
- Provide the plan, DMHC, & IRO with
  - Published studies
  - Expert opinion
  - Guidelines

What health plans may do during independent appeals

- Submit
  - Data supporting its position
  - Medical records
  - Summary of care provided by the plan
  - Any new or relevant information
  - All the plan's decisions, statements on the case

IRO responsibilities

- Complete reviews within 3 days (urgent case) or 30 days
- State clearly whether the disputed service is medically necessary
  - Peer-reviewed scientific & medical evidence
  - Nationally recognized standards
  - Expert opinion
  - Generally accepted standards of medical pratice

IRO responsibilities

- Disclose analysis underlying its decision
  - Cite supporting data
- Decide cases by majority vote of reviewers
  - Ties grant coverage of disputed care
- Keep reviewers names confidential
  - Describe qualifications for health plan, patient, and physicians

After the IRO decides…

- DMHC must
  - Adopt its decision
  - Issue a written statement to make it binding on all parties
  - Make a sanitized version of the decision available for public inspection

After the IRO decides…(cont'd)

- The health plan must
  - Implement the decision
    - Cover disputed care
    - Reimburse care already provided
  - Pay a civil penalty of up to $5,000 per day for any delay in implementation

Other elements of the independent appeal law

- Health plans bear all costs
  - No fees/expenses for enrollees, physicians
- DMHC responsible to
  - Conduct annual audit of all cases
  - Report to the legislature on March 2, 2002

Potential future fixes

- Too soon to say
- Need data to draw conclusions

Clinical trials

Statutory goal

- Require health plans to pay for routine patient care costs when enrollees participate in certain clinical trials

Essential elements

- Benefits cancer patients considering participation in Phase I – IV studies
- Applies to all health plans, HMOs, and Medi-Cal
- Ensures coverage of routine patient care costs
- Sets quality criteria for eligible trials

Your responsibilities

- Determine that the trial has meaningful potential for the enrollee
- Ensure that the trial does not simply measure toxicity
  - "Endpoint" shall have a therapeutic intent
- Bill only for covered routine services
  - What patient would get in trial or not

Health plans' responsibilities

- Cover and reimburse trials that meet specific quality criteria
- Pay nonparticipating providers
  - Negotiated rate, or
  - Lowest rate paid to participating provider
- May require enrollment in California-based trial, when available
- Ensure consumers pay deductibles, copayments

Covered trials

- Trials approved by
  - National Institutes of Health
  - Food and Drug Administration (INDA)
  - Department of Defense
  - Department of Veterans Affairs

What's covered…

- Health care services that would be provided to the patient whether or not he or she enrolled in a trial
  - Treating or preventing complications
  - Monitoring the investigational therapy
  - Providing the investigational therapy

What's not…

- Investigational drugs or devices
- Non-health care services, such as travel, housing, companion expenses
- Trial data collection or management costs
- Contractually excluded services
- Sponsor-supplied products/services

Quirks in the clinical trial law

- Immunity from liability provision
- Potentially problematic provision on therapeutic intent versus testing toxicity
  - May complicate access to Phase I trials

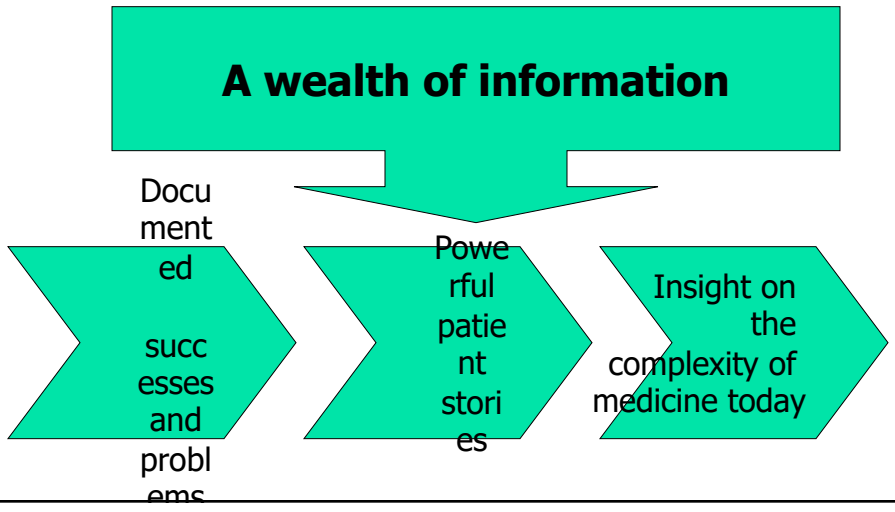
Potential future fixes

- Amend reference to therapeutic intent
  - "…ensure that the benefits of the patient's participation in the clinical trial are commensurate with potential medical risks…"
  - Allow medical record documentation to substantiate expectation of therapeutic intent

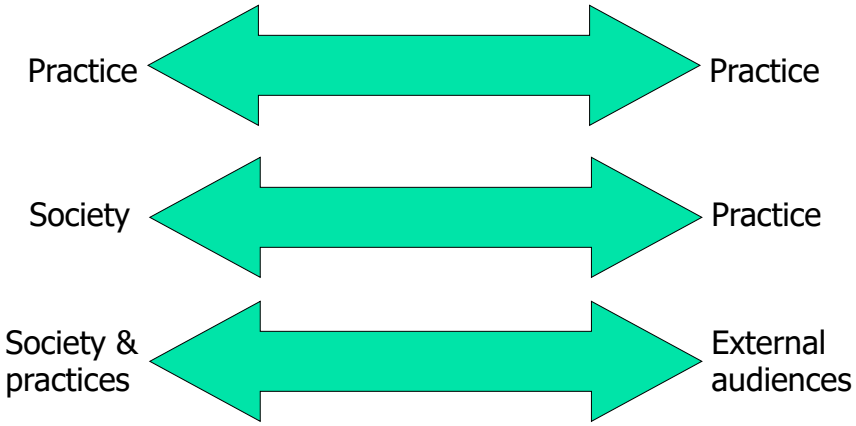
You have the rights…

- Now what do you do
  - Educate yourselves and your peers
  - Monitor implementation
  - Gather and communicate data
  - Communicate with legislators and regulators
  - Cultivate your public image

Oncology practices can offer…



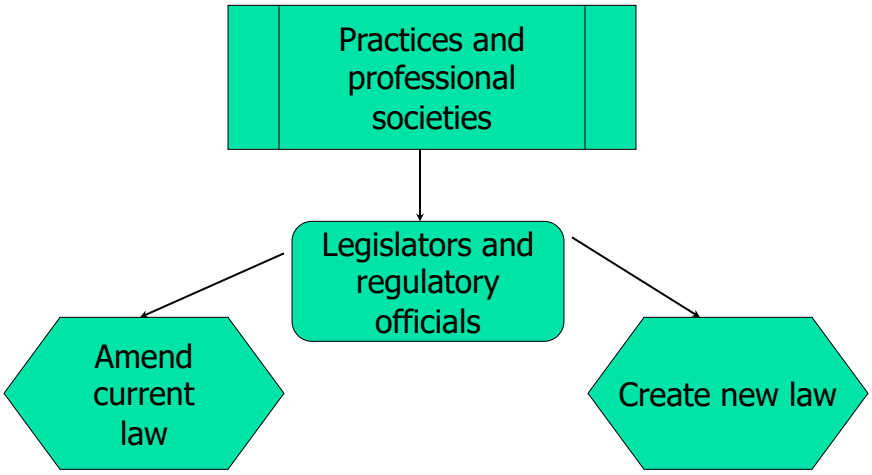
Information is a verb…



Practice to practice

- Exchange political intelligence
- Discuss statute-specific issues
- Identify problem health plans
- Gather/coordinate data on critical issues
- Contribute to society's political activities

Political communication



Society to external audiences

- Educate legislators
  - How well do the laws work
  - What amendments would help
  - What new problems need solutions
    - Practice-driven data
    - Published studies
    - Patient/physician anecdotes
  - What is medicine like today

Society: external audiences (cont'd)

- Reach out to the local media
  - Report on the laws and how they work
  - Foster an addiction
- Establish relationships with payers
  - Payer roundtables to solve, forestall problems
  - Payer presentations at society meetings

Society: external audiences (cont'd)

- Recruit patients to issue activism
  - Patient newsletter
  - Office-based materials
    - Posters
    - Fliers
    - Guides/brochures/tools

Data collection and reporting

- Map issues with health plans
  - Practice surveys (fax, mail, email)
  - Web-based reporting mechanism
  - Manager/administrator focus groups
- Release data annually to media, legislators

Getting started

- Recruit an A-team of practice leaders
  - Great communicators
- Work with experienced strategists and lobbyists
  - Public policy vision
  - Hands-on skills
  - Insider access

Getting started (cont'd)

- Develop a political gameplan
  - Find out who cares about what
  - Assess the market and political landscape
- Prioritize issues
  - Identify/quantify problems
  - Research potential policy options
  - Find potential partners and build coalitions
  - Create dialogue with health plans

Getting started (cont'd)

- Start small
  - Pick manageable issues
    - Track these four issues
    - Develop educational materials for professionals and patients
- Get legislators into your offices
  - Provide practices with support materials
  - Develop mini-internship program

Society to practice

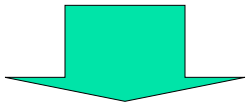
- Create, support public policy infrastructure
- Concentrate on multi-level education
- Add value to build commitment

Vik's public policy principles

- No satisfaction without action
- Progress is a process, not a destination
- Compromise is a virtue
- Change is inevitable

Conclusions

- Public policy is incremental
- No single answer solves all problems
- Winning is good, but so is losing



Participation enables success