B e t t e r H e a l t h

### Technologie

# Best Practices for eDM: Business Strategy and Legal Issues

**Presented at** 

# E-Healthcare Strategies for Chronic Disease Management

September 19, 2000
James M. Jacobson, JD
Partner, Health Law Group
Gardner, Carton & Douglas
www.gcd.com (202) 408-7191

Palm Desert, CA
Vince Kuraitis JD, MBA
Principal
Better Health Technologies
www.bhtinfo.com (208) 395-1197

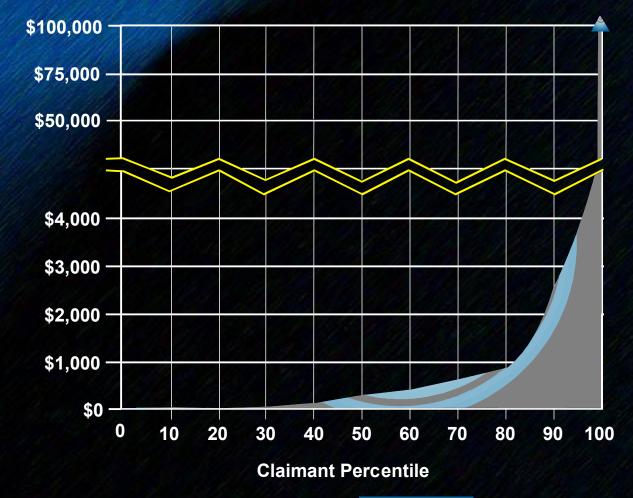
## **Presentation Overview**

- Background and Terminology
- Business and Legal Issues
  - Overview: Content, Connectivity, Commerce
  - Care Management
    - Licensure/Certification
    - Liability
    - Data Privacy/Confidentiality
    - Data Security
- Best Compliance Practices
- Summary/Implications



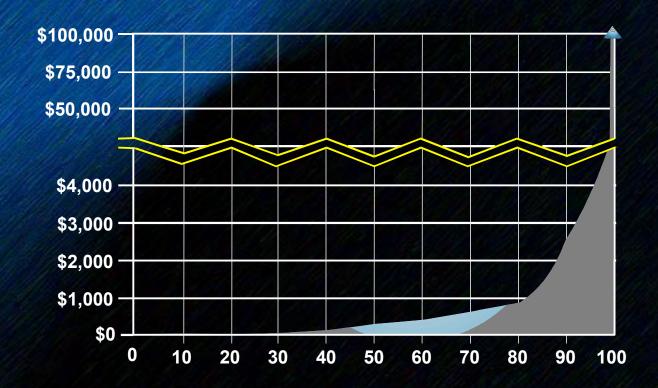
# Distribution of Health Care Costs: Conceptualizing Population Health

Cost Per Claimant Per Yr.



## 2 Differing Approaches Emerging

\$\$ Per Claimant Per Yr.



**Disease Management Services** 

eDM/eCare Management

## **Comparison of Approaches**

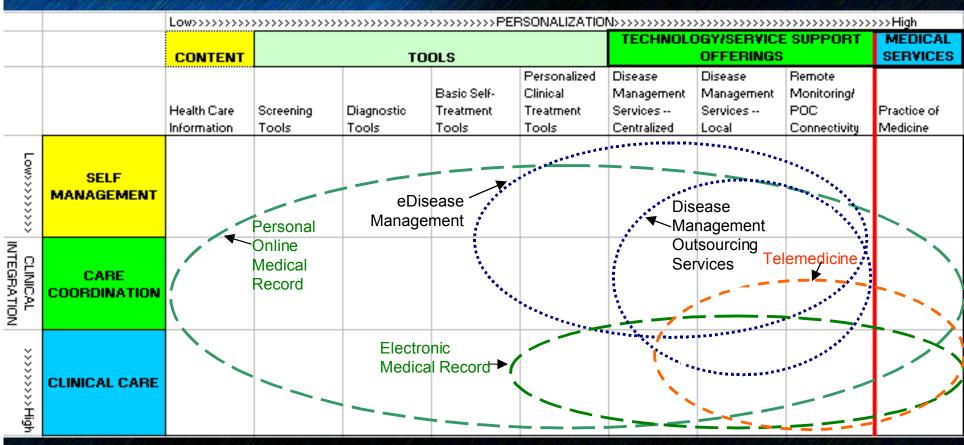
#### eDM/eCare Management

- Care Coordinator = patient
- Health care consumerism
- Save \$\$ long term on behalf of the patient
- Optimize patient health status
- Done "by" the patient
- 100+ conditions/diseases
- Not geographically bound

#### **DM Services**

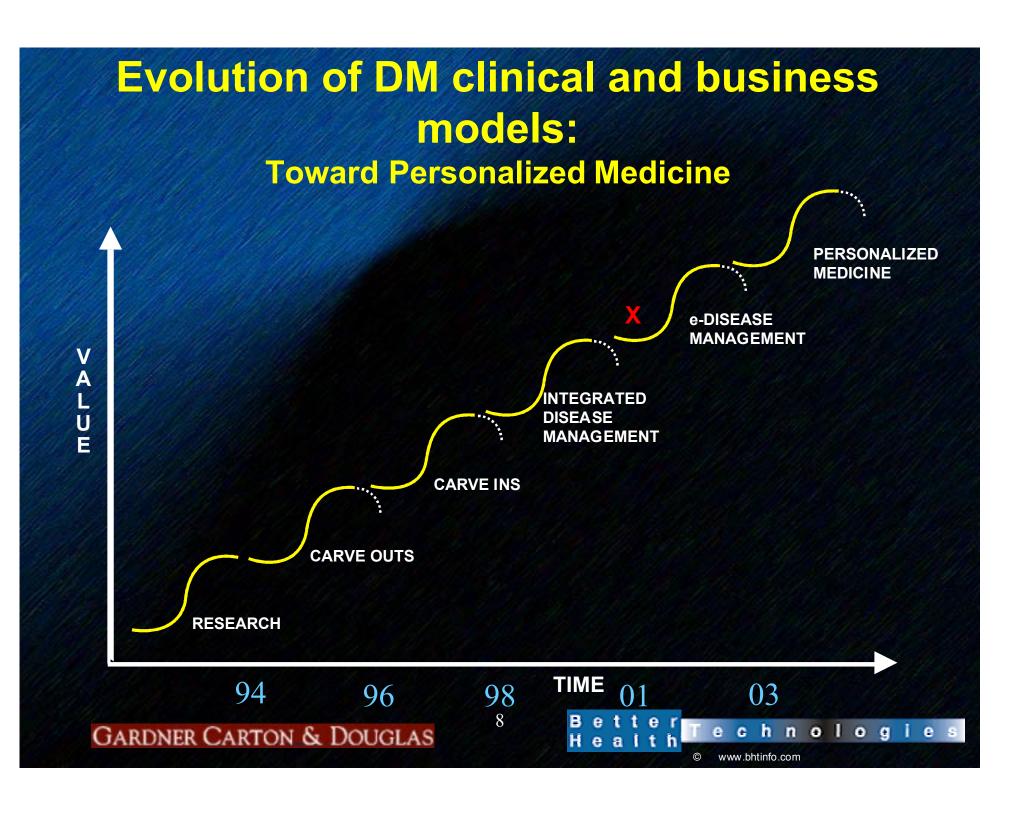
- Care Coordinator = 3<sup>rd</sup> Party
- Cost containment
- Save \$\$ short term on behalf of health plan
- Prevent unnecessary hospitalizations and ER visits
- Done "to" the patient
- 5-10 top diseases
- Local/regional focus

# A Crude Map of the New World: eHealth & Care Management Framework





Better Technologies Health

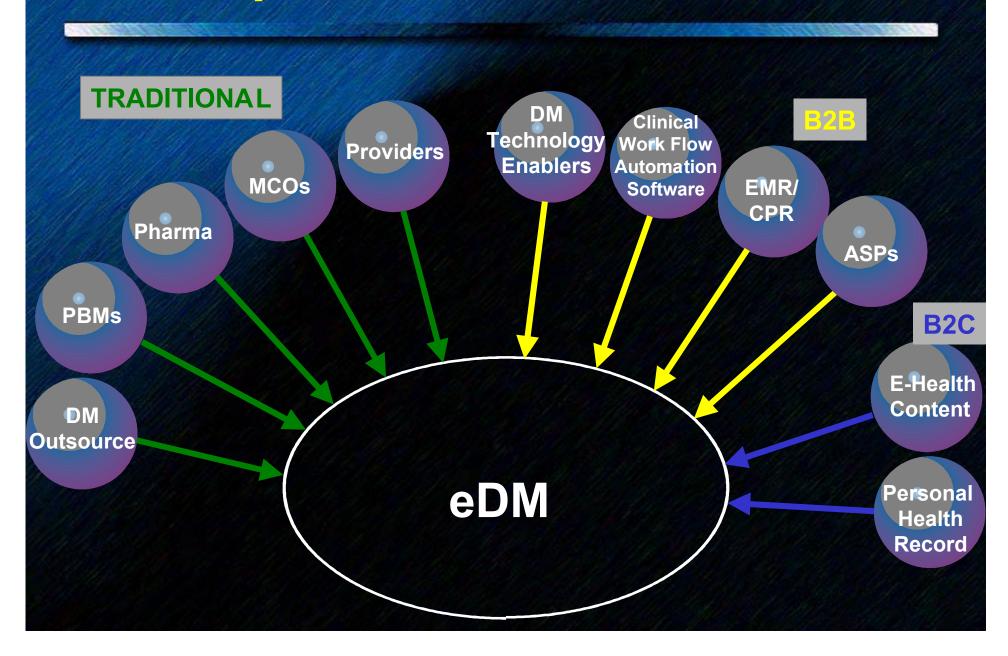


## E-DM PRODUCTS AND SERVICES

#### **DM WEB-SITE**

CONTENT	CONNECTIVITY/ COMMUNITY	COMMERCE	CARE NAGEMENT
<sup>⟨</sup> ARTICLES	〈 PHYSICIAN/ PT	PHARMA SALES/ COMPLIANCE/PERSIST	NURSE CHAT/ PT SELF-MGMT TRNG
JOURNAL REFERENCES	〈 MEDICAL RECORD- SHARING	⟨ TEST KIT SALES	PERS. HEALTH ASSESS/ RISK STRATIFICATION
LINKS TO OTHER SITES	⟨ INSTANT MESSENGING	⟨ LAB TESTS	MEDICATION MONITORING
CEXPERT STREAMING AUDIO/VIDEO	⟨ TELEPHONY/PDAs	⟨ DME SALES	SIDE EFFECT/ SYMPTOM MONITORING
⟨ NEWSLETTERS	〈 E-MAIL	⟨ CONTESTS	OUTCOMES PROFILING
⟨ BOOKS	SUPPORT GROUPS/ BULLETIN BOARDS	〈 INSURANCE/BENEFITS/ DEF'D CONTRIBUTION	⟨ TRIAGE

## **Companies Interested in eDM**





Overview: Content, Connectivity, Commerce Care Management

Licensure/Certification

Liability

**Data Privacy/Confidentiality** 

**Data Security** 

### **CONTENT: LEGAL ISSUES**

- INTELLECTUAL PROPERTY
  - Copyrights
- $\rightarrow$
- $\bigcirc$   $\bigcirc$   $\bigcirc$   $\bigcirc$   $\bigcirc$

- Trademarks
- $\rightarrow$
- ® TM ® TM

Patents

- $\rightarrow$
- abSW

 of authors, journals, p hospital, vendor, payo



or presenter's institutions (e.g., tors

- LIABILITY FOR ACCURACY
  - FTC/ FDA/ State Consumer Fraud
    - False or misleading statements
  - Tort
    - Negligent selection or review of research or advice
  - Contractual
    - Variation from stated policies re: selection or advice

### **CONNECTIVITY: LEGAL ISSUES**

- LIABILITY FOR BREACH OF CONFIDENTIALITY
  - HIPAA/ HHS Proposed Privacy Rules
  - State Laws (applicable to extent more stringent than federal)
  - State Constitutions
  - Physician/ Nurse Disciplinary Codes
- LIABILITY FOR BREACH OF DATA SECURITY
  - HIPAA/ HHS Proposed Security Rules
  - State Laws
- COPPA
- TORT LIABILITY
  - Duty to monitor these areas of the web-site for patient emergencies, and ensure follow-up care is appropriate (See Shannon v. McNulty, 718 A.2d 828 (Penn. Super. 1999)).
- IT/ TELECOM/ MEDICAL DEVICE LAWS
  - FDA Compliance
  - FCC Compliance

### **COMMERCE: LEGAL ISSUES**

#### MEDICARE AND MEDICAID ANTIKICKBACK

- Civil and criminal penalties if e-DM company
  - pays or is paid
    - any remuneration
    - in cash or in kind
    - for referrals to or from a sponsor (such as a pharma company, PBM, or DME supplier) of Medicare or Medicaid beneficiary
  - to whom or for whom M/M could pay any reimbursement

#### STATE FRAUD & ABUSE

- Antikickback
- Fee-splitting
- Commercial Bribery

## **Defined Contribution Landscape**

C		ŒO	Ø of	Total Amt	Maior Investorial				
Company	Description	Œ	Rounds	Raised (\$mm)	Major Investor(s)				
Pure-Play Defined Contribution Companies									
Defined Trust	Defined contribution administration for employers	Clive Riddle	NA.	NA.	NA.				
Lumenos / Direct Healthcare	Consumer-oriented provider of defined contr. solutions	Chip Tooke	1	4.4	KBL Healthcare, Internet Healthcare Group				
HealtheCare	Provider of online Personal Care Accounts	Tony Miller	1	23.0	Psilos, Bain Capital, KKR, Alta Partners				
HealthMarket	Online service for evaluating & purchasing health products	Steve Wiggins	NA	26.5*	Acacia, Chase Capital, Fleet, General Atlantic, JH Whitney				
HealthPlan2.0	Defined contribution products w/ well known payer partner	David Goodman	NΑ	NA.	NA.				
Med-i-Bank	Health insurance and defined contribution products	Mark Schlussel	NΑ	6.5	Wind Point Partners				
MyChoiceHealth.com	Provider of web-based content and admin. support	Steve Tough	NΑ	NA.	NA.				
MyHealthBank	Community-based health exchange	David Sanders	1	1.0	FBR CoMotion Venture Capital				
Online HR and Benefits Management Companies									
America's Choice Healthplans		Clelland Green	1	4.0	Eureka				
BenefitPoint	Benefits distribution and management	Mark Pulido	2	63.7	Comdisco, First Union, GS Capital, HarbourVest Partners, Institutional Venture Partners, Scient, Sequoia				
BeyondWork	Benefits administration	Israel Niv	1	13.4	New Enterprise Associates				
eBenX	Health insurance exchange for middle and large employers	John Davis	4	116.0	CB Health, JMI Equity, New Enterprise, N. Bridge, Trellis				
eHealthDirect	HR, payroll and benefits administration	Tuan Ha-Ngoc	1	32.0	Advanced Tech, Audax, Chase, Psilos, Utah Venture				
Employease	HR and benefits administration for middle employers	Phillip Fauver	4	36.8	21st Century, Berkshires, Bowman, Federal Prtnrs, Hummer Winblad, Madrona, Noro-Moseley, SSM Ventures				
EmployeeMatters.com	HR, payroll and benefits administration	Elliot Cooperstone	1	1.0	Frontline Capital				
EmployeeService.com	HR, payroll and benefits administration	Jay Whitehead	3	18.7	DC Ventures, eCompanies, First Analysis, Mindful Prtnrs, Wilson Sonsini				
iBenefits	HR and benefits administration	Jeffrey Graves	1	11.4	Endeavor, Forrest Binkley & Brown, Hales & Company, Trident				
Interactive Info Services	ASP for HR and benefits administration	James Fredrickson	4	10.2	CID Equity Partners, William Blair Capital Partners				
LifeCare.com	Portal for work-life issues, including health benefits	Peter Burki	1	65.0	General Atlantic Partners, First Union Capital				
Online Benefits	HR and benefits administration	Alan Cohen	3	15.0*	Firemark Investments, GE Equity				
Simpata	ASP of HR, payroll and benefits admin for small employers	Jeffrey Simon	2	25.1	Acacia, Frazier & Co, Intel, NIF Ventures, Red Rock Ventures, Shad Run Investments				
Insurance Markets									
BenefitMall	Benefit exchange for small employers	Bernard DiFiore	2	47.0	Austin Ventures, Humana, Technology Crossover				
BenefitPort	Insurance and benefits distribution network	Andrew Sawyer	NA.	60.0	The Trident Partnership				
ChannelPoint	Exchange for insurance	Ken Hollen	6	126.6	Andersen Consulting, Capital Z, GE Capital, Intel, Mohr Davidow, Pacific Venture Group, Unite Healthcare				
eBenefits	HR and benefits administration	Andrew Kurtzig	1	8.0	Draper Fisher, Glynn, New Enterprise Associates				
eHealthInsurance	Health insurance exchange for individuals	Gary Lauer	2	54.0	Dell, Goldman Sachs, Kleiner Perkins, Rocket Ventures, Sprout Group, Weiss Peck & Greer				
Health/xis.com	Health insurance exchange for individuals	Alvin Clemens	NA.	NA.	NA.				
SimplyHealth.com	Health insurance exchange for consumers and small businesses	Eric Grossman	2	30.1	Encubate Holdings, New Era Capital, Healtheon/WebMD, LiveOak Equity, SSM Ventures, Total Tech Ventures				
Health Claims Negotiation a	nd Payment			-					
eHealthClaim	Health claims organizing for consumers	David Karabinos	1	1.7	NA.				
HealthAllies.com	Preferred provider rates for individuals	Andrew Slavitt	2	36.0	American Express, GRP, Idealab, Rho Management				
onehealthbank.com	Claims adjudication	Joe Sebastianelli	NΑ	NA.	NA.				

### **COMMERCE: LEGAL ISSUES**

- CONSUMER PROTECTION LAWS/ FRAUD
  - FTC
  - FDA
  - State Consumer Laws
  - Uniform Commercial Code (for Products/ Devices)
- TORT
  - Negligence Theories
  - Strict Liability Theories (for Products/ Devices)
- TAXATION
  - IRC section 125(b)
  - Collecting Or Paying State Taxes On eCommerce

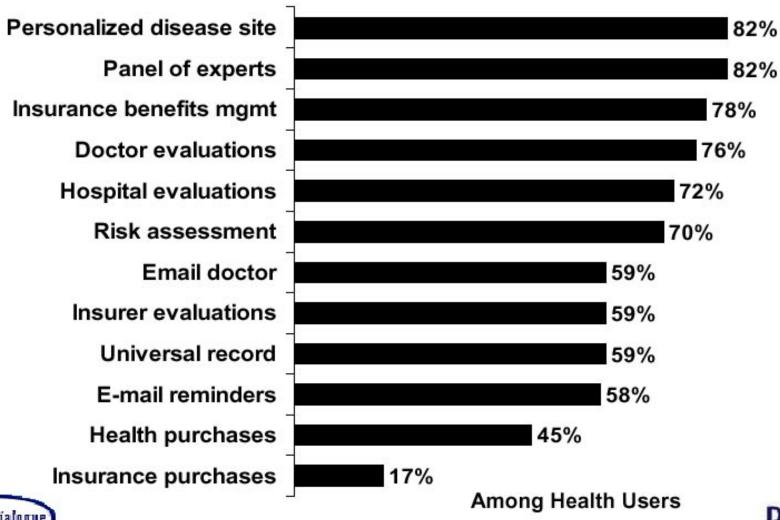
### CARE MANAGEMENT: LEGAL ISSUES ROADMAP

- LICENSURE/CERT.
  - STATE PROVIDER LAWS
  - STATE ENTITY LAWS
  - MEDICARE/MEDICAID
  - ACCREDITATION
- LIABILITY
  - TORT
  - CONTRACT
  - CONSUMER PROT. LAWS
  - STATE DOI ACTION

- DATA PRIVACY/CONFID.
  - HIPAA
  - STATE PRIVACY LAWS
  - STATE CONSTITUTIONS
  - PRIVATE ACTIONS
  - DATA SECURITY
    - HIPAA
    - STATE SECURITY LAWS
    - PRIVATE ACTIONS



### Interested in using . . .



Deloitte Consulting

# CARE MANAGMENT LEGAL ISSUES LICENSURE

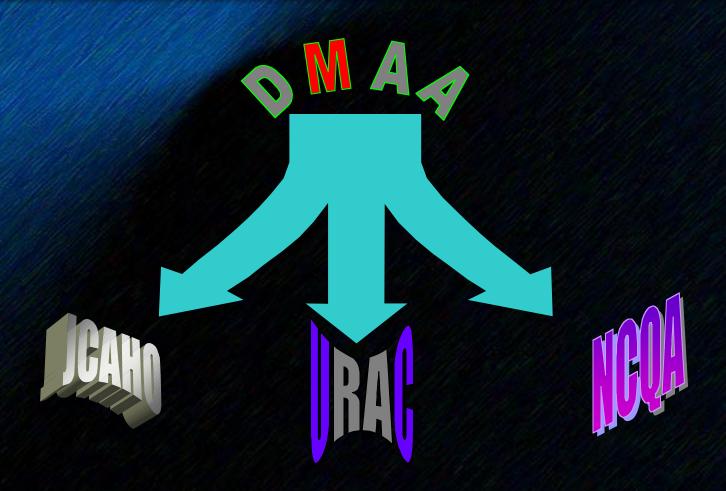
- PROVIDER LICENSURE REQUIREMENTS
  - Physicians
  - Nurses
  - Social Workers
  - Others
- DMO ENTITY LICENSURE REQUIREMENTS
  - Managed Care Licenses
    - HMO/Health Insurer
    - UR/UM
    - TPA
    - AWP/ Mandated Benefits
  - Entity as Provider
  - Delegation/ Accred/Deemed Status

## CARE MANAGMENT LEGAL ISSUES LICENSURE

#### MEDICARE/ MEDICAID

- PROVIDERS:
  - CONDITIONS OF PARTICIPATION
  - STATE LICENSURE FOR PROVIDERS
- ENTITIES
  - MEDICARE + CHOICE
    - DELEGATION: COMPLIANCE W/ HMO's LIC. CRITERIA
    - DEMOS: COMPLIANCE W/ NEW CRITERIA (E.G., QISMC)
  - FEE FOR SERVICE
    - NEW FORMS OF ACCRED OR LICENSURE???

## ACCREDITATION



21

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## CARE MANAGEMENT LEGAL ISSUES: LIABILITY

#### LIABILITY/ TORT

- Direct
  - Negligent DM/ CM/ UM
  - Negligent Credentialing of H/C Providers
  - Negligent Referral
- Indirect/ Vicarious
  - Malpractice of Nurse/ Physician
  - Failure of Nurse/ Phys to Refer or Follow Up
  - Failure of Nurse/Phys. To Catch Emergencies

## CARE MANAGEMENT LEGAL ISSUES: LIABILITY

#### LIABILITY/ CONTRACT

- Internet
  - Violation of Web-site Terms and Conditions
  - Violation of Privacy Policies
  - Good faith/ fair dealing and quasi-contract
- Offline Contracts
  - Payors
  - Vendors
  - Providers
  - Consumers
- ERISA

### CARE MANAGEMENT LEGAL ISSUES: LIABILITY

#### LIABILITY/ CONSUMER PROTECTION

- Baby FTC Acts: False and misleading statements or acts
- Liability of HMOs/ Insurers for DMO Vendor Acts

#### LIABILITY/ STATE AGENCY REGULATION

- Department of Insurance
- Department of Public Health
- Department of Managed Care (e.g., Calif.)

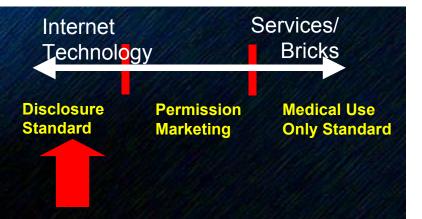
## **Clicks and Bricks**

InternetServices/<br/>Bricks050100

## **Protectionist Perspectives of eDM**

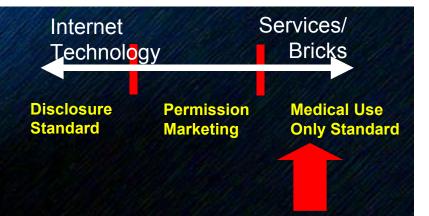


### **Disclosure Standard**



 Description: "Click here and the fine print says we can use your information for whatever purposes we want"

# Medical Use Only Standard



- Your health plan has enrolled you in a DM program. You are in unless you specifically want to opt out.
- Your data will be used only to advance your personal patient care
- We will not try to sell you anything

# Permission Marketing (Guidelines)

Internet Services/
Technology Bricks

isclosure Permission Medical Us

Disclosure Standard

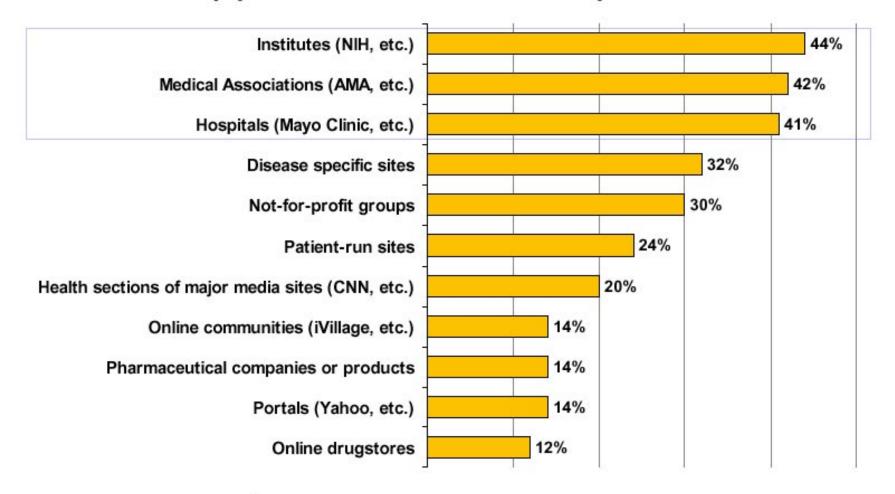
Permission Marketing

Medical Use Only Standard

- Premise: Permission must be gained to make offerings to patients.
   Permission can be withdrawn at any time by the patient.
- Premise: SOME patients will have an expectation of being able to purchase offerings related to their medical condition on the Internet
- Don't ask for more than you need right away.
- Build up information about the patient OVER TIME.
- Build up trust over time.
- The patient's data base is open to the patient for viewing and modification.
- Don't ask for info that will not be of direct, immediate benefit to the consumer.
- Avoid repetitive questioning (consumers will expect you to remember information you have given them).
- The price of perceived intrusion is high.
- Don't misuse patient data
  - Aggregating with other identifiable information (Doubleclick's plan)
  - "Excessive" data mining
- Be certain that you can deliver personalized content...don't overpromise
- Acknowledgement: Cyberdialogue, Privacy vs Personalization: A Delicate Balance, 1999



#### Sites trusted to keep personal health information private and secure



Percent of online health seekers rating 4 or 5 on 5 pt. scale where 5 = high level of trust





## CARE MANAGEMENT LEGAL ISSUES: HIPAA PRIVACY RULES

#### APPLY TO:

- Health Plans
  - Insurers/ HMOs/PPOs
  - ERISA Plans/ Govt. HPs
- Health Care Providers
  - MDs, RNs, hospitals, etc.
  - Care managers, if licensed as health care providers
  - EAPs, On-site clinics
- Other person or org. who furnishes, bills, or is paid for h/c services or supplies
- Clearinghouses
- Billing agencies
- Business Partners of Above

#### WHENEVER THEY:

- Transmit or maintain
   Protected Health Information
   Electronically
- Even if it is later reduced to paper form (BUT MAY CHANGE)
- PHI is health information received from a provider, health plan, clearinghouse, OR EMPLOYER which identifies or could lead to ID of the patient

# HIPAA PRIVACY RULES: REQUIREMENTS

- Comply With Use And Disclosure Rules
- Permit Patient Access, Amendment, And Limitation
- Disclose Privacy Policies
- Administrative
  - Accounting for disclosures
  - Designate privacy official
  - Training workforce
  - Technical and physical safeguards
  - Complaint process

# HIPAA PRIVACY RULES: USE AND DISCLOSURE REQUIREMENTS

- OBTAIN DETAILED PATIENT AUTHORIZATION UNLESS FOR:
  - Treatment
  - Payment
  - Health Care Operations
  - Enumerated Exceptions (e.g., public health, research)

# HIPAA PRIVACY RULES: USE AND DISCLOSURE REQUIREMENTS

- Minimum Necessary Rule
- De-identification Rule
- Destruction of Data Rule
- Health Care Component Rule
  - Health plans
  - Health care services

## HIPAA PRIVACY RULES: IMPACT ON E-DM

- Business Partner Obligations
  - Comply with all use and disclosure rules
  - Enter contracts with Covered Entities
    - CE DUTY TO MONITOR
    - CE DUTY TO MITIGATE
  - Subject to suit by patients for breach of the K???

## HIPAA PRIVACY RULES: IMPACT ON E-DM

#### TREATMENT EXCEPTION TO AUTHORIZATION

- "The provision of health care by, or the coordination of health care (including health care management of the individual through risk assessment, case management, and disease management) among, health care providers; the referral of a patient from one provider to another; or the coordination of health care or other services among health care providers and third parties authorized by the health plan or the individual."

## HIPAA PRIVACY RULES: IMPACT ON E-DM

- E-DM Companies as Business Partners
  - YES, if receive PHI from Covered Entities
  - NO, if receive PHI data only from patients
  - BUT, YES if nurses or other health care providers receive data and provide to company

### HIPAA PRIVACY RULES: SPECIAL ISSUES FOR eDM

### DEFINITIONAL ISSUE

- "The definition of 'treatment' includes' [disease] management as an included function. DM is not a defined term, and this creates one of the biggest loopholes in the rule. Protected health information could be disclosed to virtually anyone--including marketers and employers ... it is essential that this loophole be closed."
  - Robert Gellman, Member, National Committee on Vital and Health Statistics.

### HIPAA PRIVACY RULES: SPECIAL ISSUES FOR eDM

### POPULATION MANAGEMENT

### - HHS

 "Our definition is intended to relate only to services provided to an individual and not to an entire enrolled population."

### NCQA

- "[T]he definition ... in the proposed rule is limited to a range of services provided to individuals and not to enrolled population groups. This limited definition of what constitutes health care operations conflicts with NCQA requirements for managed care plans."
- "NCQA expects accredited health plans to institute populationbased management of care programs ... and generally be responsible for improving the outcomes of enrolled populations."

### HIPAA PRIVACY RULES: SPECIAL ISSUES FOR eDM

### PHARMA-PBM-MARKETING: PHYSICIAN PERSPECTIVE

- "The danger of equating information disclosures for DM with disclosures for treatment is not a theoretical one, as anyone knows who has received mailings at home for an alternate, competing medication after having filled a prescription at the pharmacy."
- "If the true motive of its proponents is to improve individuals' care, then they should not object to coordinating all DM activities through the individual's physician. If, however, the purpose is ...to market protected health information to commercial entities or employers, then the proponents will eschew physician participation and seek to directly influence the patient."
- The AMA opposes any "disease management" language in the proposed rule that is not qualified by requiring the coordination and cooperation of the individual's physician."

# CONFIDENTIALITY: CALIFORNIA S.B. 19

### The Law:

- "No provider of healthcare or Health Care Service Plan or contractor shall disclose medical information regarding a patient of the provider of healthcare or an enrollee or subscriber of a Health Care Service Plan without first obtaining an authorization, except . . ."

### The Exception:

— "For purposes of chronic disease management programs, information may be disclosed to any entity contracting with a Health Care Service Plan to monitor or administer care of enrollees for a covered benefit..."

### The Exception to the Exception:

- "... provided that the disease management services and care are authorized by a treating physician."

# CONFIDENTIALITY: CALIFORNIA S.B. 19

- FIREBAUGH AMENDMENT: ADVANTAGES
  - (1) No need for physician authorization if:
    - entity is a DMO, as defined in new Section 1399.900 of the Health and Safety Code, provided that the health care service plan or its contractor provides a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians.
  - (2) Uses DMAA definition of DMO and "DM services"
  - (3) DMAA compromise with CMA
  - (4) Probably will avoid similar problems in other states

# CONFIDENTIALITY: CALIFORNIA S.B. 19

### FIREBAUGH AMENDMENT: TRADE-OFFS

- (1) DMOs must still obtain physician authorization prior to the time that the DMO, its employees, or its independent contractors do either of the following:
  - Provide home health care services. (Home health visits made solely for patient assessment, monitoring, or education are not subject to the physician authorization requirement).
  - Dispense, administer, or prescribe a prescription medication. (A valid prescription written by a treating physician is adequate authorization).
- (2) DMOs are now subject to the other provisions of the California Confidentiality law, including penalties for violations.
- (3) DMOs may not use medical information to solicit or to offer for sale to a health care service plan enrollee any products or services in the provision of DM services to the enrollee.
  - Enrollee may elect to use a DMO to obtain information about health care products and services and then the DMO may offer to the enrollee health care products or services that are directly related to enrollee's condition.

# **Best Compliance Practices**

### LIABILITY/ RISK MANAGEMENT FOR eDM

- Determine if h/c services will be provided and gear compliance accordingly.
  - If NO:
    - Avoid diagnosis and treatment
    - Avoid specific referrals
    - Avoid medication or procedure recommendations
    - Continually document enrollee understanding
  - IF YES:
    - Maintain and comply with credentialing P & P
    - Require indemnification of independent contractors
    - Require providers to maintain adequate malpractice insur.
    - Maintain P & P and contracts to ensure employees comply with all applicable standards of care

### LIABILITY/ RISK MANAGEMENT FOR eDM

- DON'T rely on disclaimers
  - courts will focus on "reasonably foreseeable" harms
  - obtain continual evidence of consumer informed consent
- DON'T rely on insurance
  - Most E&O policies for DM have restrictive policy limits (e.g., \$1M)
  - Most plaintiff lawyers will seek 10x-100x policy limits
- DO Use contracts and scripts for on-line disease managers
- DO Use policies and procedures for identifying and handling patient emergent or urgent situations (e.g., automated alarms)

- Privacy/ Security/ Consumer Protection In eDM
  - Comply With Your Privacy Policies!
  - Move Beyond Privacy Policies to Compliance With HIPAA
  - Avoid Marketing Products Other than DM Services
  - Draft and require use of HIPAA compliant IT/ Vendor Agts.

### Entity Licensure

- Create and comply with corporate compliance policies for managed care and insurance licensure
- Determine licensure required by PAYORS
- Utilize reinsurance and craft reimbursement mechanisms to avoid "business of insurance" or "HMO"
- Provider Licensure
  - Physicians: Ensure medical directors not practicing medicine
  - Nurses
  - Other allieds
  - MSWs

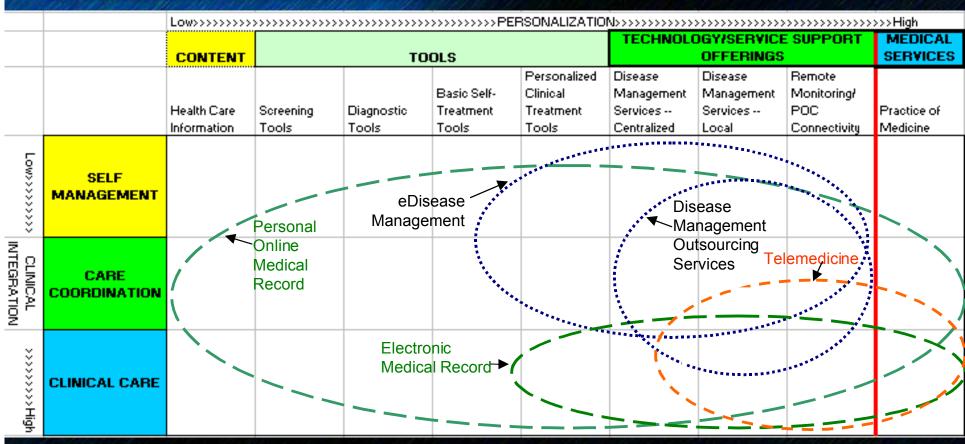
# BEST COMPLIANCE PRACTICES FOR eDM: CONCLUSION

### **DM WEB-SITE**

	CONTENT	CONNECTIVITY/ COMMUNITY	COMMERCE CA MANAG		
(	ARTICLES/ JOURNALS EXPERTS LINKS NEWSLETTERS	<ul><li>E-MAIL</li><li>PDAs</li><li>BULLETIN BOARDS</li><li>CHAT ROOMS</li></ul>	<pre></pre>	NURSE CHAT SELF-MGMT. TRNG SYMPTOM MONIT'G RISK STRATIFICATION	
\ \ \	INTELLECTUAL PROP. LIABILITY FOR ACCURACY	<ul><li>⟨ PRIVACY</li><li>⟨ SECURITY</li><li>⟨ LIABILITY</li><li>⟨ LICENSURE</li><li>⟨ COPPA</li></ul>	CONSUMER PROT. FRAUD & ABUSE FDA (DEVICES) TAXATION	⟨ PRIVACY ⟨ SECURITY ⟨ LIABILITY ⟨ LICENSURE	
	OP/P FOR REVIEW OF CONTENT	P/P AGAINST PROV H/C SERVICES, (DX, RX, REF, ADVICE)	F&A CORP COMPLIANCE PROGRAM	CONTRACTS FOR DIS. MGRS.	
	P/P & K FOR EXPERT CREDENTIALS	⟨ USE INDEP. K-ors OR NON-PROVIDERS	〈 INSURANCE REGULATORY COMPL PROGRAM	〈 IF PRAC. PROF: COMPLY W/ STDS OF CARE	
	〈 IP PROTS. IN Ks AND P/P	INDEMNIFICATION/ INSURANCE	INDEMNIFICATION/ INSURANCE	〈 IF NO PRAC. PROF: DOC PT UNDERST'G	
	DISCLAIMERS	\( \text{DISCLAIMERS}	⟨ DISCLAIMERS	P/P AND CONTR	

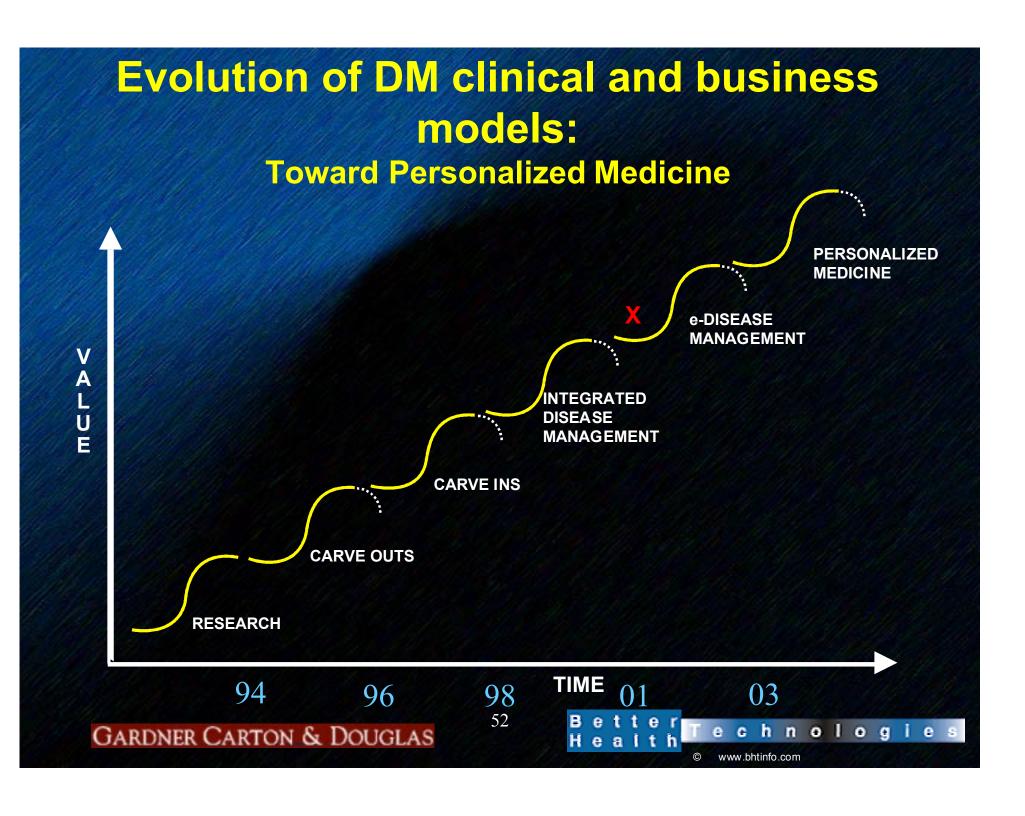
# **Summary/Implications**

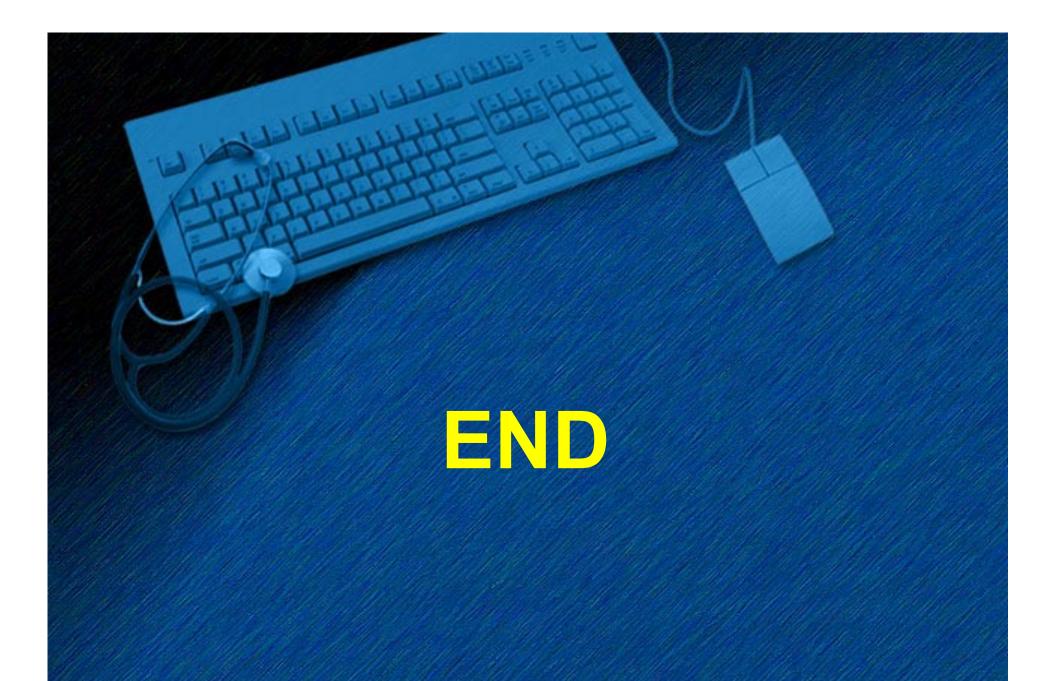
# A Crude Map of the New World: eHealth & Care Management Framework





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53

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