TOWARD A MORE ACCOUNTABLE REGULATORY SYSTEM

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AMERICA'S HEALTH CARE SYSTEM IS AT A CRITICAL JUNCTURE

- **Health care is becoming increasingly unaffordable and inaccessible.**
- **Only a small amount of care provided to patients is evidence-based.**
- **Underuse, overuse, and misuse of health care services places patients at risk and exacerbates the cost crisis.**
- **The regulatory system has become transactional and not performance-oriented.**
  - **Good intentions – without systematic analysis - may have unintended consequences.**
- **Need a change of direction to address challenges in the areas of affordability, access, and accountability.**

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MANDATES AFFECT AFFORDABILITY, ACCOUNTABILITY, AND ACCESS

- **Mandates make health care less affordable.**

- **Mandates often are enacted without accountability.**
  - **May be based on anecdote, not evidence.**
  - **In many states, there is no rigorous analysis of the costs and benefits.**
  - **Typically there is no look-back at the cumulative cost of mandates.**

- **Because the cost of mandates drives up the number of uninsured, mandates ultimately may hinder access to care.**

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MANDATES CAN BE ANTI-COMPETITIVE

- **Drive up costs for employers and consumers.**
- **Restrict consumer choice among coverage options.**
- **Discourage competition among providers (because they create a presumed right to contract).**
- **Hinder non-price competition among health plans (e.g., creative benefit design).**
- **Stifle innovative advances in treatment and diagnosis (because mandates write current medical practice into law).**

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THE VOLUME OF MANDATES CONTINUES TO RISE

- **Today's regulatory system is a patchwork of federal and state mandates affecting all aspects of health care operations.**
  - **Volume of mandates grew 25-fold from 1976-1996 – an average of 15% per year (Jensen & Morrisey, 1999).**
- **Hundreds of new mandates continue to be proposed.**
  - **States considered more than 800 new mandates this year.**
  - **Patients' Bill of Rights legislation proposed 84 new mandates.**

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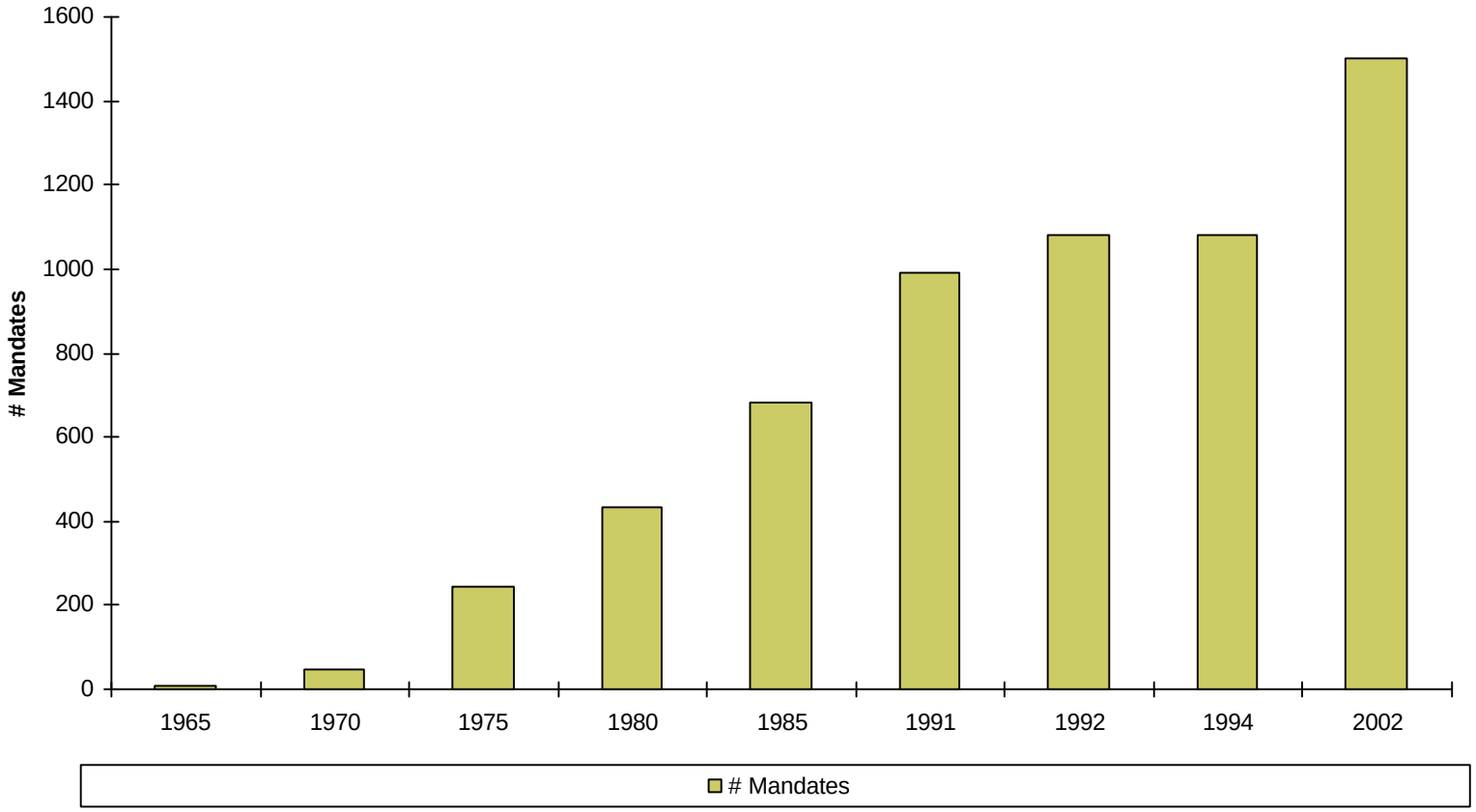
NUMBER OF MANDATED HEALTH INSURANCE BENEFITS



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FEDERAL REQUIREMENTS HAVE INCREASED

- **Federal mandates include:**
  - **HIPAA**
  - **Department of Labor claims rules**
  - **Mental health parity**
  - **48-hour maternity length of stay**
  - **Post-mastectomy reconstructive surgery**

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STATE MANDATES TAKE MANY FORMS

- **State mandates include:**
  - **Benefit mandates --autologous bone marrow transplants (ABMT), *in vitro* fertilization; hair transplants; aquatherapy**
  - **Process mandates -- 48-hour minimum stay following childbirth or mastectomy; formulary requirements**
  - **Provider mandates**
    - **Mandated coverage for select classes of providers: massage therapists; pastoral counselors; naturopaths**
    - **Contracting mandates: any-willing provider; prompt-payment of any claim, regardless of accuracy; collective bargaining; mandated definitions of medical necessity**

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THE PROLIFERATION OF MANDATES HAS CREATED A PATCHWORK SYSTEM

- **State mandates are inconsistent. For example:**
  - **42 different standards for independent medical review.**
  - **No state uses a standard based on the best available medical and scientific evidence.**

- **Federal mandates may overlap and conflict with state mandates.**
  - **HIPAA privacy rules – allow "more stringent" state laws**
  - **Department of Labor claims rules**

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NAVIGATING THE PATCHWORK OF FEDERAL AND STATE RULES CAN BE COMPLEX

Acrobat Document

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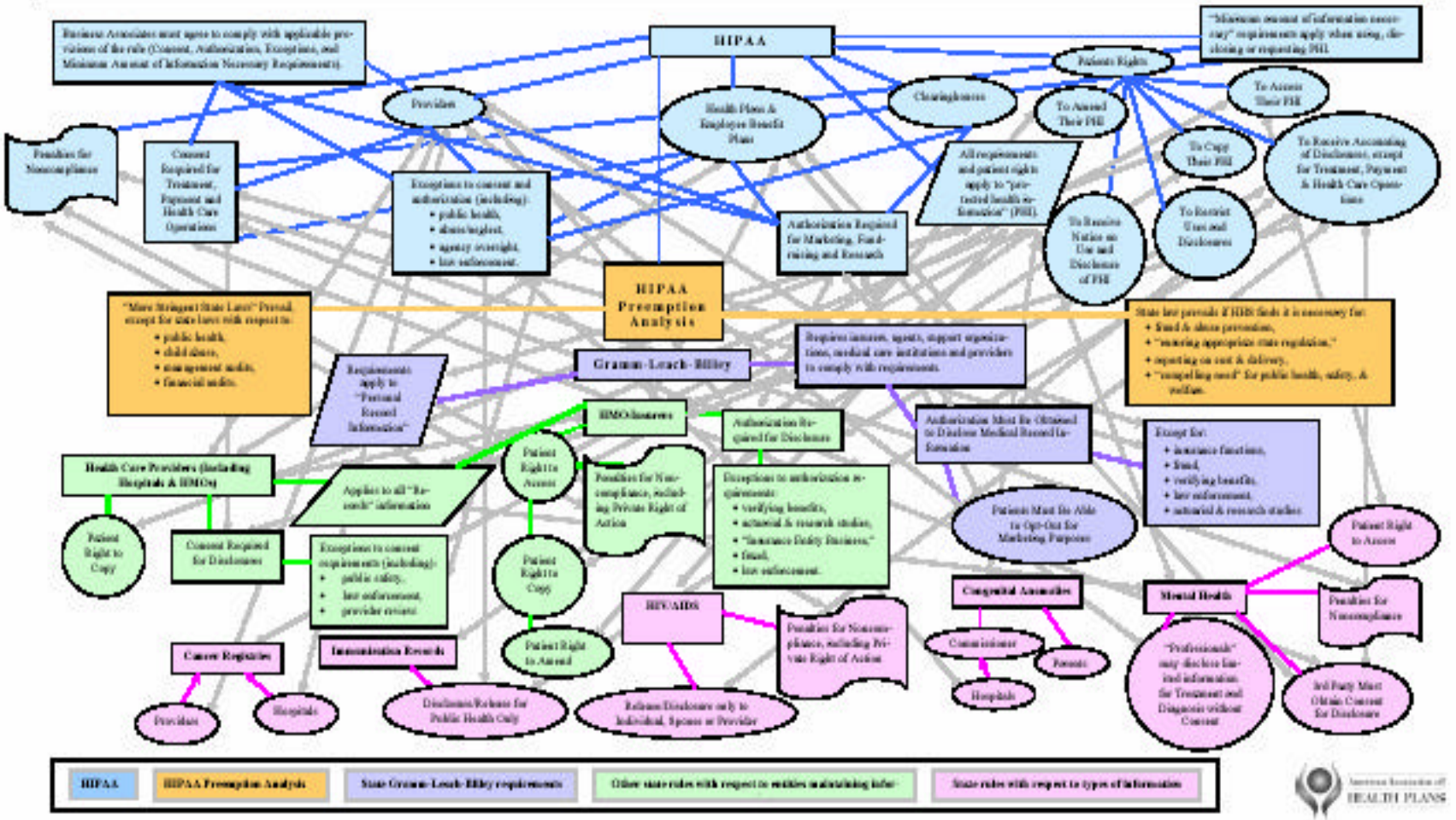
Complexity of Health Information Privacy Laws: One State Example

Significant state laws already exist with respect to the privacy of health information. In addition, the HIPAA privacy regulations recently issued by HHS and which most covered entities must be compliant with by April 14, 2003 also impose significant requirements with respect to the use and disclosure of health information. The following chart illustrates the relationship between the HIPAA privacy regulation and health privacy laws in the state of Virginia. While the state laws are specific to Virginia, the chart is illustrative of the complexity of the current system and the confusion that will ultimately arise when all state laws are evaluated under the federal preemption standard to determine if such law is preempted by the HIPAA standards.



Sources for laws found in: Federal HIPAA privacy regulation, State Insurance Code, State Health Code, State Code on Civil Remedies and Procedures, State Code on Institutions for the Mentally Ill and Mental Health Generally, and State Code on Corporation Commissions.

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MANDATES EXACERBATE THE COST CRISIS IN HEALTH CARE

- **Health care spending per insured American grew 9.6% in 2002 – more than four times faster than the overall economy (Center for Studying Health Systems Change, 2003).**

- **Health premiums for active employees increased an average of 15% in 2003, the largest increase in at least a decade (Towers Perrin/Watson Wyatt, 2003).**

- **Mandates and regulation accounted for 15% of the premium increase -- $10 billion -- from 2001-2002 (PricewaterhouseCoopers for AAHP, 2002).**

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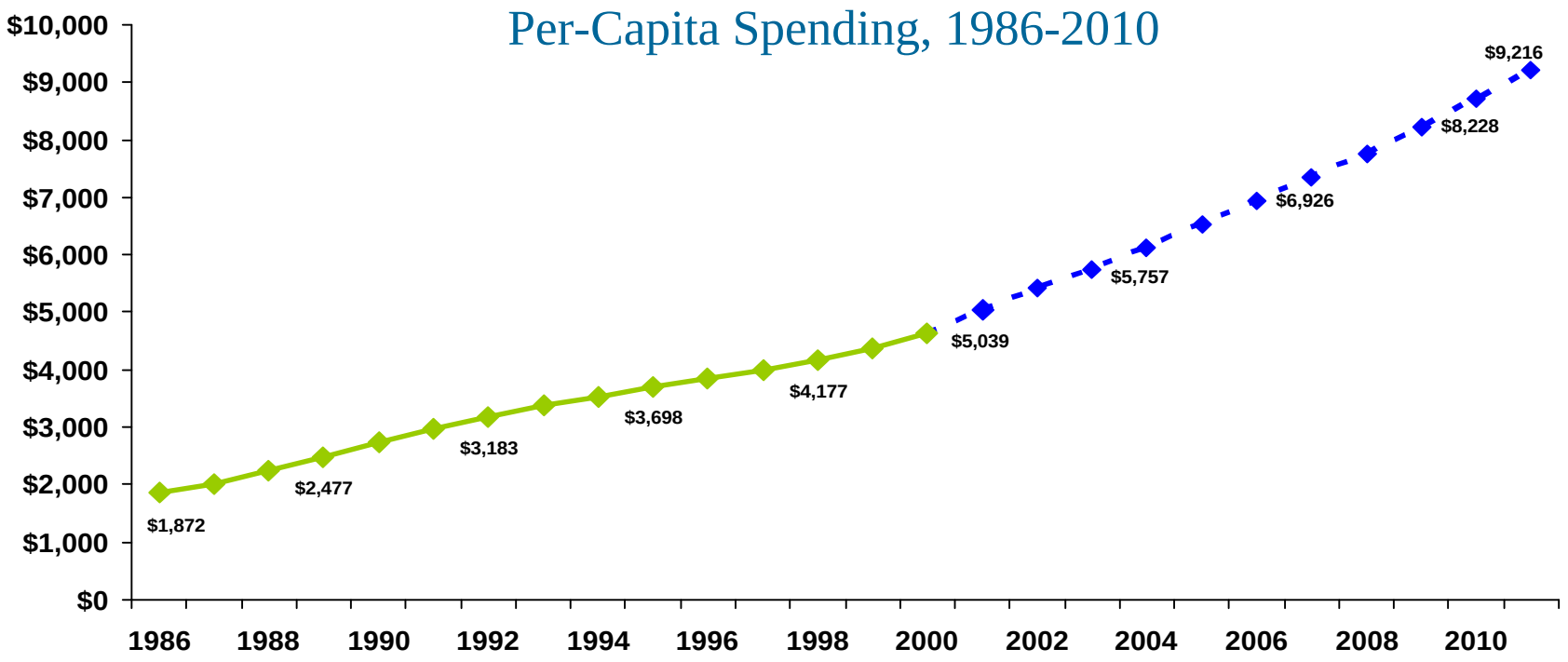
HEALTH SPENDING IS EXPECTED TO RISE FOR THE REST OF THE DECADE



Source: CMS, Office of the Actuary, National Health Statistics Group.

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EACH ADDITIONAL MANDATE HAS AN IMPACT ON COSTS

- **Any-willing provider: 7-9% average cost increase.**
- **Medical necessity mandates that can hinder efforts to avoid underuse, overuse, and misuse of services: 4-6% average cost increase.**
- **Mandated point-of-service option: reduce premium savings by 4-11 percentage points.**
- **Prohibition on physician incentive payments to promote safe and effective care: reduce savings by 3-5 percentage points.**

(The Barents Group, LLC, 1997, 1998)

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WORKING FAMILIES PAY THE PRICE

- **Working families pay for mandates in the form of lower wages and lost jobs.**

- **Over five years, a one percent increase in health care costs:**
  - **Cuts workers' wages by $2.7 billion; and**
  - **Reduces employment by 15,130 nationwide.**

(Langenfeld & Shin, 2003)

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MANDATES FUEL THE UNINSURED CRISIS

- If not for mandates, 18% of uninsured businesses would sponsor coverage (Jensen & Morrisey, 1999).
- One-quarter to one-fifth of the uninsured lack coverage due to state mandates (Sloan & Conover, 1998).
- Every 1% increase in premium costs causes 300,000 Americans to lose coverage (The Lewin Group, LLC, 1999).
- Mandates restrict choice and drive up costs.
- State mandates do not apply to Medicare, Medicaid, Federal Employees Health Benefits Plan (FEHBP), or self-insured ERISA group health plans.

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SOME MANDATES LIMIT CHOICE AND STIFLE COMPETITION

- **Example: Any-willing provider laws (22 states):**
  - **Restrict innovation and flexibility to design products tailored to customers' needs (non-price competition).**
  - **Remove incentives for providers to compete based on performance in providing safe, effective care.**
  - **Create a presumed "right to contract" that does not exist in any other industry or elsewhere in health care.**

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MANY MANDATES ARE FOR PROVIDER PROTECTION, NOT CONSUMER PROTECTION

- **Existing state mandates**
  - **Prompt-pay laws (47 states): May make it impossible to correct errors and avoid fraud.**
  - **Mandated definitions of medical necessity (27 states): Protect provider decisions that may not be consistent with medical evidence of effectiveness.**

- **Mandates proposed in AMA model contract**
  - **Mandated disclosure of provider payments, leading to a *de facto* floor on provider charges.**
  - **Restrictions on ability to correct unwarranted overpayments to providers (which may result from unintentional errors or, in some cases, fraud).**

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A CAUTIONARY TALE: ABMT MANDATE HAD UNINTENDED CONSEQUENCES

- **ABMT coverage was mandated in 10 states and for all federal employees covered by FEHBP.**
- **Because of the mandate, there was no incentive to enroll in clinical trials to test the treatment's effectiveness.**
- **Clinical trials ultimately found that ABMT was no more effective than standard therapy.**
- **Thousands of women underwent this extremely painful, sometimes fatal, yet ineffective procedure.**

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MANDATES CAN STIFLE INNOVATION

- **Length-of-stay mandates**
  - **48-hour post-mastectomy stay**
    - **Banned a new clinical advance pioneered by Johns Hopkins physicians.**
  - **48-hour maternity stay**
    - **Neither the mandate nor previous early-discharge policies affected infant health positively or negatively (*New England Journal of Medicine*, 2002).**

THE INSTITUTE OF MEDICINE'S CALL TO ACTION

- ***Crossing the Quality Chasm*** **(2001) – Key Recommendations:**
  - **Improve the safety and effectiveness of care that patients receive.**
  - **Engage in collaborative efforts to better incorporate the best available scientific evidence into everyday medical practice.**
  - **Collect and make public information about plans' and providers' performance in providing care consistent with the evidence.**
  - **Align payment incentives with delivery of safe and effective care.**

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WHERE DO WE GO FROM HERE? ROADMAP FOR POLICY

- **Promote greater accountability and transparency in regulation.**
  - **Require rigorous analysis of the benefits and costs of proposed mandates for consumers, employers, and taxpayers. (19 states require systematic review of proposed mandates.)**
  - **Place a moratorium on mandates until costs and benefits can be assessed.**
  - **Establish a mandate tax credit to offset payors' costs for each new mandate enacted.**
- **Provide flexibility, affordability, and choice for employers and consumers**
  - **Allow innovation in product design.**

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HOW THE FTC AND DOJ CAN PROMOTE GREATER ACCOUNTABILITY

- **Inform policymakers and the public about the anti-competitive effects of provider and benefit mandates.**
- **Ensure full and accurate disclosure of the costs and benefits of treatments and procedures.**
- **Take enforcement action against entities that intentionally mislead the public about effectiveness of health care products or procedures.**