Changes in Health Care Delivery and Payment

Advanced Health Care Law CLE – Friday, October 17, 2014

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Overview

- A) Volume to Value: National Trends in Population Health
  - (1) Forces of Change: What is Driving Population Health?
  - (2) Population Health Impact
- B) The Georgia Experience: Piedmont WellStar HealthPlans
- C) Legal Issues in Payor/Provider Integration
  - Fraud and Abuse
  - Antitrust
  - HIPAA/Health Information Privacy
- D) Discussion

Volume to Value:

National Trends in Population Health

Population Health – Word Game!

Managed Care

Provider Networks

Patient Centered Medical Homes

Pioneers

Care Delivery Model

Shared Savings

Contracting Vehicles

Care Management

Triple Aim

Value-Based Purchasing

Legal Entities

Payment Transformation

CIN

Clinical Integration

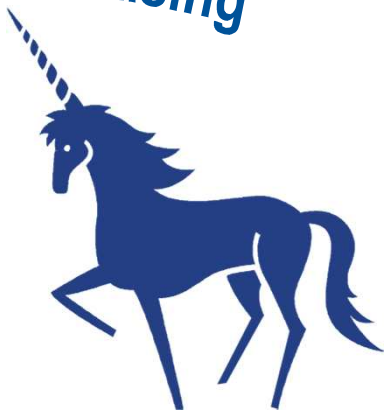
CPCI

MSSP

Demonstration Projects

Medicare Program

Bundled Payment



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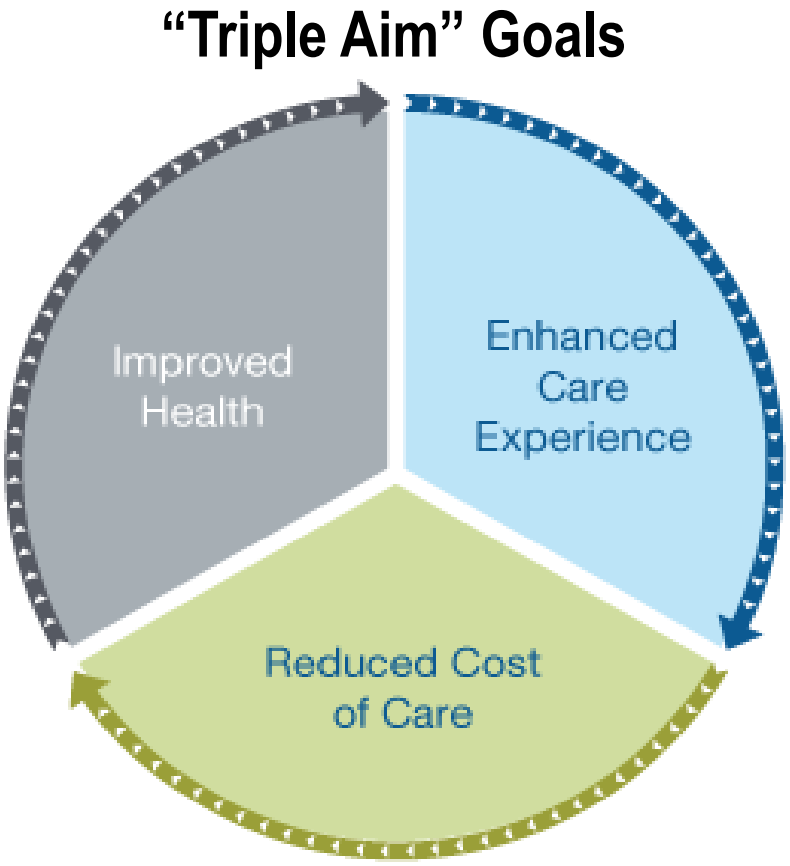
Start with the End in Mind – Achieving the "Triple Aim" of Population Health



Requires strategies that innovate new clinical delivery models that focus on the community's needs while building the infrastructure to successfully manage care across sites of care over time

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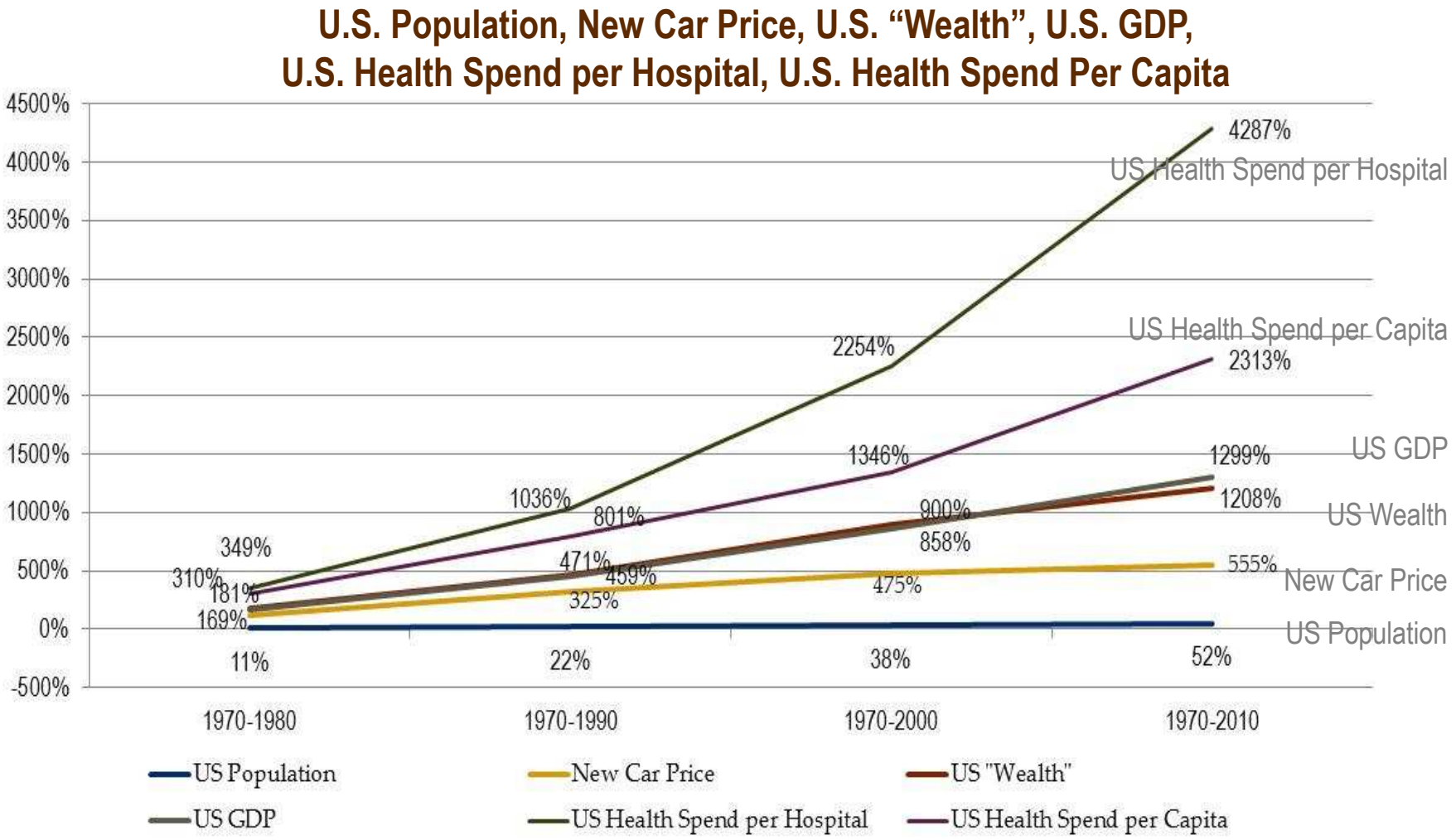
We All Know Traditional Growth Is Not Sustainable

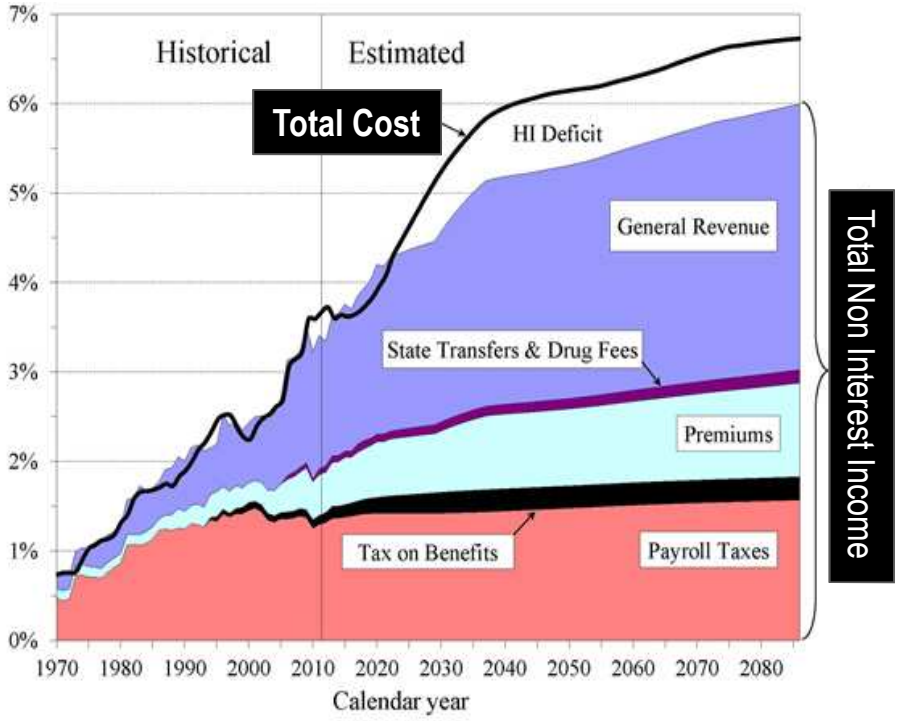


Note: "Wealth" = average household income * total households.

And that Medicare Cost Projections Outpace Revenue

Projected cost deficit requires creating *systemic change* that can maintain cost increases closer to inflation.

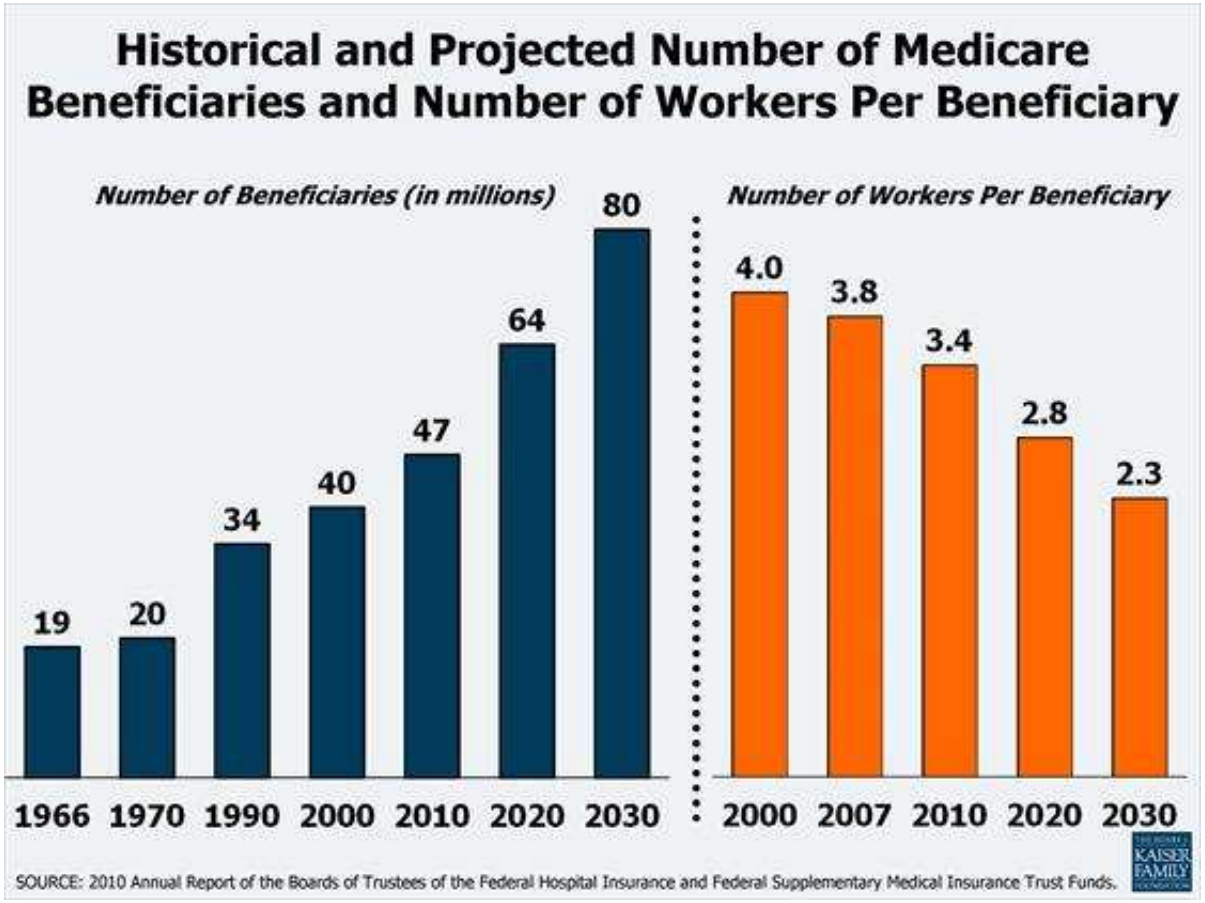
Medicare Cost and Non-Interest Income by Source as a Percentage of GDP



- **Growing cost deficit to Medicare Trust fund** creating urgency to pilot new payment and clinical delivery models
- **Establishment of Innovation Center** with $1B annual budget
- Innovation Center piloting a **combination of incentives and penalties** to reduce cost trend and create alignment between payment models and clinical performance
- **Commercial plans (are subsequently) following suit**

Complicating Matters is a Shift in Ratio of Revenue Sources and Costs to Treat

Population growth combined with a reduction in active workers per beneficiary adding to the financial strain.



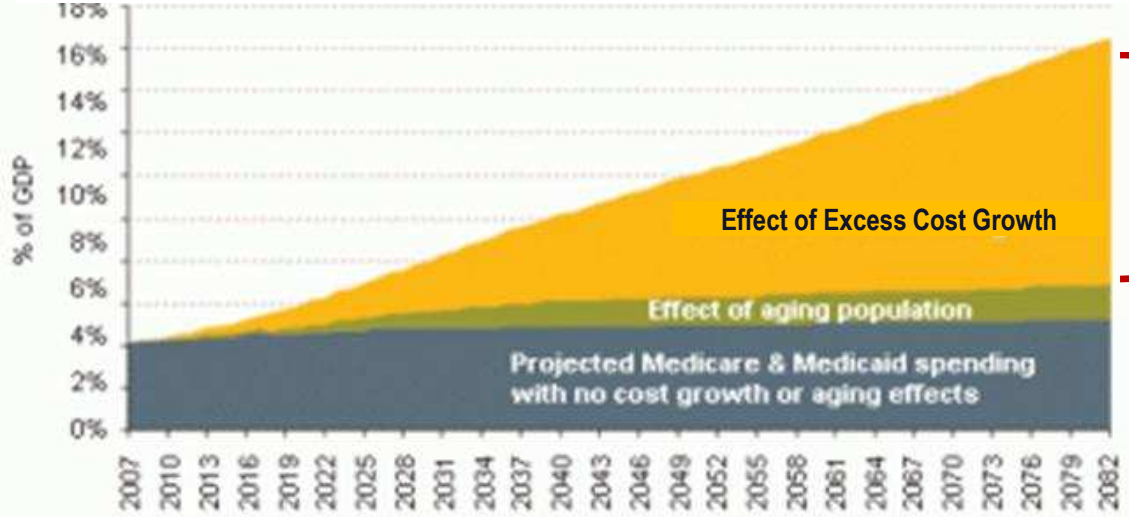
- Strong growth in number of Medicare beneficiaries as the population ages
- **Reducing number of workers per Medicare beneficiary**
- Focus by policymakers to maintain positive financials to the Trust Fund
- **Result is reduction in source of revenue coupled with increase in costs**

Despite Common Thinking, Aging a Small Contributor to Overall Cost Growth

However, population growth just a small fraction of overall growth trends. Therefore, policymakers targeting 'excess' growth through new, innovative programs.

Exhibit 2: If unchecked, the current rate of health care cost inflation is estimated to have a massive impact on the growth of U.S. government spending on health care.

Sources of Growth of Projected Federal Health Care Spending (2007 – 2082)



Source: U.S. Congressional Budget Office, Long-Term Outlook for Health-Care Spending, October 2007

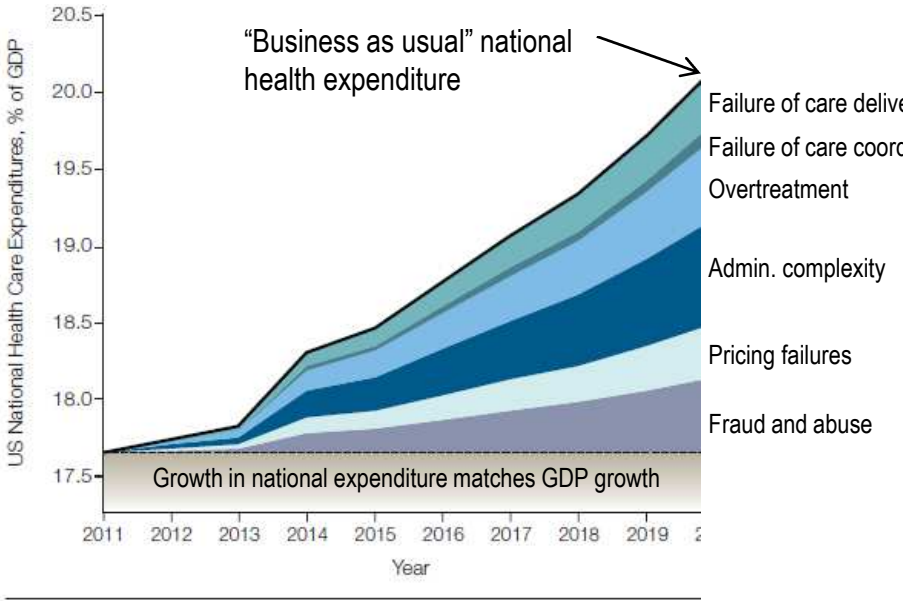
» Medicare inflation projected to remain well above overall GDP inflation

Cost inflation beyond GDP inflation driven by 'excess cost growth'

» If unchecked, current rate of health care cost inflation is estimated to have a massive impact on the growth of US government spending on health care.

Drivers of Excess Costs Largely Seen as Opportunities to Improve Care

Drivers of Cost Savings



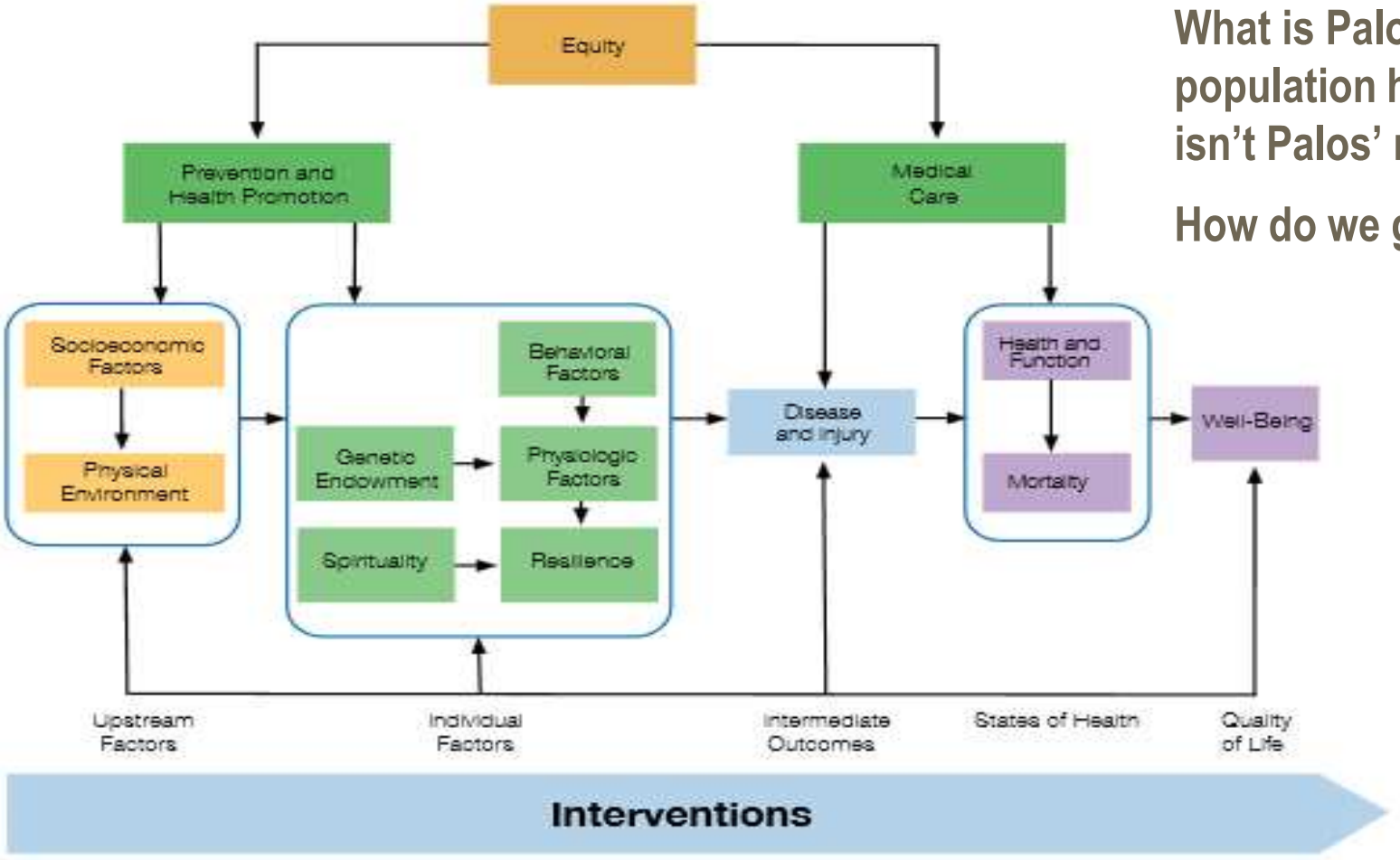
Estimates of Annual US Healthcare Waste (in billions)

	Annual Cost to US Health Care System in 2011		
	Low	Midpoint	High
Failures of care delivery	102	128	154
Failures of care coordination	25	35	45
Overtreatment	158	192	226
Administrative complexity	107	248	389
Pricing failures	84	131	178
Fraud and abuse	82	177	272
Total	**558**	**911**	**1264**
% of Total Spending	**21%**	**34%**	**47%**

- Savings estimates across the system **range from 21-47%**
- Largely driven by lack of **care coordination/failure in care delivery, overtreatment, and administrative complexity**
- How are policy experts and payers designing programs to drive out such costs? What is the impact to providers?

Source: JAMA. 2012;307(14):1513-1516; Berwick, MK; "Eliminating Waste in US Health Care"

Population Health – Holistic View



What is Palos' role in population health? What isn't Palos' role?

How do we get there?

Source: Adapted from Stiefel M, Nolan KA. Guide to Measuring the Triple Aim: Population Health, Experience of Care, and Per Capita Cost. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012. (Available on www.IHI.org)

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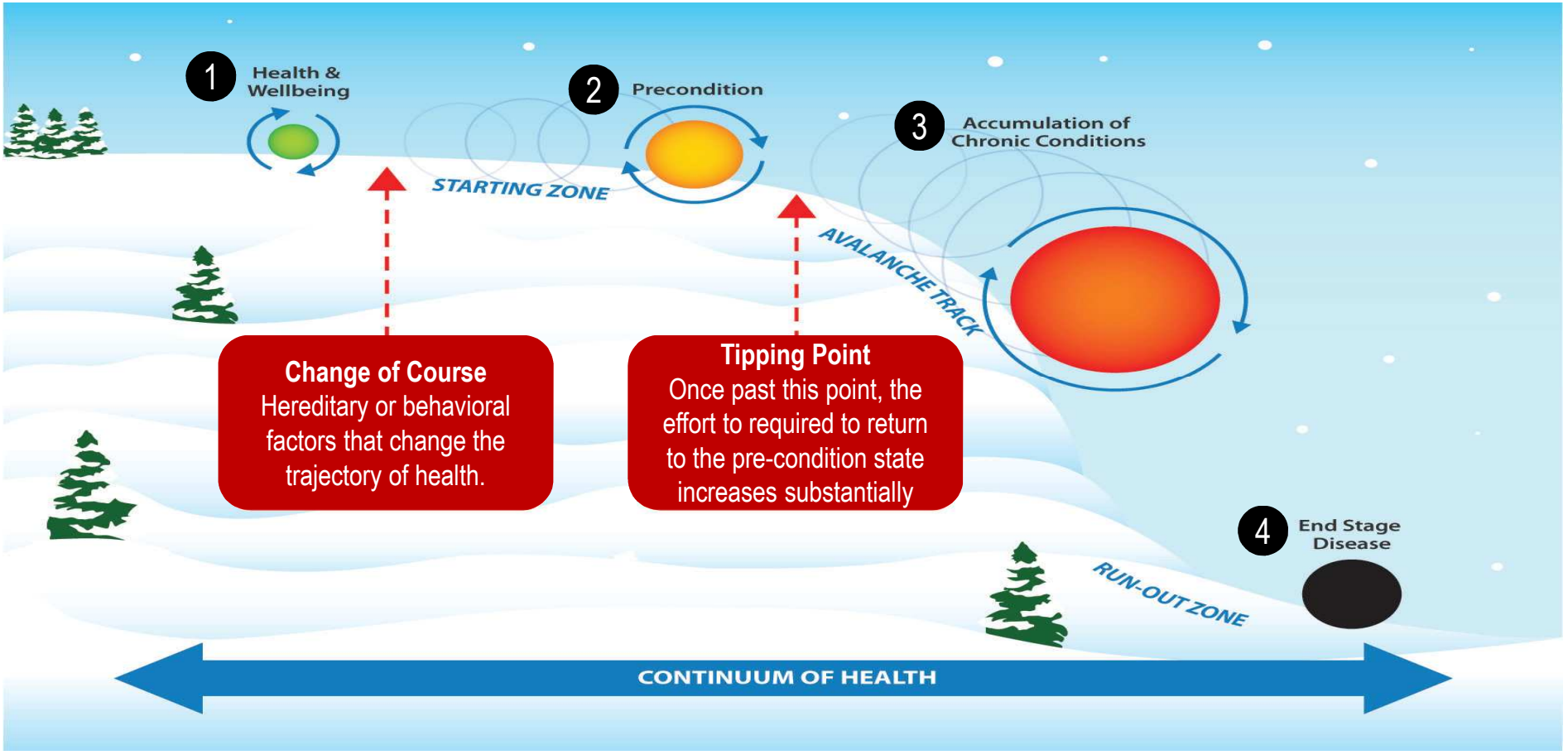
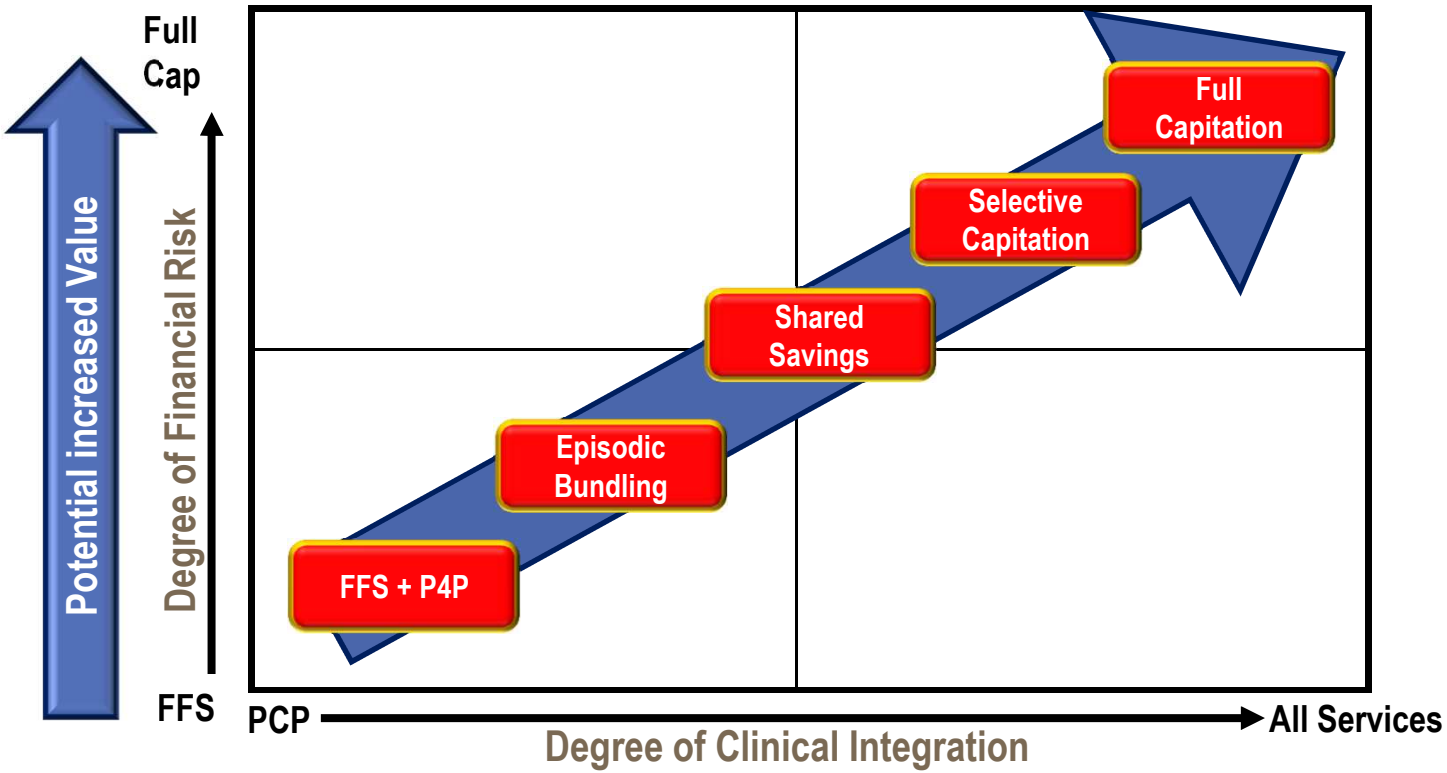
Population Health – Preventing the 'Avalanche'



What infrastructure (and work steps) needs to be developed to manage patients across the Continuum of Health?

Spectrum of payment models: "VBP" meets "Population Health"



Post fee-for-service reimbursement methodologies are still taking shape; but it clearly encompasses ***increased financial and clinical accountability***

The degree of clinical integration required to be successful increases as the payment model evolves from fee for service to capitation – as does the need for "population health management"

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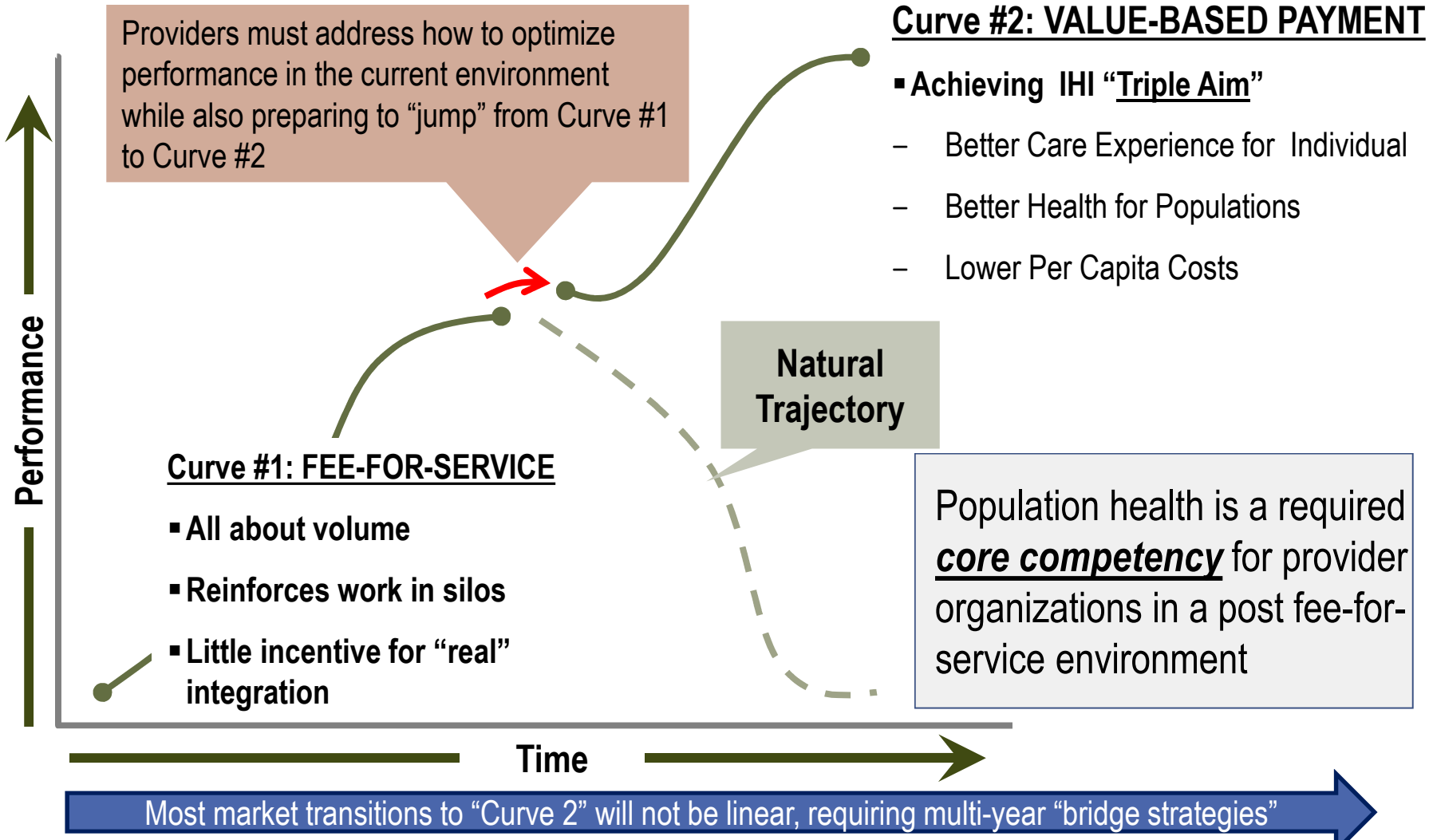
Value based payments require providers to leap to a new paradigm



Source: Futurist Ian Morrison; Institute for Health Improvement

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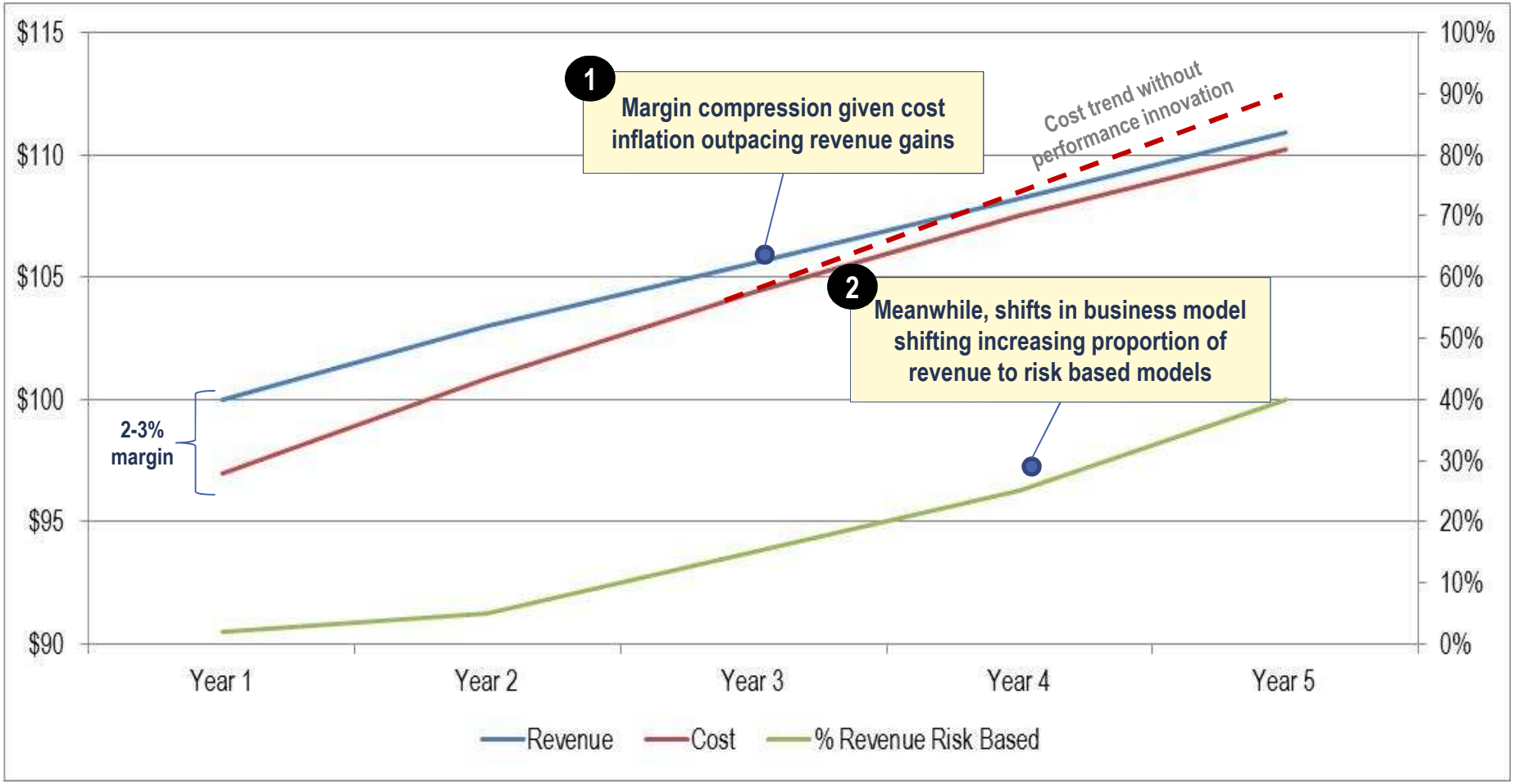
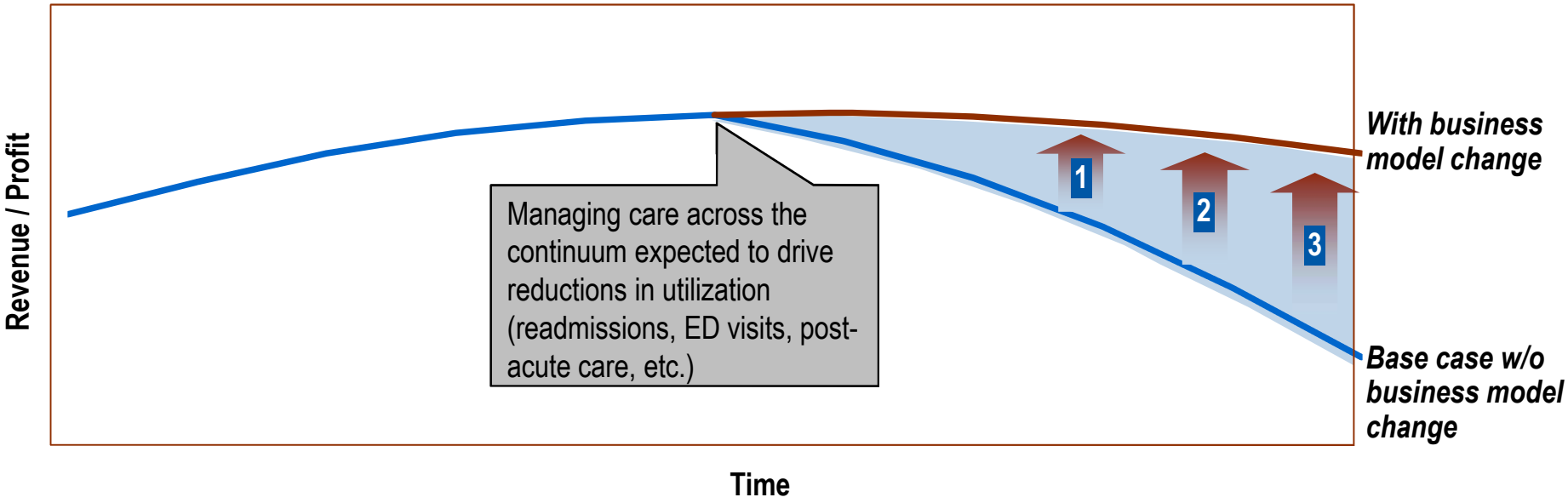
Margin Risk with Lower Revenue Trend with Increasing Percentage of Risk Based Contracts

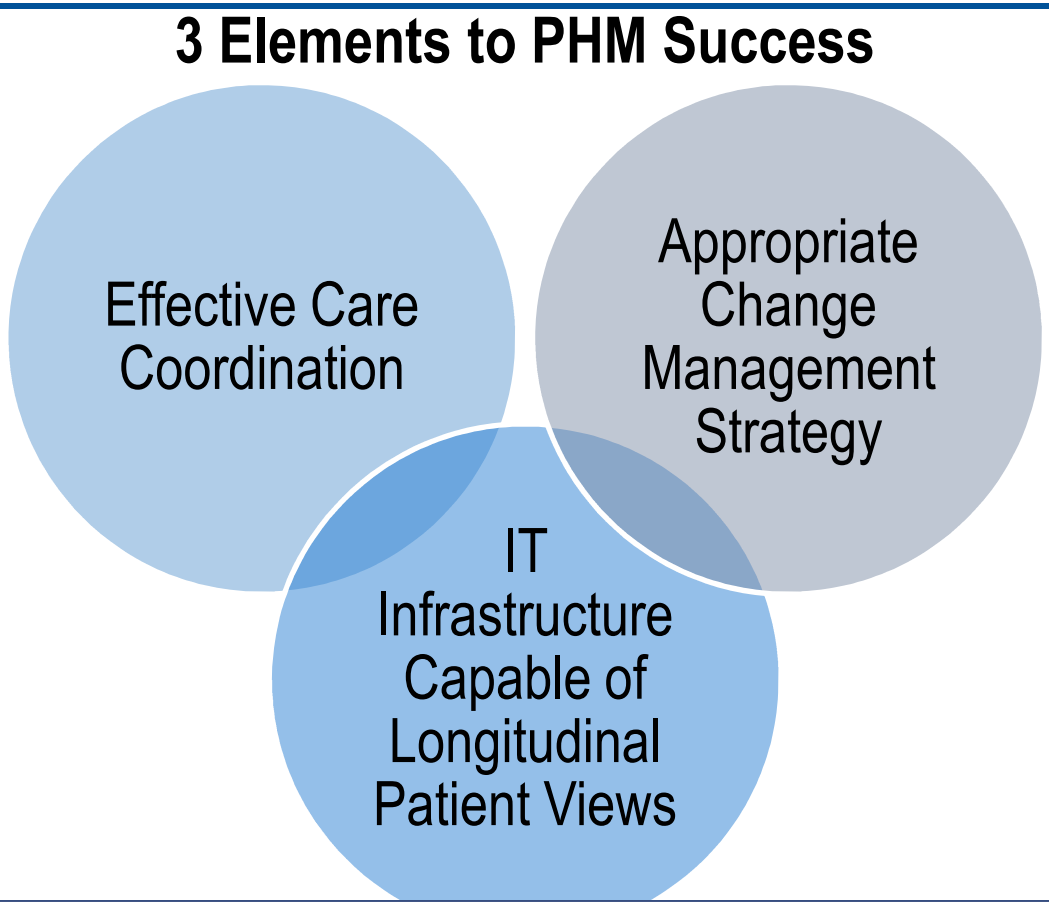


Impact of New Payment Models from a Provider's Lens



Tactic #1:	Tactic #2:	Tactic #3:
Focus efforts to manage care on self employed employees to offset high healthcare growth trends.	Consider gain or risk sharing contracts to 'capture' value created through alignment such as P4Q, episode payments, etc.	Pursue provider partners to manage care across the continuum.

Population health management success requires 3 elements

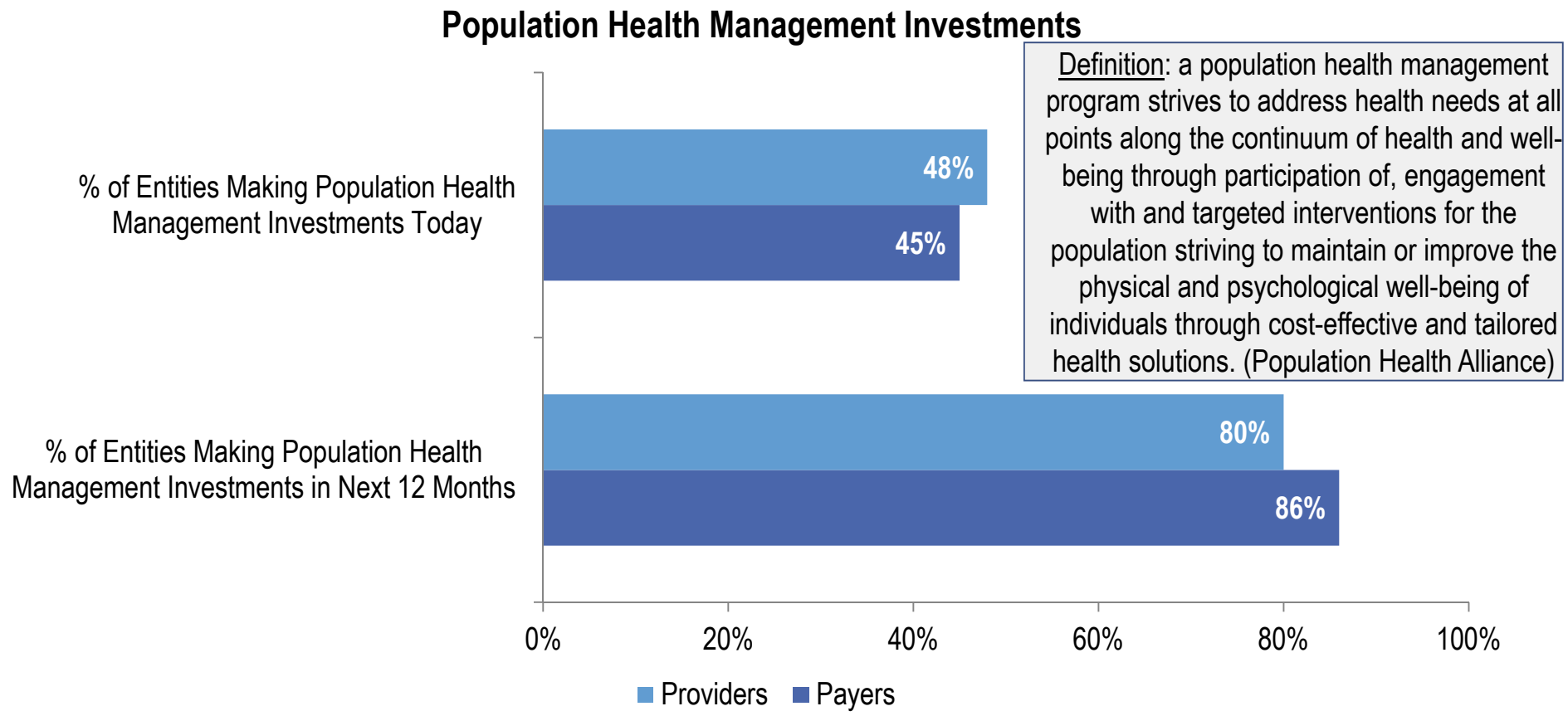


The success of early adopters of population health management strategies to achieve the "Triple Aim" leaves little doubt that population health management will gain momentum throughout the course of 2014 and beyond

Sources: http://www.beckershospitalreview.com/

With VBC delivery models comes growth in population health management investments

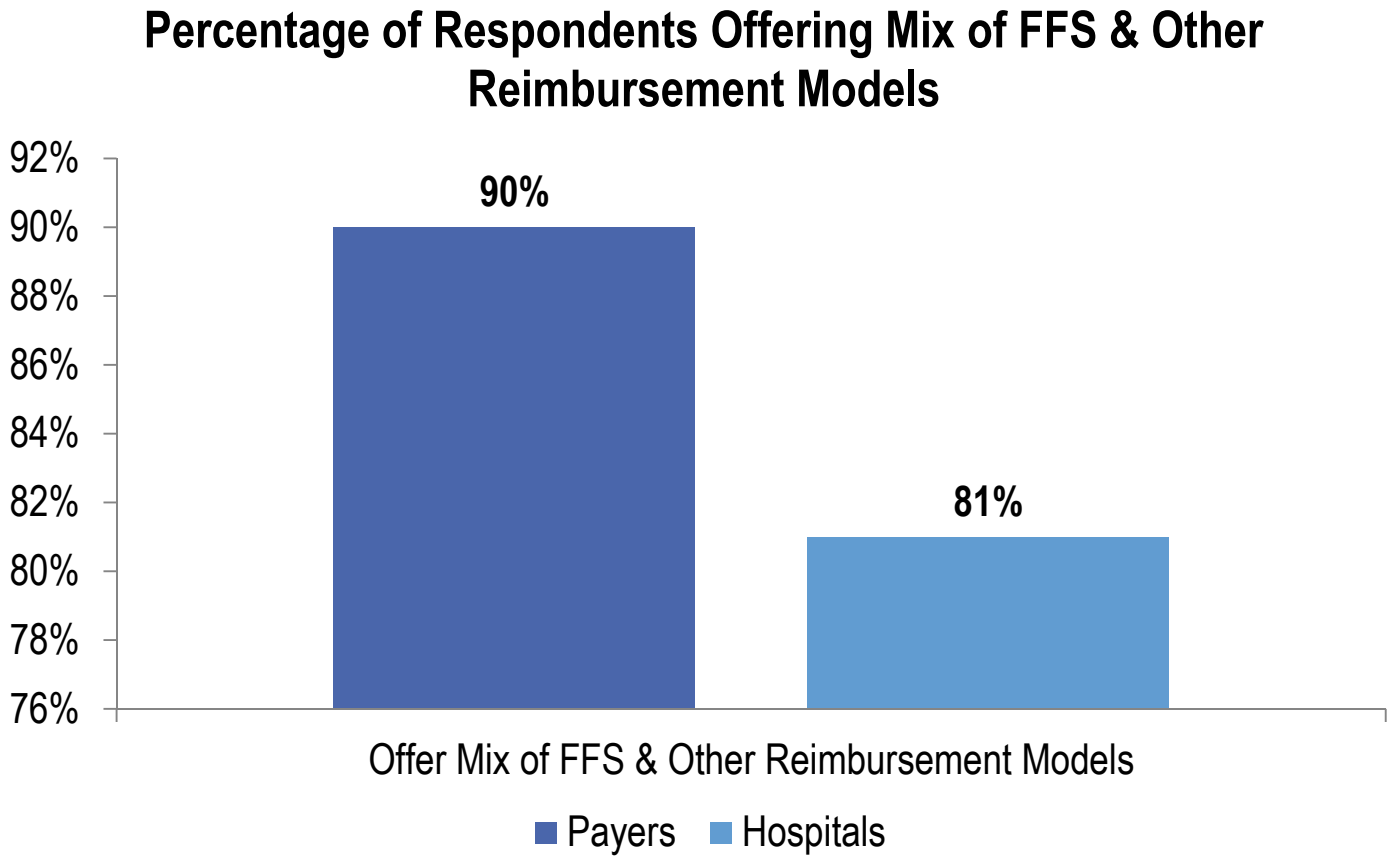
» Population health management involves core capabilities of traditional care management to support a provider-directed model that shares risk and controls cost at the population level.



Sources: Trizetto Research Report, "Industry Perspectives on Future Trends in Population Health and Care Management

New reimbursement models are expected to achieve significant penetration by 2020

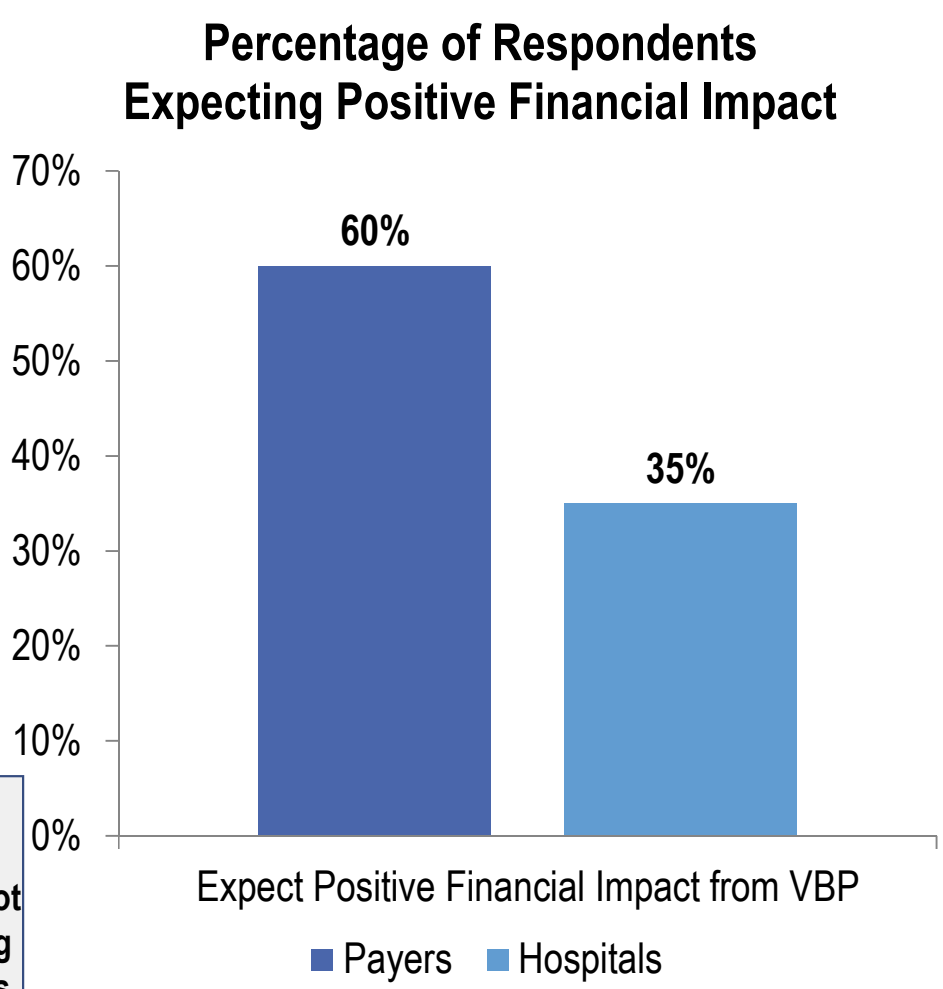
A study conducted by McKesson and ORC International found that payers and hospitals expect two-thirds of payments will be based on complex reimbursement models with value measures by 2020



Source: McKesson and ORC International Study

Payers and providers have mixed expectations on financial impact of value based payment models

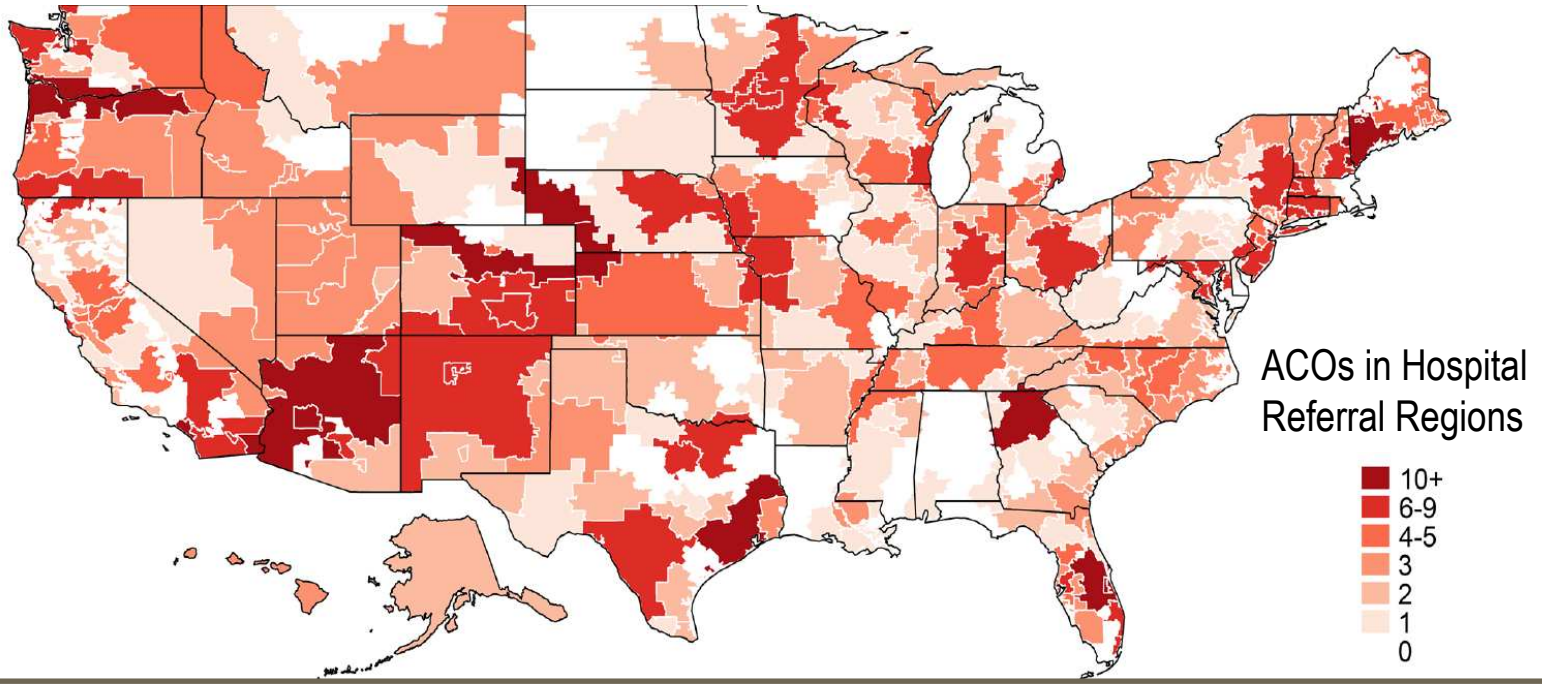
- A study conducted by McKesson and ORC International found that 60% of payers believe value based reimbursement will have a positive financial impact; whereas only 35% of providers believe there will be a positive financial impact
- A KPMG survey found that 33% of healthcare providers expect lower operating results with 12% expecting operating income to fall 10% due to value based contracting
  - Of hospital, health system, and large physician group respondents, 49% expect lower operating profits



"Ultimately, all stakeholders who drive their organizations to achieve efficiency in operations, quality outcomes, adoption of supportive technology, and a patient-centric culture, will not only survive but see their margins grow in the future. Building the bridge to that future is the key now." – Dr. Cynthia Ambres, KPMG Global Healthcare Center of Excellence

Source: McKesson and ORC International Study & KPMG Study

All Payer ACOs in All 50 States and District of Columbia



ACO FAST FACTS:

- As of January 2014, there were 607 known Public & Private ACOs
- California leads all states with 58 ACOs followed by Florida (55) and Texas (44)
- 538 ACOs have facilities in only one state
- Los Angeles (26), Boston (23) and Orlando (17) have the most ACOs

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Physician Groups Now Account for Most ACO Start-Ups

Source: Total Accountable Care Organizations by Sponsoring Entity. Leavitt Partners

The Georgia Experience:

Piedmont WellStar HealthPlans

Piedmont WellStar HealthPlans

- In December 2012, it was announced that Piedmont Healthcare and WellStar Health System were creating a provider-owned health insurance plan

PWHP will…

- Build a population management infrastructure to engage patients and physicians
- Serve the employee, Medicare, and commercial markets with more cost effective population health infrastructure

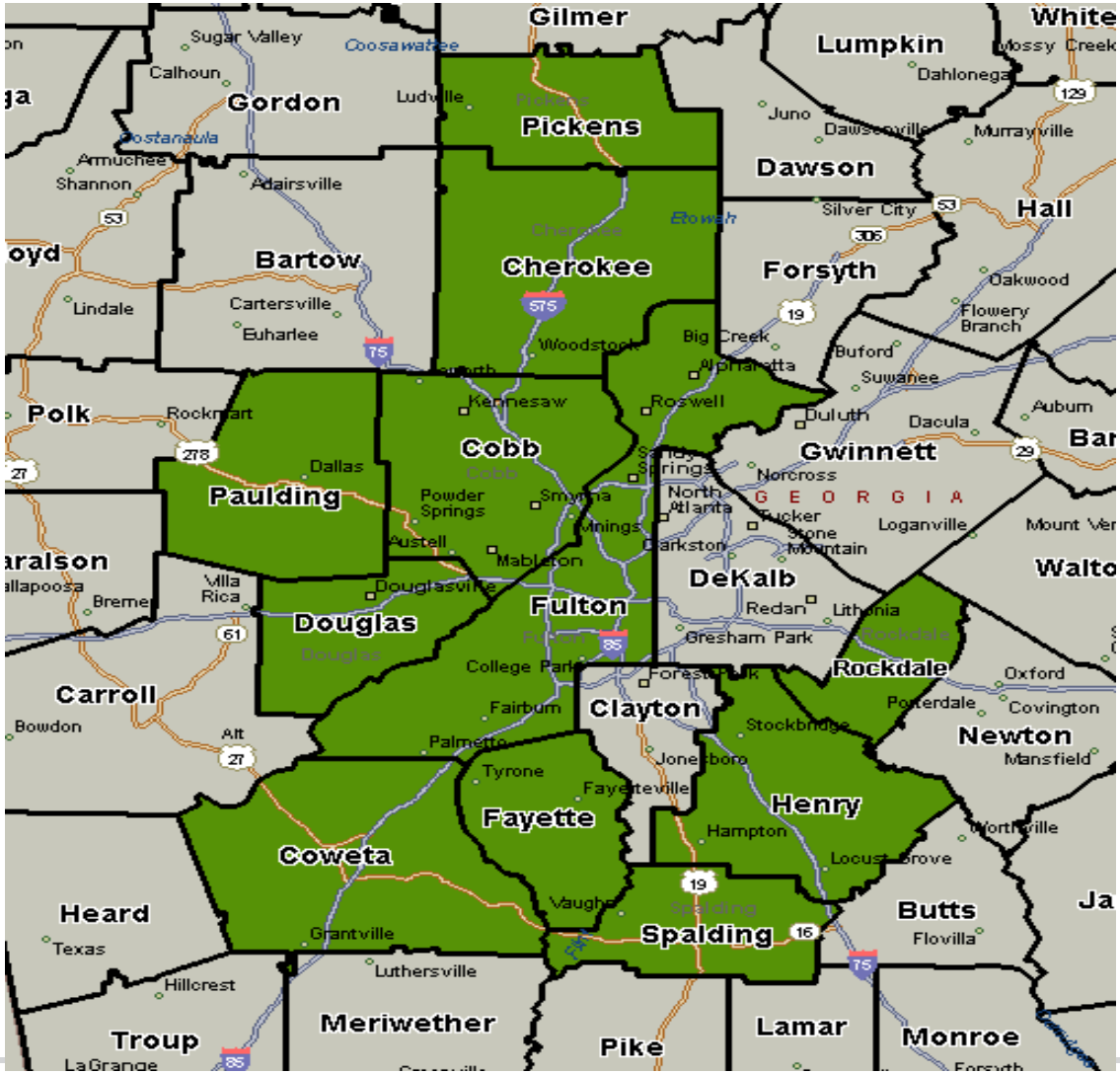
PWHP Overview

- For-profit joint venture
  - Joint Venture between PHC and WHS
  - HMO licensed in GA
  - Provides coverage for PHC and WHS employees and dependents (34,000) as of 1/1/14
  - Service offerings – Medicare Advantage (7,400), Commercial and ASO
  - Strong antitrust policy and Shareholder's Agreement govern the relationship between the two parties

PWHP Medicare Service Area

Medicare Advantage Service Area includes:

- Fulton
- Coweta
- Fayette
- Henry
- Spalding
- Rockdale
- Pickens
- Cherokee
- Paulding
- Cobb
- Douglas



Why PWHP moved to a new care model

1. The world is changing with the ACA, ACOs, and payers rewarding value not volume – “fee-for-service is an old business model”

2. The pendulum is swinging towards provider organizations holding more of the risk and therefore more of the reward

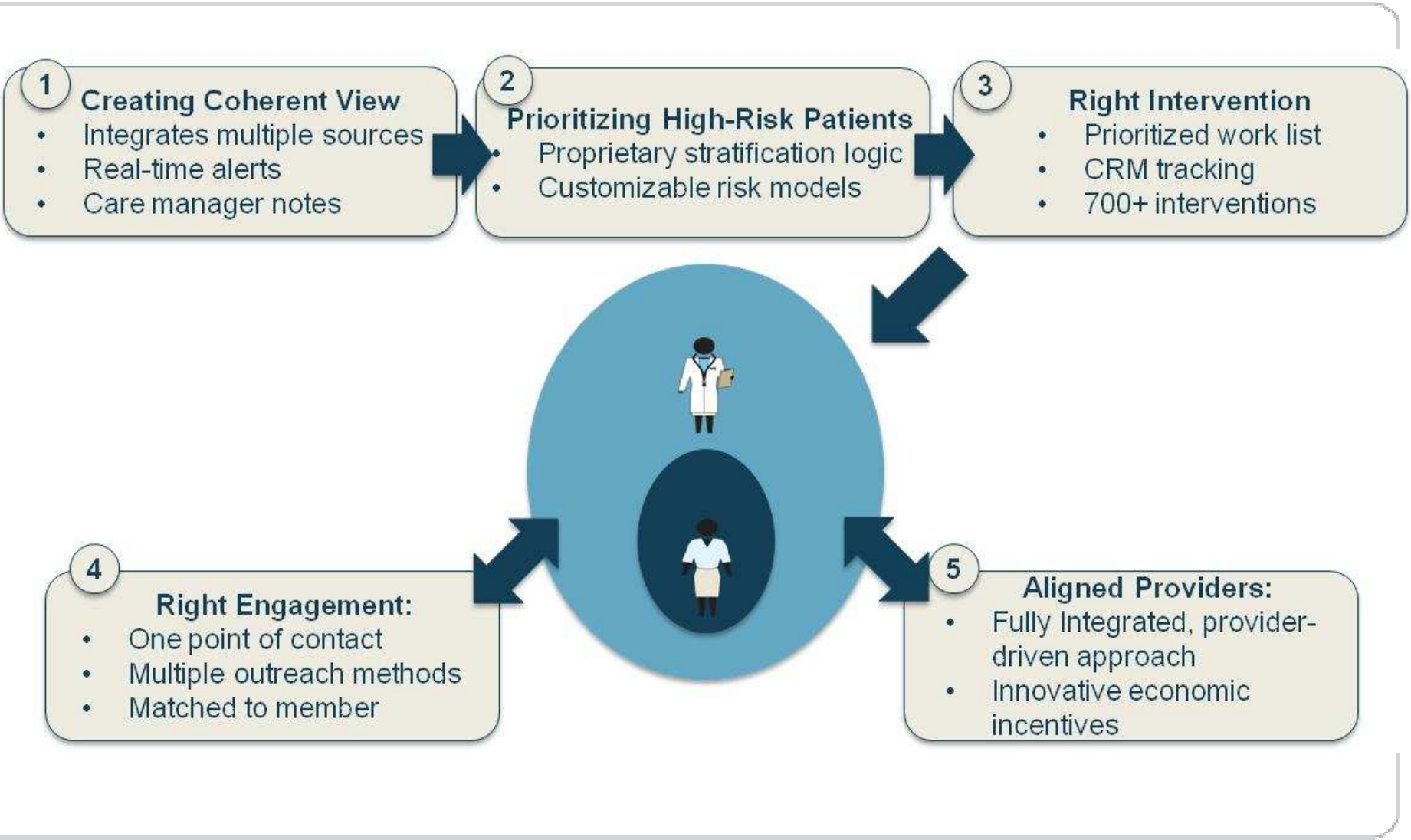
3. Simultaneously, PWHP is hoping to bring joy, excitement, and intellectual stimulation back to medicine

4. The Piedmont-WellStar care model will become the unifying approach across the systems, and not just for the health plan membership

5. Both organizations want to capitalize on their reputations for high quality, well-trained, and efficient physicians, or face irrelevance in the new world

Piedmont WellStar HEALTHPLANS

Approach to Population Health



Population Health – Data Analytics

Population Stratification

Low Risk	Medium Risk	High Risk	Complex Risk
40% of total	30% of total	20% of total	10% of total
Episodic Factors	3-4 Factors	5+ Factors	multiple comorbidities
• Pregnancy	• Medication Reconciliation	• COPD	• Multiple Comorbidities
• Lifestyle Change	• New Diabetics	• CHF	• ESRD
• Healthy Eating	• Smokers	• Asthma	• Sickle Cell, Hemophilia
• Physical Activity	• Behavioral Health	• Morbid Obesity	• Complex Behavioral Health
• Stress		• CAD	

Workflow Platform

Care Management Operations

Team

- Comprised of RNs, social workers, health coaches, many with behavioral health experience

Patient-Centric Workflow | **Activity Suppression** | **Prioritized Outreach** | **700+ Proprietary Interventions**

>700 Interventions

- **Patient Engagement: Lifestyle Management Programs**
- **Pharmacy Optimization**
- **Condition Coaching**
- **Patient Centered Medical Home**

High Cost/Complex Case Management

Piedmont WellStar HEALTHPLANS

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Legal Issues in Payer/Provider Integration – ACOs, Provider-Sponsored Health Plans, and Population Health Activities

- Fraud and Abuse
- Antitrust
- HIPAA/Health Information Privacy

Fraud and Abuse Laws

Fraud and Abuse Laws

- Anti-Kickback Statute, Social Security Act § 1128B(b), 42 USC § 1370a-7b(b)
- Physician Self-Referral Statute (Stark), SSA § 1877, 42 USC § 1395nn
- Civil Money Penalty (CMP) Statutes, SSA § 1128A, 42 USC § 1370a-7a
- Exclusion Authority, SSA §§ 1128, 1128A
- False Claims Act, 31 USC § 3729 et seq.
- State law equivalents

Anti-Kickback Statute

- Makes it a felony for individuals or entities to knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward referral of business reimbursable under any federal health care program.
- Remuneration Covered:
  - Direct or indirect, overt or covert, in cash or kind.
  - Kickbacks, bribes, rebates, etc.
- Prohibited Conduct
  - An intent-based statute ("knowingly and willfully")
  - Payment intended to induce or reward referrals of patients for services under federal or state health care programs.
  - Payment intended to induce or reward purchasing, leasing, or ordering of any goods, services or items reimbursable by any federal health care program.

Anti-Kickback Statute

- Penalties:
  - Imprisonment for up to 5 years.
  - Fines of over to $25,000 per violation.
  - Imposition of CMPs under CMP Statute.
  - Exclusion from federal health care programs under Exclusion Authority.
  - Liability under False Claims Act.
- Safeharbors include
  - Beneficiary incentives offered by Medicare or Medicaid managed care plans.
  - Risk sharing arrangements:
    - Price reductions offered to eligible managed care organizations (MCOs), MA entities that receive capitation payments, certain Medicaid MCOs, PACE, federally qualified HMOs
    - Arrangements between first-tier contractors and downstream contractors, or between successive tiers of downstream contractors.
  - Employment.
  - Personal services and management contracts.
  - Electronic Health Records (EHR) arrangements.

Stark Law

- Prohibits a physician from referring a Medicare patient to an entity (including a hospital) with which the physician (or an immediate family member) has a financial relationship for the furnishing of "designated health services" (DHS).
- Prohibits the entity receiving the referral from filing a claim or billing for services arising out of the prohibited referral.
- A strict liability statute.
- Financial Relationship:
  - Direct or indirect relationships.
  - Ownership/investment interests.
  - Compensation interests.
- Referral:
  - For Medicare Part B, request for the item or service.
  - For all other services, request or establishment of a plan of care by a physician that includes the DHS.

Stark Law

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- Penalties
  - Denial of payment for services provided in violation of Stark Law and refund of payment for such services.
  - CMP of up to $15,000 for each service that a person knows or should know was provided in violation and 3 times the amount of improper Medicare payment.
  - CMP of up to $100,000 for each scheme to circumvent the Stark Law.
  - Exclusion from federal health care programs under Exclusion Authority.
  - Liability under False Claims Act.
  - Denial of Medicaid FMAP for Medicaid services that would have been prohibited under Stark Law if Medicare covered service to same extent as under Medicaid.
- Exceptions include
  - Fair market value.
  - Managed Care Risk Sharing Arrangements (withholds, bonuses, risk pools, etc.) between an MCO and a physician for items or services for a MCO beneficiary.
  - Written indirect compensation arrangements where physician's compensation is at FMV for services and items provided (not considering volume or value), does not violate the AKS, and the physician stands in shoes of physician organization.
  - Employment or personal services arrangements.
  - In-office ancillary services.
  - EHR arrangements.

CMPs

- Statute authorizes Secretary to impose penalties and assessments on persons who defraud Medicare or Medicaid or engage in certain other wrongful conduct.
- To impose CMPs on any person who knowingly presents or causes to be presented a claim that is improperly filed:
  - For medical item or service that the person knows/should know was not provided as claimed.
  - For a Medicare item or service that the person knows/should know is false or fraudulent.
  - For a physician service that the person knows/should know was performed by an unlicensed physician.
  - For a medical or other item/service furnished during a period in which the person was excluded.
  - For a pattern of claims for medical or other item/service that a person knows/should know are not medically necessary.
- Beneficiary Inducement CMP prohibits person from offering or providing remuneration to Medicare/Medicaid beneficiary that person knows/should know is likely to influence beneficiary to order/receive covered item/service from a particular provider, practitioner, or supplier.

CMPs

- Gainsharing CMP Provision prohibits hospitals (and CAHs) from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries under the direct care of the physician.
  - Hospital or CAH making payment, and physician who knowingly accepts it are subject to CMPs of up to $2000 per beneficiary for whom payment is made.
  - Application of provision with respect to HMOs and other risk-sharing entities (included as in OBRA 1986) has been repealed.
  - Self-implementing law.
  - OIG has recognized that gainsharing can be beneficial and has issued 16 advisory opinions approving gainsharing arrangements.
  - Congress has authorized Secretary to waive – and Secretary has so waived -- provision for ACA § 3022 Medicare Shared Savings Program.
  - In October 2014 NPRM, OIG again proposed regulatory text to implement provision, and has solicited comment on defining “reduces or limits services.” No regulatory text proposed, but OIG seeks to interpret phrase broadly enough to protect beneficiaries and federal health programs, but narrowly enough to allow low risk programs that further the goal of delivering high quality health care at a lower cost.

Exclusion Authorities

- Secretary has the authority to exclude persons from federal health care programs and direct State agency to exclude persons from any State health care programs.
  - Mandatory and permissive exclusion authority.
  - Death sentence for excluded provider.

HHS Waiver Authority

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- HHS can waive Anti-Kickback, Stark and CMP Statutes in limited circumstances – usually limited to demonstrations, e.g.,
  - CMMI Projects, SSA § 1115A: HHS can waive such requirements of Titles XI, and XVIII and §§ 1902(a)(13) and 1903(m)(2)(A)(iii) as necessary to carry out CMMI Medicare and/or Medicaid projects/demonstrations to test innovative payment and service models.
  - Health Care Quality Demonstration Program Projects, SSA § 1866C: HHS can waive such requirements of Titles XI and XVIII as necessary to carry out health care delivery demonstrations that encourage delivery of improved quality of care.
    - Medicare Acute Care Episode Demonstration: HHS waived the requirements of Title XVIII necessary to allow bundled payments and the provisions of Title XI (e.g., §§ 1128A and 1128B) necessary to conduct a shared savings or gainsharing program at the demonstration sites and to allow payment to beneficiaries of part of the Medicare savings.
  - ACO Shared Savings Program, SSA § 1899: Authorizes HHS to waive such requirements of SSA §§ 1128A and 1128B and Title XVIII as necessary to carry out the ACO Shared Savings Program. Finalized waivers:
    - ACO pre-participation waiver for start-up arrangements.
    - ACO participation waiver for arrangements during participation in Program.
    - Shared savings distribution waiver for distributions and uses of shared savings payments earned.
    - Compliance with Stark Law waiver for arrangements that implicate Stark and meet an exception.
    - Patient incentive waiver for medically related incentives offered to beneficiaries to encourage preventive care and compliance with treatment regimes.

False Claims Act

- A person who commits certain act(s) in connection with a claim for payment by the federal government can be held liable to the US government.
- Prohibited acts include:
  - Knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval.
  - Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.
  - Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government.
- Penalty: $5,000 to $10,000 (adjusted for inflation) per claim, plus three times the amount of damages sustained by the government.
- Private litigants can bring an FCA action on behalf of US (*qui tam* relators) and, if successful, receive between 15% and 30% of the proceeds of the action.

Implications

- Shared savings/performance-based payments from private/commercial plan do not necessarily implicate fraud and abuse issues.
  - However, consider potential fraud and abuse implications , e.g.,
    - Whether funds are calculated or used in downstream payments in ways that influencing referrals of or ordering for Medicare/federal health care program patients.
    - Whether private payer arrangements are sensitive to volume of business generated for downstream providers/suppliers, which may have Stark implications.
  - Can the commercial shared savings arrangements be structured to fit within
    - Stark exception for risk-sharing arrangements, or other Stark exceptions?
    - Anti-kickback Statute safe harbor, e.g., managed care safe harbor?
  - Is a provider-sponsored/created commercial plan truly operating independently of its provider sponsor/owner?

Implications

- Innovative Health Care Delivery/Payment Models for Care to Medicare or Medicaid Patients – Bundled Payments, Shared Savings/Shared Discounts
  - Stark: Arrangements can create financial relationship between hospital and physicians. Is there an applicable Stark exception? Depending on structure and flow of funds, there may arguably be no applicable exception.
  - Anti-kickback Statute: Given the methodology for splitting bundled payments or sharing savings or discounts, could regulators view payments to physicians as kickbacks?
  - Gainsharing CMP: Does the design/methodology for provider incentives fit into the OIG's approach in advisory opinions? Does it meet the OIG considerations outlined in the NPRM concerning a narrower interpretation of "reduce or limit services"?
  - Beneficiary Inducement CMP: In seeking patient engagement, are incentives which qualify as "remuneration" offered or provided to beneficiaries? Is there an applicable exception?
  - Depending on design, it may be difficult to implement some innovative models outside a demonstration project. Is there one that could be joined?
    - Specific new safe harbors and exceptions may be needed to take full advantage of innovative models.

Antitrust Issues

Antitrust Laws

- Sherman Act § 1 (agreements to restrain trade).
- Sherman Act § 2 (monopolization).
- Clayton Act § 7 (mergers and acquisitions substantially lessening competition).
- Federal Trade Commission Act § 5 (unfair trade practices).
- Robinson Patman Act (price discrimination).
- State Law Equivalents

Sherman Act § 1

- Prohibits "contracts, combinations and conspiracies" that unreasonably restrain competition/trade.

  Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several State or with foreign nations is declared to be illegal.

- Agreements do not need to be in writing.
- Per se violations: Agreements on
  - Price fixing.
  - Market division (customers, territories, etc.).
  - Limiting output or capacity.
  - Bid rigging.
  - "Concerted refusals to deal": Group boycotts or refusals to deal with a customer or supplier.
  - Other competitively sensitive topics.

Sherman Act § 1

- Other agreements judged under the civil liability "rule of reason":
  - Is the practice likely to increase prices or otherwise reduce competition in the market? Does the practice promote or suppress market competition?
  - Requires identification of the market and market share.
  - A "totality of the circumstances" test, based on analysis of actual effects in defined market.
  - Intent and motive are relevant.

Sherman Act § 2

- Prohibits exclusionary or predatory conduct by an organization to maintain monopoly power or conduct that creates a serious probability that monopoly power will be achieved.

  > Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States or with foreign nations, shall be deemed guilty of a felony.

- Requires the possession of monopoly power in the relevant market and the willful acquisition or maintenance of that power (as compared to growth or development as a consequence of superior product(s), business acumen, or historic accident).
- Courts tend to define “monopoly power” as the power to control prices or exclude competition.

Sherman Act § 2

- As with the rule of reason, the definition of the affected market is important.
- Requires line drawing between prohibited exclusionary or predatory conduct and aggressive competition.
- Examples:
  - Tying of one's products/services.
  - Acquisition of competitors.
  - Use of monopoly power in one market to obtain power in another market.
  - Exclusive contracts with suppliers or customers.

Sherman Act Penalties

- Criminal penalties:
  - Fines of up to $100 million for corporations or $1 million for other persons.
  - Imprisonment for up to 10 years.
- Civil penalties:
  - Treble damages.
  - Costs of suit, including attorneys' fees.
  - Interest.
  - Injunctions.

Provider Creation of Insurer, or Insurer Acquisition of Providers

- Antitrust law generally presumes vertical integration can be beneficial:
  - Better integration.
  - Eliminates transactions costs and “middlemen.”
- Potential Issues:
  - Ability to obtain competitively sensitive information – price, etc. – about one’s competitors.
    - Increased possibility of price-fixing or other anticompetitive activities.
  - Bias, unfair pricing or trade practices with respect to non-affiliated insurers or providers.
  - Exercise of market power.

Accountable Care Organizations

- DOJ and FTC guidelines concerning antitrust implications of ACOs:
  - ACOs following CMS ACO eligibility criteria presumptively viewed as bona fide quality-enhancing clinical integrations – judged under "rule of reason," so not per se illegal.
  - Presumptive "safety zone" (safe harbor):
    - Overlapping primary service area shares, calculated based on a specific methodology, of 30% or less when overlapping physician, inpatient, or outpatient services are combined.
    - Participating hospitals or ambulatory surgery centers do not use the ACO as their exclusive contracting vehicle (regardless of share).
    - Dominant providers (with 50% share) are non-exclusive to the ACO.
- Outside the safe harbor: Reduce/minimize antitrust risk by taking steps to not
  - Share excessive competitively sensitive information.
  - Prevent payers from using selection devices that ensure inclusion of variety of providers.
  - Tie non-ACO services to ACO services.
  - Exclusive contracting and other exclusive arrangements/refusals to deal.
  - Restrict payers' ability to communicate quality/cost information to members.

HIPAA/Health Information Privacy

HIPAA Privacy Rule

- Establishes the permitted and required uses and disclosures of protected health information (PHI) by covered entities and their business associates:
  - Covered entities and business associates can use or disclose PHI (without authorization by the individual) only if the use or disclosure is permitted (or required) under the Privacy Rule.
- Establishes certain rights of individuals with respect to their PHI, and the corresponding obligations of covered entities (and their business associates).
- Covered health care providers and health plans are required to
  - Establish policies and procedures about the requirements of the Privacy Rule.
  - Provide individuals with notices of their privacy practices.
  - Train the members of their workforces on the Privacy Rule and their privacy policies and procedures.
  - Impose sanctions on workforce members who violate the Privacy Rule or the privacy policies and procedures.

Other HIPAA Rules

- HIPAA Security Rule requires covered entities and business associates to implement certain administrative, physical, and technical safeguards to protect electronic PHI's
  - Confidentiality, so that electronic PHI is not made available to or disclosed to unauthorized persons or processes.
  - Integrity, so that electronic PHI is not altered or destroyed in an unauthorized manner.
  - Availability, so that electronic PHI is accessible and useable upon demand by an authorized person.
- HIPAA Breach Notification Rule requires covered entities to provide notice to the affected individuals, to HHS/OCR, and in some instances to the media (and business associates to provide notice to covered entities), if there is an impermissible use, disclosure, access or acquisition of unsecured PHI that compromises the security or privacy of the PHI.

Privacy Rule and Use/Disclosure of PHI

- In order to determine whether a use or disclosure is permissible (without authorization), one has to consider:
  - Is the information PHI?
  - Who is using or disclosing the PHI?
  - To whom is the PHI being disclosed?
  - What is the purpose of the use/disclosure? Is there an applicable permission under the Privacy Rule for the use or disclosure?

Privacy Rule: PHI

- What is "Protected Health Information" (PHI)?
  - Information relating to:
    - The physical or mental health of an individual;
    - The provision of health care services to an individual; or
    - Payment for health care services to an individual,
  - Coupled with:
    - Information that identifies the individual; or
    - As to which there is a "reasonable basis to believe" that information could be used to identify the individual.
- PHI excludes individually identifiable health information in
  - Educational records addressed by FERPA.
  - Employment records.
  - Records concerning persons deceased for more than 50 years.

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Privacy Rule: Entities

- Covered Entities:
  - Health Plans
  - Health Care Clearinghouses
  - Health Care Providers who transmit PHI electronically in connection with a transaction for which HHS has adopted a standard.
- Business Associates: Entities that perform certain services for or on behalf of covered entities that involve the use/disclosure of PHI.
  - Business associate agreement with covered entity required.
- Affiliated Covered Entities: Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of Privacy, Security and Breach Notification Rules:
  - Designated covered entities have to be under common ownership or control.
    - Common control exists if an entity has the power, directly or indirectly, to influence or direct the actions or policies of another entity.
    - Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.
  - Designation has to be documented and maintained.

Privacy Rule: Entities

- Organized Health Care Arrangement (OHCA):
  - A clinically integrated care setting in which individuals typically receive health care from more than one health care provider.
  - An organized system of health care in which more than one covered entity participates and in which the participating covered entities:
    - Hold themselves out to the public as participating in a joint arrangement; and
    - Participate in joint activities that include at least one of the following:
      - Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;
      - Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or
      - Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.
  - Certain relationships between group health plans maintained by the same sponsor and/or between such group health plan(s) and a health insurance issuer or HMO with respect to such group health plan, but only with respect to PHI created or received by the issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan.

Privacy Rule: Uses and Disclosures

- Covered entities may only use and/or disclose PHI for covered functions and as permitted under the Privacy Rule.
- A covered entity that performs multiple covered functions must comply with the requirements applicable to the covered functions performed, and may use or disclose PHI of individuals who receive the entity's health plan or provider services, but not both, only for purposes related to the function being performed.
- Under the Privacy Rule, covered entities can use or disclose PHI without individual authorization for treatment, payment, and health care operations.
  - **Treatment**: "The provision, coordination, or management of health care … by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another."
  - **Payment**: Activities undertaken by
    - A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan.
    - By a health care provider or plan to obtain or provide reimbursement for the provision of health care.
    - And the activities relate to the individual to whom health care is provided.

Privacy Rule: Uses and Disclosures

- **Health Care Operations**: Any of the following activities of the covered entity to the extent that the activities are related to covered functions:
  - Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.
  - Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider or health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities.
  - Certain underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance).
  - Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs.
  - Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies.
  - Business management and general administrative activities of the entity.

Privacy Rule: Uses and Disclosures

Specifically, a covered entity may:

- Use or disclose PHI for its own **treatment, payment, or health care operations**.
- Disclose PHI for **treatment** activities of a health care provider.
- Disclose PHI to another covered entity or a health care provider for the **payment** activities of the receiving entity.
- Disclose PHI to another covered entity for **health care operations** activities of the receiving entity, if each entity has/had a relationship with the individual, the PHI relates to such relationship, and the disclosure is
  - For a purpose listed in the first two paragraphs of the definition of health care operations; or
  - For the purpose of health care fraud and abuse detection or compliance.
- If it participates in an organized health care arrangement (OHCA), disclose PHI about an individual to other participants in the OHCA for any **health care operations** activities of the OHCA.

HIPAA/Health Information Privacy

- HIPAA limitations applicable to specific types of PHI:
  - Limitation on the use or disclosure of psychotherapy notes.
  - GINA limitation on the ability of a health plan to use/disclose genetic information for underwriting purposes.
  - HITECH Act prohibition on disclosure of PHI to health plan if individual so requests and pays for the health care service in full, out-of-pocket.
- Federal Mental Health Regulations:
  - Require federally assisted alcohol or drug abuse treatment programs to obtain patient's written authorization for disclosure of information that would identify a patient as receiving such diagnosis, referral, or treatment.
  - Prohibits a health care provider that has/receives such information from disclosing/redisclosing without patient authorization.
- Privacy Rule does not preempt State laws more protective of individual privacy, so consider State law requirements applicable to use/disclosure of specific types of PHI. E.g., under Georgia law:
  - Information derived from genetic testing is privileged and confidential; may be released only to the individual and to persons specifically authorized by the individual.
  - Diagnosis-specific laws protecting the confidentiality of HIV, AIDS, mental health, developmental disabilities, and substance abuse.
    - Generally permit disclosure only with a patient's authorization, a specific court order, or in a medical emergency or when deemed necessary for treatment.

HIPAA Implications

- Covered entities need to have business associate agreements in place with vendors.
- Care management is health care provider treatment activity, but a health care operation of health plan.
- When asked to share data for care management, covered entities/business associates have to be aware of limitations on/requirements for disclosing certain PHI.
  - Need for consent/authorization for certain types of sensitive PHI.
  - Agreed upon/required restrictions on use or disclosure of PHI.
- Health care provider disclosure of PHI to health plan:
  - Can only disclose PHI of health plan members.
    - Security Rule access management and access control implications if health plan has access to health care provider's information systems.
  - Can only disclose sensitive PHI with consent.
  - Permissible purposes for disclosure:
    - Payment.
    - Limited health care operations of health plan: case management, care coordination, quality improvement, etc.
  - Minimum necessary rule applies.

HIPAA Implications

- Covered entity (e.g., hybrid covered entity) may play different roles. The implications of those different roles must be recognized in the HIPAA use/disclosure analysis.
- Hospital System that creates a commercial health plan:
  - Hospital: Health care provider governed by HIPAA. Health information is PHI.
  - Employer: Not governed by HIPAA. Human Resources data is not PHI. But --
  - Hospital's Employer Group Health Plan: HIPAA-governed health plan. Health and health insurance information on employees and dependents is PHI.
  - Commercial Health Plan: HIPAA-governed health plan. Health information and health insurance information is PHI.
  - Shared Services (e.g., IT Department): Provides business associate services to health care components/commercial health plan.
    - Hybrid entity: Shared Services components that handle PHI have to be included in designation of covered components.
    - Separate legal entities (commercial health plan): Business associate agreement is needed for Shared Services components that provide services (which involve access to PHI) to separate legal entities that are covered entities.

HIPAA Implications: Care Management

- Potential Information Flows and Issues:
  - Employer to Plan: Not PHI, not governed by HIPAA, but other law may apply.
  - Provider to Provider: Disclosure for treatment purpose.
    - Not subject to minimum necessary rule.
    - May be able to disclose some sensitive PHI without consent if "necessary for treatment."
    - May be an issue with respect to some agreed upon restrictions on use or disclosure of PHI.
  - Provider to Plan (including managed care organization): Disclosure for health plan's health care operations.
    - Limited to certain health care operations purposes.
    - Limited to PHI concerning health plan's members.
    - Cannot disclose sensitive PHI without consent.
    - Subject to minimum necessary rule.
  - Plan to Provider: Disclosure for provider's treatment purpose.
    - May be able to disclose some sensitive PHI without consent if "necessary for treatment."
    - Not subject to minimum necessary rule.
  - Disclosures within ACO/other entity functioning as OHCA: Disclosure for participating health care providers' treatment or OHCA's health care operations.
    - Permitted disclosures for health care operations (even to participating health plan) are broader than permitted health care operations disclosures to health plans.
    - Participating covered entities can perform services that benefit OHCA (and, thus, the OHCA participants) without business associate agreement.
    - OHCA can hire/contract with care manager or third party vendor to provide services to multiple OHCA participants with one (rather than many) business associate agreements.