Navigating the Frontiers of Innovation and Value

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Agenda

- Why Value? Growing Opportunities for Innovation to Improve Health and Well-Being – and Potentially to Lower Costs
- Overview of Value-Based Health Care Payment and Delivery Reform
- Supporting Faster, More Efficient Biomedical Innovation
- Access, Coverage, and Payment Issues for Getting Value from New Biomedical Innovation
- Questions

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Why Value? Growing Opportunities for Innovation to Improve Health and Well-Being – and Potentially to Lower Costs

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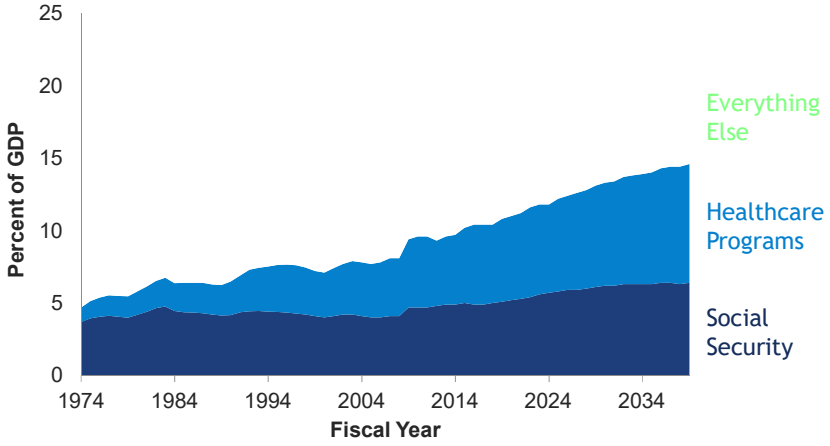
Healthcare and the US federal budget



Source: Congressional Budget Office, 2018 Long-Term Budget Outlook.

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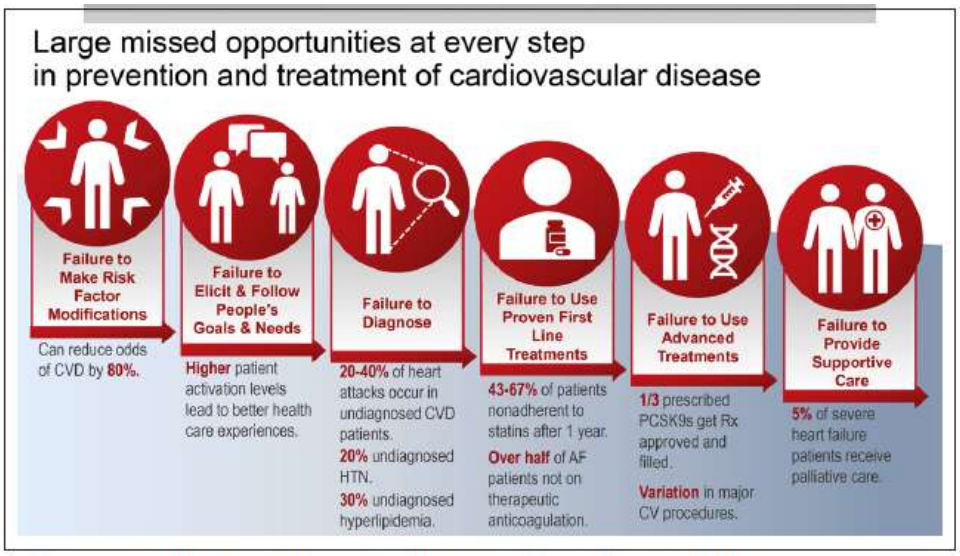

Figure 6. Cardiovascular care challenges waterfall showing the challenges at each stage of the disease continuum.
AF indicates atrial fibrillation; CV, cardiovascular; CVD, cardiovascular disease; HTN, hypertension; Rx, prescription; and PCSK9, proprotein convertase subtilisin/kexin type 9. Data derived from Yusuf et al,[32] Hibbard and Greene,[33] Dalen et al,[34] Zalliman et al,[35] Turin et al,[36] Pokorney et al,[37] Navar et al,[38] and Warraich et al.[39]

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Future care

Enhanced Prevention – Including Behavioral and Social Factors Influencing Health	Earlier and More Accurate Diagnosis
More Definitive Treatments for Disease Interception or Cure	More Efficient and Effective Supportive Care for Remaining Health Gaps and Functional Impairments

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Opportunities for higher-value health care

- More effective diagnostics and treatments for unmet health needs

- Innovations to better target use of medical technologies to patients who will benefit
- Wireless/ remote personal health tools and supports, telemedicine
- Lower-cost methods of treatment or sites of care
- Better care coordination
- Non- medical strategies for health improvement – such as targeted assistance and support for accessing social and community services to prevent costly medical complications

Opportunities for higher-value health care

OFTEN COST INCREASING

- More effective diagnostics and treatments for unmet health needs

POTENTIALLY COST DECREASING AND OFTEN POORLY REIMBURSED

- Innovations to better target use of medical technologies to patients who will benefit
- Wireless/ remote personal health tools and supports, telemedicine
- Lower-cost methods of treatment or sites of care
- Better care coordination
- Non- medical strategies for health improvement – such as targeted assistance and support for accessing social and community services to prevent costly medical complications

Overview of Value-Based Health Care Payment and Delivery Reform

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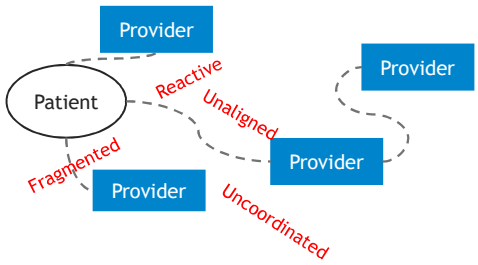
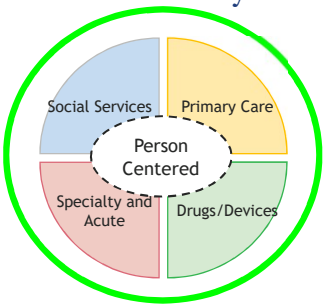
Volume-Based Care: Fee-for-Service Pricing and Coverage Controls



- Core focus on specific services, with provider-centered financing and organization
- Individually reimbursed services and providers may be high-quality, especially for acute care
- Often missed opportunities for prevention of chronic disease progression, avoidance of low-value services, and inefficient sites and methods of care

Value-Based Care: More Coverage Flexibility with More Accountability for Results



- Core focus in financing and organization is on **value** for each patient defined as **measurably better health outcomes and care experience relative to total costs of care**
- Aims to provide **person-centered care** that is **coordinated**, **comprehensive**, **anticipatory**, and **longitudinal**.
- Requires resource shifts to services with limited FFS or budget support from low-value, well-reimbursed services
- Person-based payment supports accountability

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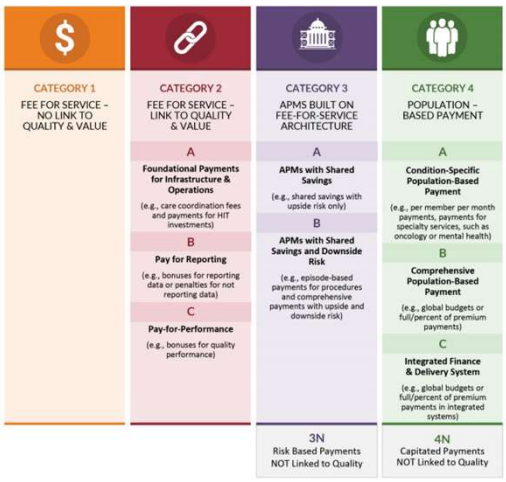
Alternative Payment Models (APMs) to support value-based care

Figure 1: The Updated APM Framework



Category 3 and 4 models shift from paying for specific services or providers, to paying at episode or person level – payment depends on performance against benchmarks

Limited shifts in Category 3 (for example, "shared savings") and greater shifts in Category 4 (for example, partial or full capitation with risk and performance adjustment)

Source: Health Care Payment Learning and Action Network. APM Framework. 2017

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APM measurement results at a glance

CATEGORY 1: *FEE-FOR-SERVICE - NO LINK TO QUALITY & VALUE*

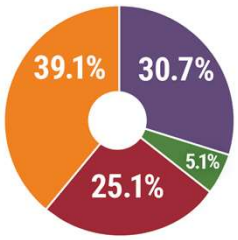
39.1%

CATEGORY 2: *FEE-FOR-SERVICE – LINK TO QUALITY & VALUE*

25.1%

Foundational Payments for Infrastructure & Operations
+
Pay-for-Reporting
+
Pay-for-Performance

AGGREGATED DATA



Based on 62 plans, 7 states, Traditional Medicare

14.5%
Combination of Categories 3B, 4A, 4B, & 4C Represents Shared Accountability APMs.

CATEGORY 3: *APMS BUILT ON FEE-FOR-SERVICE ARCHITECTURE*

21.3% Upside Rewards for Appropiate Care

9.4% Upside & Downside for Appropiate Care

CATEGORY 4: *POPULATION-BASED PAYMENT*

1.8% Condition-Specific Population-Based Payment

2.9% Comprehensive Population-Based Payment

0.4% Integrated Finance & Delivery Systems

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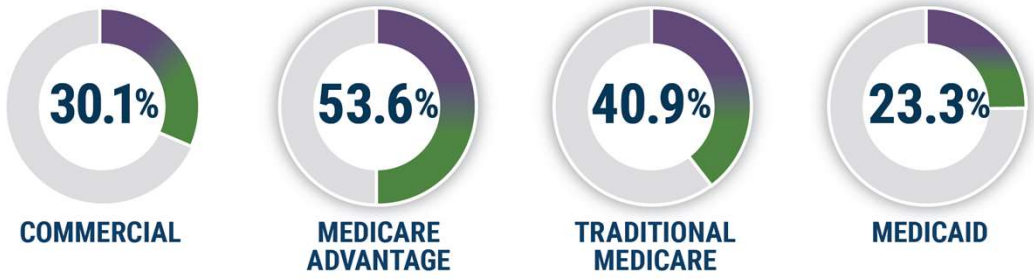
Recent LAN national payment reform survey: most APM use in traditional Medicare, Medicare Advantage

In **2018,**
35.8% of U.S. health care payments, representing approximately **226.5 million** Americans and **77%** of the covered population, flowed through Categories 3&4 models.
In each market, Categories 3&4 payments accounted for:



Representativeness of covered lives: Commercial - 61%; Medicare Advantage - 67%; Traditional Medicare - 100%; Medicaid - 51%

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LAN's new payment reform goals (HHS/CMS, participating states, private payers)

GOAL STATEMENT
Accelerate the percentage of US health care payments tied to quality and value in each market segment through the adoption of shared accountability alternative payment models.

	Medicaid	Commercial	Medicare Advantage	Traditional Medicare
2020	15%	15%	30%	30%
2022	25%	25%	50%	50%
2025	50%	50%	100%	100%

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Payment and care reforms combine to support value-based care

SUPPORTING POLICIES

- Support for sharing data and analytics to improve care
- Performance measures derived from care data and patient reports
- Evidence development on best clinical care models
- Team workforce development
- Evaluation, modification, and scaling of successful payment and care reforms

Medical Home Payments for Primary Care

Bundled Episode Payments for Specialized Care

Accountable Care Organization/ Care Integrator to Support Comprehensive Care

Value-Based Payments for Drugs and Devices

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Supporting Faster, More Efficient Biomedical Innovation

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The changing face of biomedical innovation

- Greater focus on early diagnosis, disease intervention, and in many cases cures
  - advanced diagnostics based on genomics and proteomics paired with gene therapies
  - targeted immunologic interventions like CAR-T
  - cellular and regenerative therapies
  - advanced medical devices that provide long-term improvements in organ function
- Increasingly supported by digital technologies that use big data, AI, and machine learning to continuously improve impact of technology
- These development pipelines are growing rapidly

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Bipartisan legislation continues to support regulatory innovation for biomedical progress

21st Century Cures Act provided new tools including:

- FDA/private collaborations to develop real-world evidence for safety surveillance and questions of effectiveness that are difficult or costly to address in randomized trials
- Patient-focused drug development
- Enhanced benefit-risk framework for clarity in product development
- Drug development tools - e.g., qualification process for biomarkers, surrogate endpoints

Five-year user fee legislation cycles support further improvements:

- Includes performance expectations for FDA staffing, review timelines, agenda setting, and organizational improvements - e.g., improving information technology
- Creates new programs and policy tools - e.g., Breakthrough Therapy Designation
- Mandates guidance and regular meetings on key issues in product development

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Expedited FDA drug pathways are leading to faster approvals

Year	Fast Track Status	Priority Review	Accelerated Approval	Breakthrough Designation
2018	24/59 (41%)	43/59 (73%)	4/59 (7%)	14/59 (24%)
2017	18/46 (39%)	28/46 (61%)	6/46 (13%)	17/46 (37%)
2016	8/22 (36%)	15/22 (68%)	6/22 (27%)	7/22 (32%)
2015	14/45 (31%)	24/45 (53%)	6/45 (13%)	10/45 (22%)

Fast Track
- Drugs with the potential to address unmet medical needs
- Increases communication between developer and FDA and implements "Rolling Review"

Priority Review
- Drugs with the potential to provide a significant advance in medical care
- FDA completes review within 6 months (instead of typical goal of 10 months)

Accelerated Approval
- Drug for a serious or life-threatening disease that offers a benefit over current treatments
- Early approval based on a "surrogate endpoint"
- Phase IV confirmatory trials required

Breakthrough Designation
- Expedited pathway for promising drugs intended to treat a serious disease where preliminary clinical evidence suggests substantial improvement over existing therapies
- Unlike Fast Track, requires clinical evidence

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Recent FDA initiatives and bipartisan support to accelerate development and improve devices

- Priority review for "breakthrough technologies" that represent a substantial clinical advance or address an unmet medical need
  - Ongoing contact with CDRH regulatory review team
  - Support for "efficient and flexible clinical study design" (adaptive trials, intermediate and surrogate endpoints, composite endpoints, use of "real-world" study designs and controls)
- Emerging regulatory strategies for AI-related technologies that are expected to improve continuously
  - Pilot program for clinical decision support software "precertfication": organization that meets precertification program may follow a streamlined submission process, for faster time to market – with expectation of postmarket evidence performance reporting
  - Consideration of revised framework for claims at different levels of predictive value – to reflect improving capabilities (modest, moderate, or "diagnostic test level" accuracy and reliability)
  - Methods for regulatory assessment of AI tools using proprietary data or ML algorithms in process

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Access, Coverage, and Payment Issues for Getting Value from New Biomedical Innovation

Concerns about high up-front prices of potentially transformative therapies

- **Budgetary impact of high upfront costs**
  - A development pipeline of high-cost innovative treatments may create short-term budgetary pressures for healthcare payers within fee-for-service (FFS) system
- **Uncertainty of long-term results**
  - Although treatments (like gene therapies) hold the promise of long-term benefits, clinical evidence used for regulatory approval includes limited evidence regarding longer term durability of effects – and complex technologies may improve over time with additional experience
- **Uncertainty of impacts in different types of patients and as combination therapies**
  - New technologies including CAR-T and gene therapies may have different benefits in different types of patients, including elderly patients or those other conditions
- **Uncertainty in recouping investment with multiple payers**
  - While patients want treatments that provide long-term benefits, potential savings from avoiding costly disease complications and treatment costs may not necessarily accrue to the payer that assumed the original treatment cost

VBP arrangements for drugs and devices

- Prices and coverage may be adjusted for *expected* value – for example, prices may differ for clinical indications, or broader coverage with evidence development, or prices that adjust as evidence gets stronger
- Outcomes-based contracts link payment for medical products to that product's *actual* performance in patients who receive treatment.
- Subscription payments shift toward paying for access and better outcomes in a *population* – for example, using per-member per-month payments with adjustments for impacts on outcomes

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When are outcome-based payment arrangements likely to add value?

- Promising, but uncertain, health benefits with high cost impacts.
- Uncertain longer-term impacts.
- Potential for treatments to improve with experience and support from better postmarket evidence on their impact.
- Potential for reliable measurement of results and methods that link product to outcomes.
- Alignment with value-based payment reforms for health care providers and value-based insurance design reforms for patients.

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Potential benefits of moving toward value-based payments

- **Better results with more value:** More pressure on manufacturers and payers to use new technologies in ways that improve outcomes and lower costs – less incentives simply to drive up sales
- **Faster/improved access:** Manufacturer risk-sharing can help reduce uncertainty that payers have about the cost and value of the new technology
- **Can reinforce value-based payment reforms for providers** (E.g., bundled and episodic payments, medical homes, ACOs) leading to better aligned care.
- **Can support collection of better real-world data and evidence**: Incentives or requirement to measure outcome and cost impacts over time, which would support better care and payment decisions in the future

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Challenges in moving to value-based payments

- **Better supporting infrastructure needed:** While FDA legislation has provided substantial public and private resources for determining if medical products are *safe and effective*, including postmarket evidence systems, much less infrastructure investments have been made to clarify whether a new treatment is *reasonable and necessary,* and to improve the evidence available for clinicians, patients, and payers to use treatments effectively
- **Limited experience:** With limited examples to date, much work in each contract to address measures, how additional value is shared among parties, and other key design issues
- **Regulatory barriers:** Many regulations for medical products are designed for protecting program integrity and avoiding excess costs in fee-for-service payments – and like rules for health care providers, need to be modified for payments that are substantial shifts from fee-for-service

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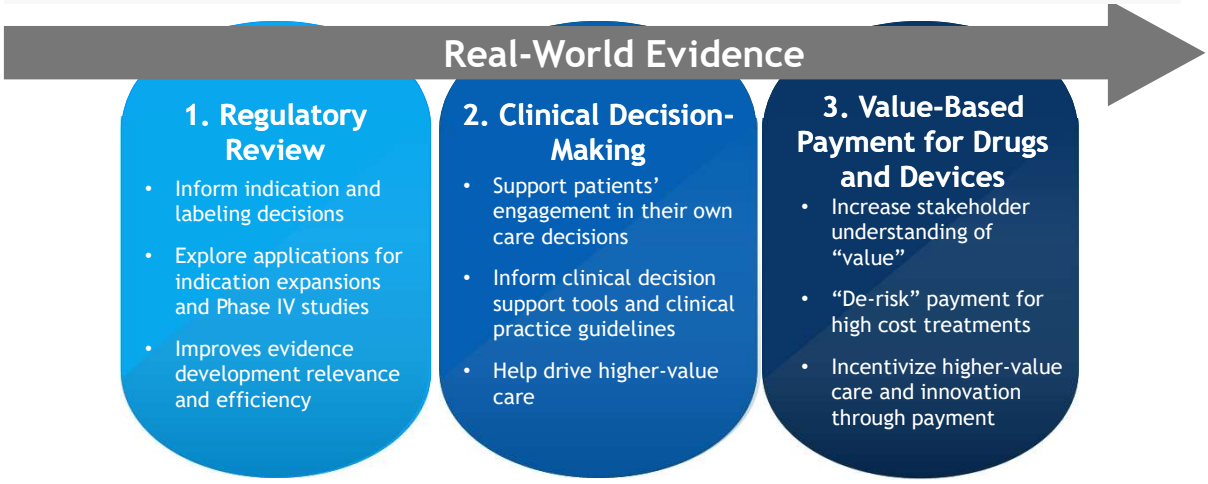
Learning from real-world patient experiences can support better informed health care decision-making across the health system by a range of stakeholders to reduce waste and improve value



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