

Value-Based Care Delivery and Payment (VBC) Issue Brief September 2023

What is value-based care? Value-based care (VBC), also called value-based payment (VBP), value-based arrangements, accountable care, accountable care arrangements, or alternative payment models (APMs) are programs and/or contracts between a public or private payer and providers of health care services (e.g., physicians and/or hospitals/health systems, or networks of physicians and/or hospitals/health systems) that hold the providers of health care services accountable to varying degrees for cost of care, quality/outcomes, and consumer/patient experience.¹

Examples include advanced patient-centered medical homes, accountable care organizations, and episodic or bundled payments that hold providers of health care services accountable for cost, quality, and experience through incentives.² The programs, pilots, and/or models are primarily found in Original Medicare, but they are increasing in prevalence in Medicare Advantage, Medicaid, and commercial health plans. These arrangements should not be confused with managed care organizations.

Less sophisticated VBC arrangements still rely on fee-for-service payments (in other words, the providers still get reimbursed or paid based on the approved services they render to patients), but the providers have the ability to get bonuses for improving cost, quality, and experience. Intermediate VBC arrangements are also grounded in fee-for-service, but in addition to being eligible for bonuses if cost, quality, and experience targets are met, the providers are held accountable for losses (i.e., not meeting the predetermined targets). The more sophisticated models involve a different type of payments such as population-based payment or capitated payments that are also linked to quality and experience. The Health Care Learning & Action Network (HCP LAN) Alternative Payment Model (APM) Framework below depicts a continuum from left to right, with the least sophisticated (Category 1) on the left to the most sophisticated models or contracts on the right (Category 4).³ See Exhibit A: HCPLAN Framework (page 3).

¹ Corinne Lewis et al., "Value-Based Care: What It Is, and Why It's Needed" (explainer), Commonwealth Fund, Feb. 7, 2023. https://doi.org/10.26099/fw31-3463

² https://www.cms.gov/priorities/innovation/models#views=models

³ https://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf

Why do we need to move away from fee-for-service to new models of care and payment that hold providers accountable for cost, quality, and experience? The United States spends far more per capita on health care than any other country even though it does not guarantee universal coverage for Americans. 4 We also perform poorly on overall indicators of population health compared with other developed countries and our health disparities are profound. 5 Our fee-for-service system rewards doing more, not better, focuses on sickness rather than health and prevention, has manifested in fragmentation of care, and is provider centric not consumer or patient centric. VBC, if done correctly, holds significant promise for improvement across five main areas: better experience of care, better health of populations, smarter spending, improved health equity and optimization, and enhanced provider accountability, support, and satisfaction.

What is the AHA position on VBC? AHA has published extensively on this topic and supports efforts to transform to a more effective system that recognizes and pays for better care and outcomes over volume. We support a health care system that is person-centered, focused on improving individual and population level experience and health outcomes, promotes health equity, and rewards our health care workforce for how well they do versus how many billable services they can provide regardless of outcomes.

For a comprehensive overview of AHA statements on VBC, please see **Exhibit B** (pages 4-16).

What is the AHA doing to advance VBC through advocacy? The AHA supports a measured approach away from fee-for-service and into increasingly sophisticated accountable arrangements tied to quality and equity across the risk continuum as providers gain experience in population health management. The AHA is monitoring the policy landscape and assessing what policies and at what level of government to focus our advocacy efforts.

For more information:

- For a resource from CMS that provides an overview of the basics of value-based care, go to CMS Value-Based Care Spotlight.
- For additional information about the CMS Medicare Shared Savings Program, click <u>here</u>. For information about CMS Innovation Center models of care, click here.

⁴ https://www.commonwealthfund.org/series/mirror-mirror-comparing-health-systems-across-countries

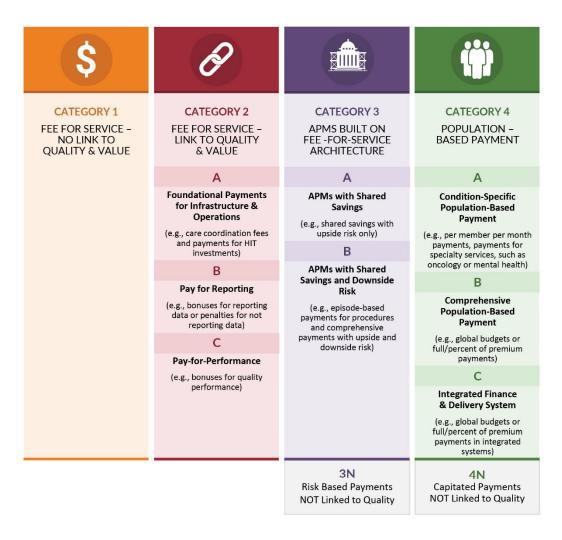
⁵ America's Health Rankings: https://www.americashealthrankings.org/

- For a glossary of select terms from CMS, please see Exhibit C (pages 17-19).
 Also, a more comprehensive glossary of terms from CMS can be found here.⁶
- For additional information about alternative payment models, visit the <u>Health Care Payment Learning & Action Network (HCPLAN or LAN) website</u>. The HCPLAN is an active group of public and private health care leaders dedicated to providing thought leadership, strategic direction, and ongoing support to accelerate our care system's adoption of alternative payment models (APMs). AHA is a member of the Accountable Care Action Collaborative.
- For state specific information from the National Conference of State Legislators, click here.

⁶ https://www.cms.gov/files/document/value-based-healthcare-video-series-what-every-clinician-should-know-glossary-terms.pdf



Exhibit A



This Framework represents payments from public and private payers to provider organizations (including payments between the payment and delivery arms of highly integrated health systems). It is designed to accommodate payments in multiple categories that are made by a single payer, as well as single provider organizations that receive payments in different categories—potentially from the same payer. Although payments will be classified in discrete categories, the Framework captures a continuum of clinical and financial risk for provider organizations.





Exhibit C

AHA Health System Transformation Guiding Principles

Principle	Description
	General
AHA supports efforts to gradually move away from feefor-service as the primary provider payment mechanism and the adoption to value-based care delivery and payment models (VBP) AHA sources: • 2023 Clinician Value-Based Payment • 2022 Improving Heart Health Through Value-Based Payment • 2022 Strategies to Reduce Low Value CV Care • 2021 Call to Action: Maternal Health and Saving Mothers • 2020 Value in Health Care Initiative • 2020 Advancing Value-Based CV Care • 2020 Frontiers of Upstream Stroke Prevention and Reduced Stork Inequity 2020 Advancing Value-Based Model for Heart Failure • 2020 CV Patient Perspectives on Value in Healthcare Experience • 2017 AHA Call to Action for Payment and Delivery System Reform	VBP represents a fundamental shift in the way that US healthcare is financed and organized. It holds the potential to transform care and deliver better clinical outcomes, lower costs, and improved equity • To be transformative, VBP programs must move away from the fee-forservice (FFS) model toward more flexible funding that allows clinicians to focus resources on the interventions that best help patients. Current FFS payment system fails to provide incentive for care redesign, does not promote longitudinal management, focuses on illness rather than wellness, underutilizes nonphysician clinicians, encourages invasive and intensive treatments for later-stage disease instead of shared decision-making abut treatment options or palliative care that improves quality of life, and separates PC from specialty care. FFS hinders the quality and value of CV Care. • Programs should reflect the five key aims that seek to improve: • Triple Aim: • Individual experience, including quality and satisfaction. • Population health. • Per capita health care spending. • Quadruple Aim: Clinician support and satisfaction • Quintuple Aim: Health equity/health optimization for allexpansion of value-based payment should be a tool for improving equity, which is central to quality of care and should be a focal point of program design and evaluation. • Clinician and provider accountability is a cornerstone of VBP. • Coordination and integration of care is an essential element of VBP. • Benefit design should support the goals of VBP.
	including MA and managed care plans) is desired to facilitate broader
Eive	adoption of VBP.
1. Improved experience of care for individuals and their caregivers Note: this in one of the three aims of the IHI Triple Aim that is widely embraced to guide the direction of new health care delivery and payment models.	Individual experience of care (quality/outcomes and satisfaction): • Promote health care that is safe, effective, patient-centered, timely, efficient, and equitable. • "Person- (or patient-) centric" programs and services. • Shared decision making. • Quality and satisfaction should be measured at the individual level. • Home or community-based care bolstered by telehealth and remote monitoring should be supported where practicable given the individual's condition and circumstances.

Principle	Description
2023 Clinician Value-Based Payment 2022 Improving Heart Health Through Value-Based Payment 2021 Call to Action: Maternal Health and Saving Mothers 2020 Value in Health Care Initiative 2020 CV Patient Perspectives on Value in Healthcare Experience 2020 Advancing Value-Based CV Care 2020 Frontiers of Upstream Stroke Prevention and Reduced Stork Inequity 2017 AHA Call to Action for Payment and Delivery System Reform Internal SharePoint: 2018 The Importance of Community Health Workers 2007 Nonfinancial Incentives for Quality	Flexibility re the provision of services crucial to good care, such as care coordination, team-based care, remote monitoring, behavioral tools, and social and community interventions. See also Health Equity/Health Optimization for All below
2. Improved population health Note: this is also one of the three aims of the IHI Triple Aim • 2023 Clinician Value-Based Payment • 2022 Improving Heart Health Through Value-Based Payment • 2020 Advancing Value-Based Model for Heart Failure • 2020 Advancing Value-Based CV Care • 2020 Frontiers of Upstream Stroke Prevention and Reduced Stork Inequity • 2017 AHA Call to Action for Payment and Delivery System Reform • 2015 Social Determinants of Risk and Outcomes for CVD • Internal SharePoint: 2018 The Importance of Community Health Workers	 To support better health of populations, VBP should include a focus on: Care delivery models that promote evidence-based, high-quality guideline implementation, and longitudinal follow-up. Policies that promote more person-centered care and eliminate barriers to the receipt of evidence-based, appropriate care by patients. Quality/health outcomes measurement Stratified by standardized race and ethnicity, and overall. Prioritization of high-risk patient groups. Social determinant of health (SDOH) and upstream prevention. Partnering with community organizations to meet individuals where they are. Leveraging any existing infrastructure or data for population health tracking and management.
 3. Reduced per capita health care spending Note: This is the third Aim of the IHI Triple Aim 2023 Clinician Value-Based Payment 	 Reduced (or controlled) per capita health care costs require: Payment policies that move away from FFS toward population-based payments (see Exhibit A for HCP LAN framework). Cost measurement that: Safeguards against unintentionally lowering quality by concurrently evaluating quality, appropriately weighting the relative importance of cost and quality, and excluding the cost of select high-value healthcare services.

es adequate cost-quality alignment.
orates risk adjustment for functional status and social risk.
sses over and underutilization.
es on cost of care that clinicians can potentially influence.
rts appropriate and accurate coding for those who are caring for
risk and underserved populations.
clinician satisfaction and support including:
ıl and technical supports that:
te actionability through:
a sharing—making key data available to providers;
ing with clinicians timely and granular data re their performance
provides direction for improving care and that supports
itudinal care models, especially for individuals with more
plex conditions;
itation of data analysis using real-time electronic dashboards to
ide actionable breakdowns of individual clinician and group level
ormance as well as comparison with other individual clinician
peer groups;
ater use of digital technology in the delivery of care for heart-
red conditions; the use digital tools, wearables and patient-
erated data to reimagine what cardiovascular care could look
use of care to appear to address social and behaviour shallon ass for
use of care teams to address social and behavioral challenges for
vidual patients including nonphysician clinicians such as PAs, pharmacists, Community health workers (CHWs), social workers,
ical assistants, care navigators and coordinators, etc., so that
sicians can be used more appropriately.
der-resourced providers who care for higher-risk patients, ensure
d resources needed to be successful in VBP are available (e.g.,
at payments for small practices and for providers caring for
ations at high-risk for experiencing inequities to help build
ilities).
ng collaboratives.
mentation science support strategies
ssist in the uptake of new models of evidence-based practices
routine clinical care;
ffer evidence-based, systematic approaches critical to improving
value of care.
d administrative burden for clinicians:
tion management (UM) should be transparent and
orative/collegial, electronic, and automated (upstream at POC),
common prior authorization (PA) data standards and universal
m, gold carding for clinician that consistent receive PA approvals,
rt a multistakeholder group should design clear treatment
thms and criteria that apply to PA (of CV therapies).
n care organizations under value-based contracting should take
r UM responsibility and adopt UM processes that are
arent, collegial, peer-to-peer (including rotating physician
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Principle	Description
	through UM Board) and integrate PA with the EHR (including clinical
	decision support)
	o Efforts should be made to ameliorate the burden of documentation on
	the health care delivery system.
	Accounting for clinician readiness for risk, including a graduated
	approach to taking on increasing risk and that with increasing risk should
	come increasing flexibility to pay for team-based care, and other
	services and supports to enhance care.
	o When determining value for payment adjustment, benchmarking
	measures for overall performance, relative performance, and
	improvement over time.
	o For advanced VBP, a streamlined waiver process to allow payments for
	services such as CHWs, CR via telehealth, pharmacist-directed
	medication therapy mgt, etc.
	Channeling of clinicians' intrinsic motivation to improve their own performance.
	Opportunities for specialists (i.e., cardiology, neurology, etc) to serve as
	leaders in these care models.
	Provide financial and technical assistance to providers who need help
	establishing performance measures and infrastructure for improvement.
5. Health Equity/Health	Focusing on health equity/health optimization for all requires:
Optimization for All	Formal assessment of equity in care delivery
	Measures that are stratified and reported by race and ethnicity; provide
Note: While equity is part of	resources for addressing heart health-related inequities including
the improved experience of	underlying social drivers of health risks.
care aim, worsening	Focusing on heart health as a priority area for elimination of inequities
disparities have lead to this	(smoking status, hypertension, hyperlipidemia, and diabetes control
being a separate aim of new health care delivery and	rates). • Inclusion of a pre-specified evaluation plan that captures the impact on
payment models. With the	quality, cost, and equity. The equity evaluation should capture the
Triple and Quadruple Aims, it	effects on access and outcome disparities. These results should
is often referred to as the	determine program scaling or deimplementation.
Quintuple Aim.	An explicit focus on equity in terms of reducing unintended
	consequences.
• 2023 Clinician Value-Based	Measures that address variations within clinical practices.
Payment2022 Improving Heart Health	Ensuring that VBP programs are tested and monitored for negative
Through Value-Based Payment	impact on equity especially for historically disadvantaged groups.
• 2020 Value in Health Care	Risk adjustment that accounts for social risk.
Initiative 2020 Advancing Value-Based CV	• The evaluation of the effect of a VBP program on (1) access to care, (2)
Care	absolute measures of cost of care and quality among high-risk groups,
2015 Social Determinants of Risk	and (3) differences in cost and quality between groups
 and Outcomes for CVD Internal SharePoint: 2018 The 	Efforts to implement diverse, multi-disciplinary care teams under VBP models
Importance of Community Health	models. • Improving health equity through elevating team-based, patient-
Workers	centered care with attention to SDOH.
2007 Nonfinancial Incentives for Quality	Workforce:
Quality	Hiring of diverse, multi-disciplinary care teams.
	Inclusion of CHWs especially in Medicaid

Principle	Description
	 Ensuring equitable access to emerging digital tools, wearables, and patient-generated data. Model evaluation should incorporate an equity focus through: Inclusion of a pre-specified evaluation plan that captures the impact on quality, cost, and equity. The equity evaluation should capture the effects on access and outcome disparities and be integrated into the design and implementation of models including: Measuring differences in processes and outcomes across subpopulations of interest (e.g., race, ethnicity) at the beginning, in the interim and at the end of the reporting period; Measuring absolute performance to determine if there have been improvements across all populations; and Measuring access to care. These results should determine program scaling or deimplementation. Longer-term evaluation of longitudinal care of chronic illness requires examination beyond an early decrease in emergency department or urgent care visits to specific, not general, measures of quality.
A	Clinician and Provider Accountability
Accountability for Payment 2023 Clinician Value-Based Payment 2022 Improving Heart Health Through Value-Based Payment 2020 CV Patient Perspectives on Value in Healthcare Experience 2020 Advancing Value-Based CV Care 2020 Frontiers of Upstream Stroke Prevention and Reduced Stork Inequity 2017 AHA Call to Action for Payment and Delivery System Reform	VBP must move away from fee-for-service toward more flexible funding that allows clinicians to focus resources on the interventions that best help patients. • Performance on measures should affect payment.
Accountability for Quality 2023 Clinician Value-Based Payment 2022 Improving Heart Health Through Value-Based Payment 2020 Advancing Value-Based CV Care 2020 CV Patient Perspectives on Value in Healthcare Experience 2017 AHA Call to Action for Payment and Delivery System Reform 2007 Nonfinancial Incentives for Quality	Quality measures and evaluation that assess: • Evidence-based guideline adherence, • Prevention of (HF) hospital admissions, readmissions, and mortality; and • PROMs/PREMs for quality of life and shared decision making. Guidelines, quality measures, and registries should be used to define and measure value. Performance on measures should affect payment. Quality measures should be standardized, evidence-based, and risk-adjusted.
	Quality measures should be evaluated and updated in a timely manner. Programs should be reevaluated periodically and should be responsive to changes in the evidence-based research, including consensus-based

Principle	Description
	treatment guidelines. Incentives should be aligned to support systems- focused reforms in healthcare delivery.
Accountability through Incentives 2023 Clinician Value-Based Payment 2022 Improving Heart Health Through Value-Based Payment 2017 AHA Call to Action for Payment and Delivery System Reform	Programs should carefully weigh the incentives and find the right balance between lowering cost and improving quality of care and ensure there is adequate focus on quality of care.
-Accountability for Appropriate Use 2023 Clinician Value-Based Payment 2022 Improving Heart Health Through Value-Based Payment 2017 AHA Call to Action for Payment and Delivery System Reform	Appropriate use of medical imaging, with significant impact on cardiovascular and neurological specialties (i.e., Choosing Wisely campaign). -See also Benefit Design below.
Accountability promoted by Alignment - 2023 Clinician Value-Based Payment - 2022 Improving Heart Health Through Value-Based Payment	Common accountability measures to help align incentives between plans and their clinicians and patients, and to foster payment and insurance benefit design reforms to help support whole-person (cardiovascular) care pathways. • Accountability in measurement includes: • Key (cardiovascular) outcome measures (building on goals and outcome metrics for Million Hearts and other programs, such as hypertension and hyperlipemia and improved functional status) and accountability (e.g., prevention of acute cardiovascular events, functional status measures, patient experience/activation/coordination measures). • Total costs; and • Reduced hospitalizations with avoidable (cardiovascular) complications or procedures, with improvements in use of evidence-based treatments to slow or halt disease progression.
	Additional Factors Needed for Success
Better longitudinal coordination and integration across the care continuum 2022 Improving Heart Health Through Value-Based Payment 2020 Advancing Value-Based CV Care 2017 AHA Call to Action for	To improve (CV) care and treatment, payment reforms are needed that move away from FFS and encourage care coordination, team-based care, remote monitoring, behavioral tools, and social and community interventions, through: • Primary care-focused longitudinal models that tie payments to population-level cost benchmarks and quality performance metrics, with an emphasis on longitudinal care, care coordination, and risk factor identification and modification (e.g., ACOs).
Payment and Delivery System Reform	 Collaboration between primary and specialty care. More advanced, "whole-person," coordinated, person-centered care with strong primary care and well-integrated specialty care. Whole-person

Principle	Description
Principle Internal SharePoint: 2018 The Importance of Community Health Workers 2007 Nonfinancial Incentives for Quality	includes social and behavioral factors that impact health as well as preventing, diagnosing, treating, and managing disease throughout the life journey. Team-based and multi-disciplinary approaches to care, including efficient virtual coordination between primary and specialty care. Inclusion of CHWs in VBP models, particularly those involving Medicaid, and ensuring policy support for funding of the community health workers role is critical to sustainability of culturally appropriate interventions. Efforts to implement diverse, multi-disciplinary care teams under VBP models. Care teams that also address social and behavioral challenges for individual patients including nonphysician clinicians such as Pas, NPs, pharmacists, CHWs, social workers, medical assistants, care navigators and coordinators, etc., so that physicians can be used more appropriately. Improved data exchange and performance measures to facilitate care coordination between primary and specialty care with technical support. Improvements that encourage more and better coordination between primary and specialty care clinicians, which is critical to achieving effective whole-person cardiovascular care, with a focus on integrating not just prevention and high-quality intensive care but also chronic condition management. Person-focused payment approach via specialized care payment reforms that "nest" (chronic cardiovascular disease) management and acute episodes into comprehensive population/primary care payment reforms. Greater integration of specialists and supportive services into (heartfocused) care models Encourage local innovation in quality improvement and in the pursuit of
Multi-payer Alignment (applies to public and private	national goals. Multi-payer alignment around and with clear and transparent: • Attribution
or commercial payers including MA and managed care plans) • 2023 Clinician Value-Based Payment • 2022 Improving Heart Health Through Value-Based Payment • 2007 Nonfinancial Incentives for Quality	 Attribution Benchmarking Risk adjustment that includes functional status and social risk Accountability measures with better alignment across programs (public and private) for quality improvement and reporting: Parsimonious set of quality metrics that include: combination of process and outcomes that are relatively easy to collect (i.e., eCQMs); are most important to patient and clinicians (relevant and impactful); include PROMs and PREMs. Aligned incentives between plans and their clinicians and patients to foster payment and insurance benefit design reforms to help support whole-person (cardiovascular) care pathways. Accountability in measurement includes key (cardiovascular) outcome measures (building on goals and outcome metrics for Million Hearts and other programs, such as hypertension and hyperlipemia and improved

Principle	Description
Benefits Design Re: High	functional status), total costs, and reduced hospitalizations with avoidable (cardiovascular) complications or procedures, with improvements in use of evidence-based treatments to slow or halt disease progression. Rey (cardiovascular) outcome measures and accountability (e.g., prevention of acute cardiovascular events, functional status measures, patient experience/activation/coordination measures). Increasing transparency around the quality and spending on (cardiovascular) care. Better alignment of measures across programs (public and private) for quality improvement and reporting. For clinicians and providers the focus is on education, clinical decision
Value and Low Value Services	support, and behavioral science approaches
2023 Clinician Value-Based Payment 2022 Improving Heart Health Through Value-Based Payment 2022 Strategies to Reduce Low Value CV Care 2020 Frontiers of Upstream Stroke Prevention and Reduced Stork Inequity	For consumers and patients, the focus is on: • Education • Shared-decision making; • Value Based Insurance Design (VBID)—no or lower cost sharing for high value services; higher cost sharing for low value services • For early-stage VBP—limited reductions in co-pays for high-value services or products related to heart health. • For later-stage VBP: • reduced or no co-pays for high-value tools or services (related to heart health) • beneficiary incentive payments for participation (in heart health-related activities) • administrative flexibilities and higher co-pays for heart-related services determined to be "low-value"
Beneficiary Awareness,	AHA should work to:
 2022 Improving Heart Health Through Value-Based Payment 2020 Value in Health Care Initiative 2020 Advancing Value-Based CV Care 2020 CV Patient Perspectives on Value in Healthcare Experience 2017 AHA Call to Action for Payment and Delivery System Reform 	 Better incorporate the consumer/patient voice into assessments of value. Ensure that the best interests of the consumers/patients remain central. Advocate for elevating the consumer/patient experience and/or perspective when developing and implementing value-based care and payment models. Enhance beneficiary awareness of and involvement with CMMI VBP efforts. Better incorporate the consumer/patient perspectives into problemsolving deliberations and assessments of value. Advocate for a focus on individuals and populations experiencing persistent disparities in heart health-related care and outcomes by working with consumer-focused organizations (e.g., American Heart Association) to facilitate beneficiary involvement in VBP redesign efforts. Support beneficiary education on VBP's influence on their care experiences and how to use VBP-related information and data (e.g., priority quality and outcome measures) to inform care decisions. Enable individual beneficiary's long-term engagement in (heart health-related) prevention and management behaviors. Support home or community-based care bolstered by telehealth and remote monitoring.

Principle	Description
	Recognize that CVD patients value:
	o The quality of care they received;
	o Open communication and trust with their providers;
	o Focus on whole person,
	o Timely access to care and support, and
	o Reasonable costs.
Future Research	Prioritize research that investigates:
2017 AHA Call to Action for	The intergenerational transmission of social disadvantage and the subsequent
Payment and Delivery System Reform	cardiovascular health consequences.
• 2015 Social Determinants of Risk	Mechanisms by which social networks affect health.
and Outcomes for CVD	New model evaluations
2009 AHA Principles for Comparative Effectiveness	
Comparative Effectiveness Research	Comparative effectiveness research should be guided by the following 4 factors:
	Conducting and interpreting comparative effectiveness research
	according to fundamental scientific principles;
	 Defining value for patients through comparative effectiveness research;
	 Applying comparative effectiveness research to patient
	treatment decisions; and Treatment decisions; and
	Funding and oversight of comparative effectiveness research.
	Con also Hawlth Cours During and Review Particut Contoured Recognish halour
	See also Health Care Drug and Device Patient-Centered Research below
Maternal Health	Models Addressing Specific Conditions To improve maternal health outcomes, it is imperative to:
Maternal Health	
• 2022 Policy Change Needed to	Modernize the health care delivery infrastructure and expanding care coordination,
Improve Maternal CV Health	Promote payment model innovation that:
2021 Call to Action: Maternal	Are predicated on achieving high-value, patient-centered care for
Health and Saving Mothers	pregnant individuals before, during, and after pregnancy.
	Transform provider payments to incentivize quality improvement and
	the provision of historically underused services (e.g., maternal health
	education, home visits, midwifery care, and doulas) and deprioritize
	the provision of unnecessary care.
	Include evidence-based models of care such as pregnancy medical
	homes and value-based payment models that bundle payments for
	treatments and services across the continuum of maternity care should
	be explored among public and private plans
Heart Failure	Elements of a VBP Model for Heart Failure include:
	Population health (i.e., shared saving or pmpm for care management to
2020 Value in Health Care Proposed	hold clinician financially at risk for certain outcomes directly or indirectly
New Value-Based Payment Model for Heart Failure	related to HF).
Tot Healt Fallare	Population target Stage C HF and secondary Stage B high-risk pre-HF.
	Triggers to enter models:
	o Patient hospitalized or ED visits for Stage C HF complications
	(confirmatory diagnosis post-hospitalization)
	o Physician refers patient to the model
	o 2-step process: patient proposed by clinician, confirm by payer (or vice
	versa)
Healt	th Care Drug and Device Patient-Centered Research

Principle	Description
Goals of drug and device	Goals:
research	• Increasing patient participation in clinical trials and patient engagement in clinical trial design and end point selection,
2020 Improving CV Drug and Device	Better leveraging of real-world evidence,
Development and Evidence Through Patient-Centered Research and	Ensuring clinical trial evidence meets the needs of regulators and payers
Clinical Trials	(multiple stakeholders), and
	Expanding the number of health care organizations involved in clinical
	trials.
Evidence generation process	Improving the evidence generation process for CV drugs and devices requires
for (CV) drugs and devices	The promotion of strategies to enhance patient engagement in trial
	design, convenient participation, and meaningful end points and
	outcomes to improve patient recruitment and retention in trials.
	Introduction of new digital technologies to expand real-world evidence
	to streamline data collection and reduce cost and time of trails along
	with the need to standardize data, manage data quality, understand
	data comparability, and ensure real-world evidence does not worsen inequities.
	Streamlining and standardizing efficient and innovative trials to reduce costs and delays.
	The expansion of CV evidence-generation sites and medical product development.
	Continued policy research into better ways to pay for and equitably
	develop therapies to reduce the cost and complexity of drug device
	research, development, and trials.
Establishment of a more	Establishing a more collaborative and inclusive research process requires:
collaborative and inclusive	Conceptualizing and realizing opportunities for patient involvement.
research process	o The FDA should recommend industry's pretrial Research and
	Development design include patients from a variety of backgrounds and perspectives.
	o The NIH (particularly NHLBI) should have a diverse committee of
	patients advising their grant offerings for patient-centric research.
	Ensuring outcomes used in end points are meaningful to patients.
	 The FDA's PFDD should expand its reach to multiple cardiovascular conditions.
	o The AHA should build from PFDD infrastructure to create its own
	patient-centered cardiovascular therapy development forum.
	o The NIH (especially NHLBI) and other funders should support research
	to develop patient-centered cardiovascular outcomes for use in trials.
	o Existing cardiovascular registries (e.g., for hypertension) should capture
	patient-centered and patient-generated health data.
	Using new tools to enable convenient recruitment and participation. The
	AHA and FDA should focus their trial innovation convening efforts on how
	equitable use of technologies, including smartphones, wearables, and
	artificial intelligence, may streamline diverse participant recruitment and
	accessible "site-less" cardiovascular trials.
	• Expanding the research community network. The AHA should work to
	identify and actively connect community-based organizations, including
	patient advocacy groups, to the investigators, health systems, and

Principle	Description
	hospitals participating in trials and expand their availability in
	underserved areas.
	Developing a cardiovascular core outcome set. The AHA should work with
	FDA to build from the Clinical Outcome Assessment Compendium and
	develop a cardiovascular core outcome set.
	Allowing patients to own, use, and share their trial data. The AHA and FDA
	should operationalize sharing trial data with patients, including bring your
	own device designs.
Leveraging real-world	To leverage real-world evidence and data to improve biomedical
evidence and data to	innovation:
improve biomedical	Using technology and real-world data to assess and improve currently
innovation	licensed cardiovascular drugs and devices.
	o The AHA and FDA should focus their trial innovation convening efforts
	on how to use technology and patient data to streamline and enhance
	phase IV studies' patient-centricity.
	o The NHLBI should:
	■ Fund implementation science studies on cardiovascular therapy
	adherence, including strategies related to decision aids and
	communicating risks and benefits.
	 Dedicate research funding to learn how to use smartphones,
	wearables, artificial intelligence, and other technologies to improve
	medication adherence and uptake of current cardiovascular drugs
	and devices, especially in underserved populations.
	o The FDA should:
	Provide guidance on equitable use of smart devices and other personal technologies in trials, which may include the direct provision.
	personal technologies in trials, which may include the direct provision of devices to patients.
	 Place a higher weight on patient-centered end points and quality of
	life metrics in all clinical trial phases.
	Standardizing cardiovascular real-world data.
	o The AHA and FDA should develop clear guidelines for obtaining and
	analyzing cardiovascular real-world data and transforming them into
	real-world evidence acceptable in cardiovascular clinical trials.
	The NHLBI should dedicate research funding for implementation
	science studies to learn to scale interventions directly importing
	cardiovascular data from patients' third-party apps into electronic
	health records for clinicians and into trial portals as evidence.
	Developing innovative, affordable, and equitably available, personal
	technologies for cardiovascular trial use. The AHA and FDA should
	focus longer-term trial innovation efforts on working with industry and
	technology companies to encourage production of inexpensive
	wearables/smartphones capable of biometric data collection.
Ensuring clinical trials meet the	Ensuring clinical trials meet the evidence needs of regulators and payers
evidence needs of regulators	requires:
and payers	Including industry and researchers in trial design innovation.
	o The FDA/CDER should develop a forum similar to FDA/CDRH's Payor
	Communication Task Force where stakeholders can get feedback on a
	new drug submission.

Principle	Description
	 The AHA should create a regular convening for industry, researchers, and other stakeholders to meet with the FDA and other regulators affecting research or implementation (eg, NIH, Centers for Medicare & Medicaid Services). This convening may focus on barriers to innovation and ideas for innovative design and may not be specific to a particular therapy application.
Creating cardiac research	To create cardiac research collaborative of excellence, the following needs to
collaborative of excellence	occur:
	 Better capturing trial successes by creating cardiac research collaboratives of excellence. The AHA should work with the NHLBI to create a program to recognize regional collaboratives of clinics, health systems, community-based organizations, and other relevant stakeholder groups with a demonstrated track record of successful cardiovascular trials. Engaging a broader network of providers in research by creating a community cardiovascular research program. The AHA should create a research network to boost provider engagement in cardiovascular clinical trials, with a focus on community-based providers and underserved populations (similar to the National Cancer Institute's Community Oncology Research Program). Expanding the research community network. The FDA should consider stronger and broader recommendations that women and racial and ethnic minorities be equitably included in trials. The AHA and FDA should focus longer-term trial innovation convening efforts on how to make recruitment, participation, and retention more equitable and culturally competent, including how to build better trust in the medical and research establishment, and how to better include underserved rural and urban community settings.

Exhibit B

Glossary of Terms

Note: terms below are from the CMS Value-Based Healthcare Video Series. To see the full glossary of terms, click <u>here</u>.

ACO (Accountable Care Organization) - Groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to a population of patients they serve. When an ACO succeeds in both delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program (U.S. Centers for Medicare & Medicaid Services/CMMI, 2019).

ACO REACH (Accountable Care Organization Realizing Equity, Access, and Community Health) -

Alternative Payment Model (APM) - A value-based payment approach that gives added incentive payments to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a patient population (U.S. Centers for Medicare & Medicaid Services/QPP, 2019).

Advanced APM – Advanced APMs (AAPMs) are alternative payment models that include both up- and down-sided risk. AAPMs are a track of the Quality Payment Program that offer [an added incentive] for achieving threshold levels of payments or patients through Advanced APMs (U.S. Centers for Medicare & Medicaid Services/QPP, 2019).

Attribution - The process that commercial and government payers use to assign patients to the physicians who are held accountable for their care (Fiesinger, 2016).

Beneficiary - The name for a person who has health care insurance through the Medicare or Medicaid program (U.S. Centers for Medicare & Medicaid Services/Glossary, 2006).

Bundled payment - Models of care which link payments for the multiple services beneficiaries receive during an episode of care (U.S. Centers for Medicare & Medicaid Services/CMMI, 2019).

Capitation - A specified amount of money paid to a health plan or doctor. This is used to cover the cost of a patient's health care services for a certain length of time (U.S. Centers for Medicare & Medicaid Services/Glossary, 2006).

Downside Risk – Downside risk in healthcare refers to assuming risk for actual costs of care. If the cost of care falls below the targeted costs, the practice will share in savings.

If the cost of care exceeds the targeted or budgeted costs, the practice will be responsible for a portion of the difference between actual total costs and targeted or budgeted costs (American Academy of Pediatrics, 2019). Downside risk puts providers at financial risk in the event that added resources are needed to care for a patient (in situations where additional care could have been avoided). The most common examples apply to hospitals, such as non-payment for preventable hospital-acquired conditions or readmissions (Delbanco, 2014).

Episode of Care (episode) - The set of services provided to treat a clinical condition or procedure (U.S. Centers for Medicare & Medicaid Services, 2016).

Episode-Based Payment Initiatives - Under these models, health care providers are held accountable for the cost and quality of care beneficiaries receive during an episode of care, which usually begins with a triggering health care event (such as a hospitalization or chemotherapy administration) and extends for a limited period of time thereafter (U.S. Centers for Medicare & Medicaid Services/CMMI, 2019).

Fee-For-Service (FFS) - A method in which doctors and other health care providers are paid for each service performed. Examples of services include tests and office visits (U.S. Centers for Medicare & Medicaid Services/HealthCare.gov, 2019).

Full Risk (also known as two-sided risk) - In two-sided risk models, providers still share in the savings but are also responsible for some of the loss if spending is above the benchmark (Chernew & Frakt, 2018). Participating in these models can generally earn larger shared savings payments if they are successful, but they also face "downside" risk because they are responsible for repaying a portion of any losses to the government (Mechanic, Perloff, Litton, Edwards, & Muhlestein, 2019).

Global Payment - A fixed prepayment made to a group of providers or a health care system (as opposed to a health care plan), covering most or all of a patient's care during a specified time period. Global payments are usually paid monthly per patient over a year, unlike fee-for service, which pays separately for each service (National Conference of State Legislatures, 2010).

Healthcare Disparities - Differences and/or gaps in the quality of health and healthcare across racial, ethnic, and/or socio-economic groups. It can also be understood as population-specific differences in the presence of disease, health outcomes, or access to healthcare (Riley, 2012).

High Value Care - The best care for the patient, with the optimal result for the circumstances, delivered at the right price (Smith, Saunders, & Stuckhardt, 2013).

P4P (Pay-for-Performance) - An umbrella term for early initiatives aimed at improving the quality, efficiency, and overall value of health care by addressing how providers are paid for healthcare. These early efforts paved the way for value-based payment reform by focusing on patient outcomes and provider performance (CMS/ORDI/MDPG, 2005)

PCMH (Patient Centered Medical Home) - An approach to providing comprehensive primary care for children, youth and adults by transforming how care is organized and delivered. The PCMH re-designs primary care to provide comprehensive, personcentered care coordinated among patients, patient's families, specialty care, hospitals, home health, and/or community-based supports and services (American Academy of Family Physicians, 2007), (Agency for Healthcare Research and Quality, 2019).

Risk-Based Contracting - Risk-based contracts come in a variety of shapes and sizes. The highest form is full capitation in which hospitals or physician groups receive a monthly payment to provide all care for a patient (Barkholz, 2016).

Risk Based Payment Model - There are a variety of risk-based payment models being developed. Riskbased models are predicated on an estimate of what the expected costs to treat a particular condition or patient population should be (American Academy of Pediatrics, 2019).

RVU (Relative Value Unit) - A national standard used for measuring productivity, budgeting, allocating expenses, and cost benchmarking. RVUs do not represent monetary values. Instead, they represent the relative amount of physician work, resources, and expertise needed to provide services to patients. The actual dollar amount of a payment for the physician's services results only when a conversion factor (CF), dollar per RVU, is applied to the Total- RVU (Quan, 2007).

SDoH (Social Determinants of Health) - Conditions in the places where people live, learn, work, and play that affect a wide range of health risks and outcomes. These include conditions impacted by the distribution of wealth and resources (Centers for Disease Control and Prevention, 2018).

Upside Risk (also known as one-sided risk) – Upside risk includes value-based payment models where the provider only shares in savings and not the risk of loss. For example, if the actual total cost of care of patients assigned to a physician's practice are lower than projected budgeted costs, the practice receives a bonus payment (shared savings). If, however, the total cost of care of patients assigned to a physician's practice are higher than projected budgeted costs, the practice would not be

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penalized financially in an upside-only risk payment model (American Academy of Pediatrics, 2019).

Value-Based Healthcare (VBH) - A healthcare delivery model in which providers, including hospitals and physicians, are paid based on patient health outcomes. (NEJM Catalyst, 2017) Value-based programs reward health care providers with incentive payments for the quality of care they give to people with Medicare (U.S. Centers for Medicare & Medicaid Services, 2019).