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Optimizing medicine.  
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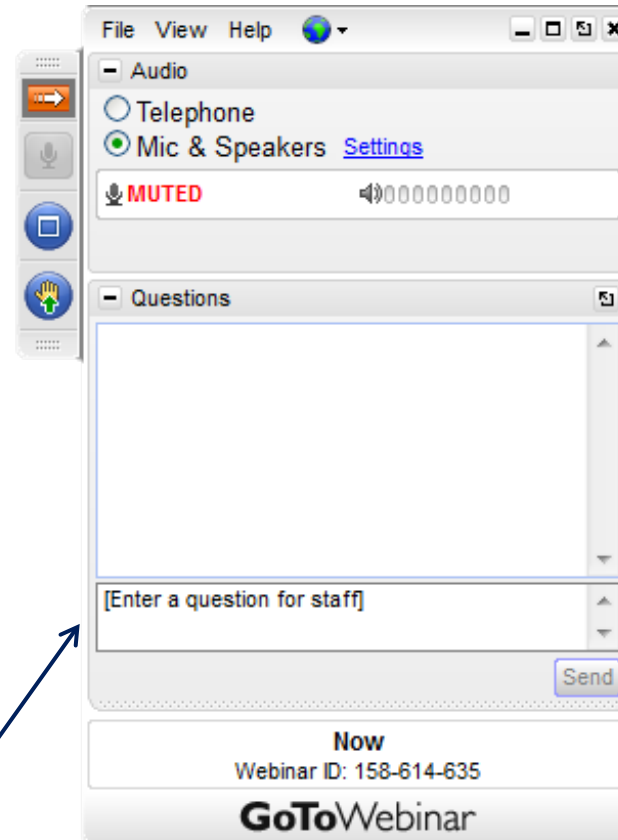
# **Policy & Government Relations Agenda – 2022 and Beyond**

***April 7, 2022***

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# How to Ask a Question



Type your question in the 'Questions' area

# SPEAKERS



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# Introduction

## Midwest Academy Strategy Chart

After choosing your issue, fill in this chart as a guide to developing strategy. Be specific. List all the possibilities.

Goals	Organizational Considerations	Constituents, Allies, and Opponents	Targets	Tactics
<p>1. List the long-term objectives of your campaign.</p> <p>2. State the intermediate goals for this issue campaign. What constitutes victory?</p> <p><i>How will the campaign</i></p> <ul style="list-style-type: none"> <li>• Win concrete improvement in people's lives?</li> <li>• Give people a sense of their own power?</li> <li>• Alter the relations of power?</li> </ul> <p>3. What short-term or partial victories can you win as steps toward your long-term goal?</p>	<p>1. List the resources that your organization brings to the campaign. Include money, number of staff, facilities, reputation, canvass, etc.</p> <p>What is the budget, including in-kind contributions, for this campaign?</p> <p>2. List the specific ways in which you want your organization to be strengthened by this campaign. Fill in numbers for each:</p> <ul style="list-style-type: none"> <li>• Expand leadership group</li> <li>• Increase experience of existing leadership</li> <li>• Build membership base</li> <li>• Expand into new constituencies</li> <li>• Raise more money</li> </ul> <p>3. List internal problems that have to be considered if the campaign is to succeed.</p>	<p>1. Who cares about this issue enough to join in or help the organization?</p> <ul style="list-style-type: none"> <li>• Whose problem is it?</li> <li>• What do they gain if they win?</li> <li>• What risks are they taking?</li> <li>• What power do they have over the target?</li> <li>• Into what groups are they organized?</li> </ul> <p>2. Who are your opponents?</p> <ul style="list-style-type: none"> <li>• What will your victory cost them?</li> <li>• What will they do/spend to oppose you?</li> <li>• How strong are they?</li> <li>• How are they organized?</li> </ul>	<p>1. Primary Targets</p> <p>A target is always a person. It is never an institution or elected body.</p> <ul style="list-style-type: none"> <li>• Who has the power to give you what you want?</li> <li>• What power do you have over them?</li> </ul> <p>2. Secondary Targets</p> <ul style="list-style-type: none"> <li>• Who has power over the people with the power to give you what you want?</li> <li>• What power do you have over them?</li> </ul>	<p>For each target, list the tactics that each constituent group can best use to make its power felt.</p> <p>Tactics must be</p> <ul style="list-style-type: none"> <li>• In context.</li> <li>• Flexible and creative.</li> <li>• Directed at a specific target.</li> <li>• Make sense to the membership.</li> <li>• Be backed up by a specific form of power.</li> </ul> <p>Tactics include</p> <ul style="list-style-type: none"> <li>• Media events</li> <li>• Actions for information and demands</li> <li>• Public hearings</li> <li>• Strikes</li> <li>• Voter registration and voter education</li> <li>• Lawsuits</li> <li>• Accountability sessions</li> <li>• Elections</li> <li>• Negotiations</li> </ul>

# AGENDA

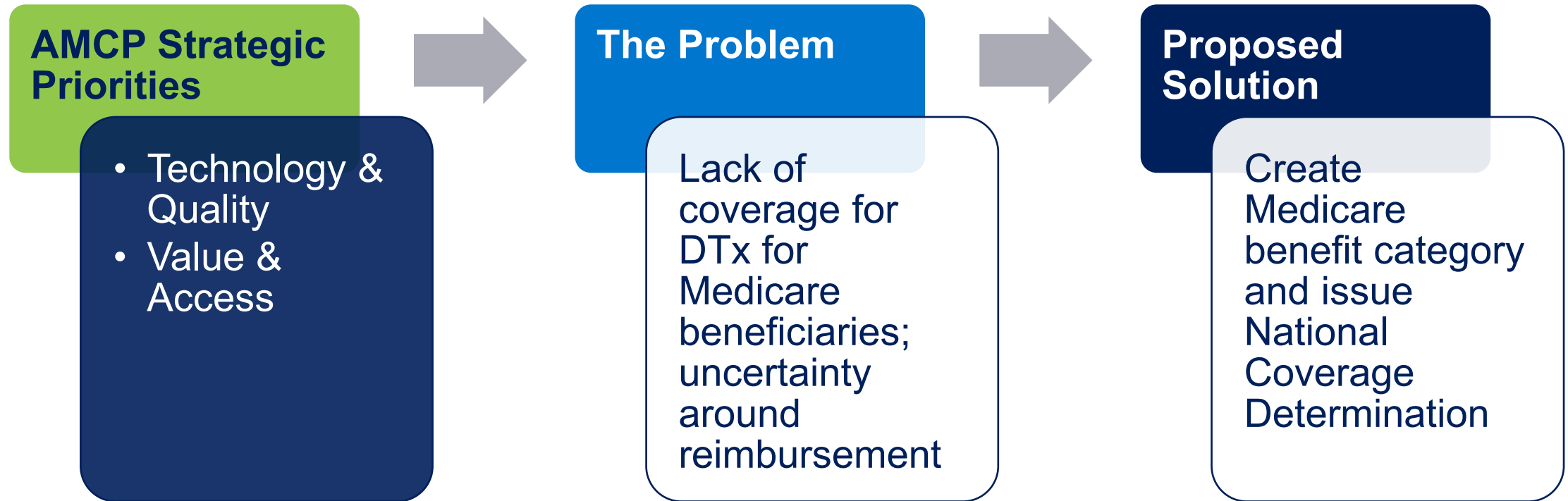
- Prescription (Rx) Digital Therapeutics
- Biosimilars Research Fund
- Pay for Performance Principles (P4P)
- Pre-Approval Information Exchange (PIE)



# **Rx Digital Therapeutics**



# Rx Digital Therapeutics



# Rx Digital Therapeutics: Goals

Short-Term: In 2022, AMCP will:

- By July 2022, introduce legislation creating a new Medicare benefit category for Prescription Digital Therapeutics (S. 3791/H.R. 7051 intro'd March 10)
- Attach legislative language to moving vehicles (e.g., Cures 2.0, NOVEL)
- Use May 18 Legislative Day to recruit 5-10 cosponsors

# Rx Digital Therapeutics: Goals

Mid-Term: Within 3 years, AMCP will advocate Congress to enact legislation creating a Medicare benefit category for Prescription Digital Therapeutics

Long-Term: Within 5 years, CMS issues its first National Coverage Determination (NCD) for a Prescription Digital Therapeutic

# Rx Digital Therapeutics

## Organizational Benefits

- Raise AMCP's profile as a leader in Prescription DTx
- Engage AMCP membership in grasstops and grassroots activities

## Success Factors

- Organizational willingness to bring clarity and focus to AMCP's role in elevating managed care
- Set proper expectations and educate AMCP's membership on congressional process and timing
- Adequate investment of resources

# Rx Digital Therapeutics: Potential Allies and Opponents

## Potential Allies:

- Digital Therapeutics Alliance (DTA)
- Manufacturers:
  - Pear Therapeutics (+)
- National Health Council
- Behavioral health patient groups
- Substance use disorder groups
- Disease-specific groups (e.g., diabetes, heart disease)
- Pharmacy groups:
  - APHA
  - NCPA
  - (+)

## Potential Opponents:

- App/Software Developers
- Those opposed to FDA review/approval process

## Undetermined:

- AMA
- Managed care groups (AHIP, BCBSA, etc.)
- Physicians
- NACD
- PCMA

# Rx Digital Therapeutics: Top Initial Targets

## House

- Rep. M. Thompson\*
- Rep. McKinley\*
- Ways & Means Committee:
  - Chairman Neal
  - Ranking Member Brady
- Energy & Commerce Committee:
  - Chairman Pallone
  - Ranking Member McMorris Rodgers
  - Health Subcommittee Chair Eshoo
  - Rep. Burgess
  - Rep. Guthrie

## Senate

- Sen. Moore Capito\*
- Sen. Shaheen\*
- Sen. Murray
- Finance Committee:
  - Chairman Wyden
  - Ranking Member Crapo
  - Sen. Burr
  - Sen. Menendez
  - Sen. Warner
  - Sen. Cornyn

\*original sponsor

# Rx Digital Therapeutics: Early Potential Tactics

- Build relationship with Digital Therapeutics Alliance (DTA) to ensure steadfast allyship
- Push FDA to issue definition of Prescription Digital Therapeutics by end of Q2 2022
- Upon introduction, issue Action Alert + identify press opportunities to raise visibility
- Conduct internal education for AMCP members
- Recruit 50-70 targeted AMCP members, including Board and leadership, for 2023

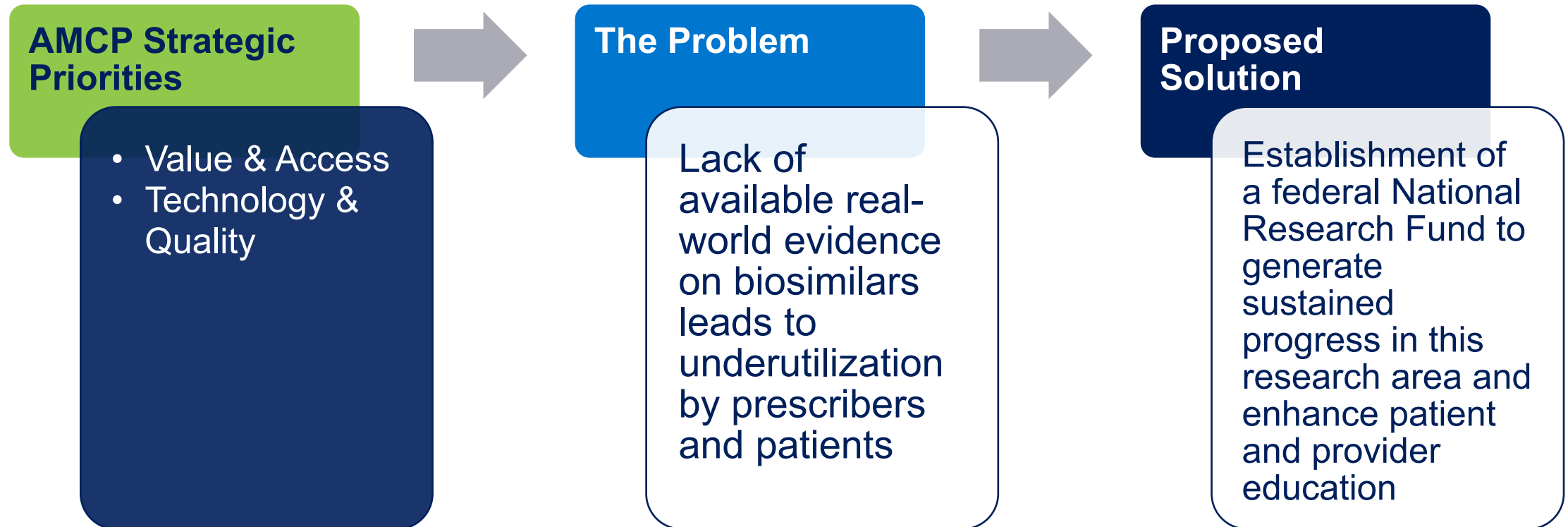
Legislative Day



# **Biosimilars Research Fund**



# Biosimilars Research Fund



# Biosimilars: Goals

Short-Term: In 1-2 years, AMCP will work to:

- Secure appropriations for NIH or another agency to fund large population, epidemiological research on biosimilars (\$2 – 5 million per grant, opening position \$40 million total)
- Exclude biosimilars (for 2 years) from inflationary pricing limits in BBBA (or similar vehicle)
- Block adoption of 106% reimbursement model at CMS

# Biosimilars: Goals

Mid-Term: Within 3-5 years, change statutory definition of interchangeability to allow biosimilar-to-biosimilar interchangeability, or substitution, at the pharmacy counter

Long-Term: Within 5-7 years, pass National Biosimilars Project Act with dedicated “Biosimilars Research Fund” and possible CDC Co-op Agreement

# Biosimilars

## Organizational Benefits


- Raise BBCIC/AMCP's profile as the biosimilars champion
- Provide opportunities to engage leadership, the Board, members in grassroots activities

## Success Factors

- Educate members about future biosimilars landscape to improve engagement with congressional offices
- Set proper expectations and educate AMCP's membership on congressional process and timing
- Ongoing investment of resources

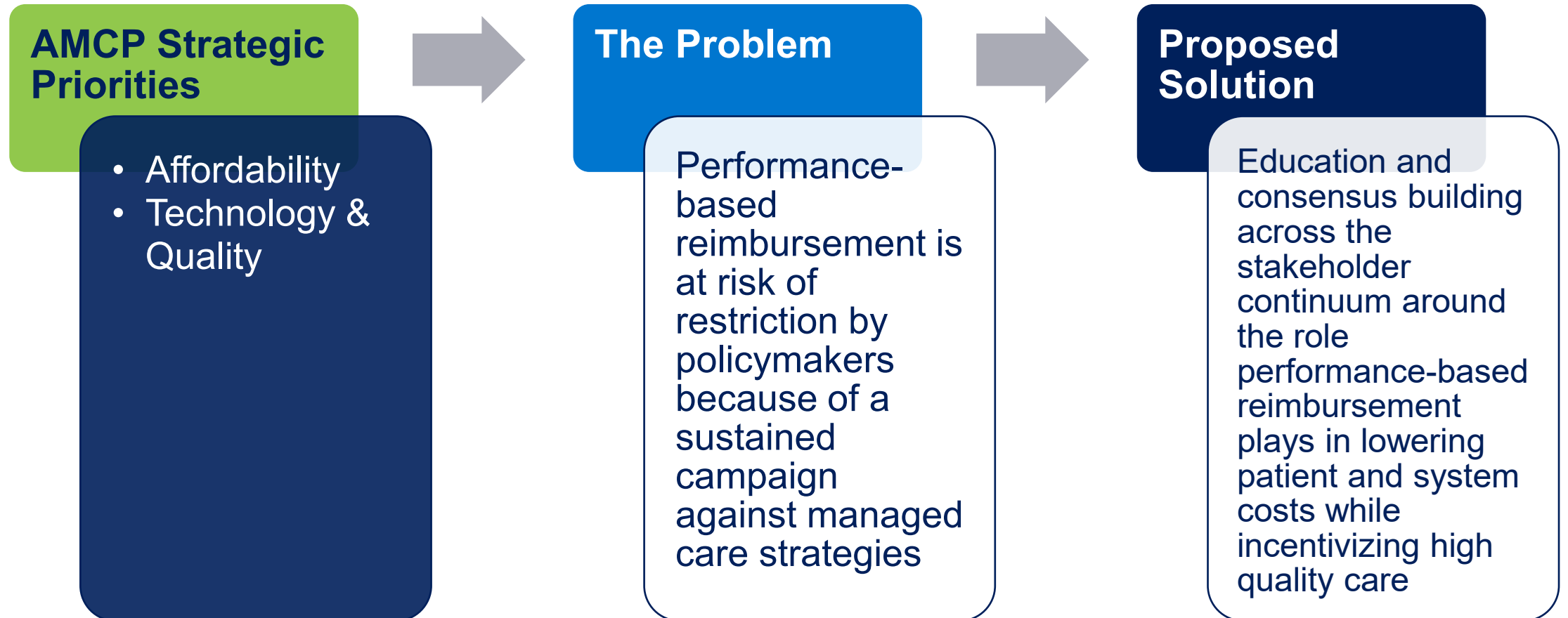
# Biosimilars: Early Potential Tactics

- Educate physicians about benefit of patient access to biosimilars
- Draft and vet National Biosimilars Act with AMCP member input and socialize with internal and external audiences, including Congress and the administration
- Meet with CMMI to advocate for blocking adoption of 106% reimbursement rate
- Draft and vet updated interchangeability definition
- Develop “ask” for the Appropriations committee to fund large population epidemiological research in 2023

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# Pay for Performance (P4P)

# Pay for Performance



# P4P: Goals

Short-Term: In the next 1-2 years, AMCP will work to:

- Influence the CMS rulemaking process to include pharmacy performance measures
- Get CMS to incorporate at least one of AMCP's recommendations (priority on principle 2: health plan flexibility language)
- Continue to provide CMS with input on pharmacy performance measures
- Cultivate relationships in managed care space



# P4P: Goals

## Mid-Term:

- Within 3 years, influence CMS to adopt a core set of pharmacy performance measures
- Within 3 years, positively influence rhetoric around pharmacy performance measures
- Within 3-5 years, introduce AMCP's Value & Outcomes-Based (V&OB) Contracts model legislation in at least 1 state

Long-Term: Within 5 years, establish leadership in pharmacy performance-based reimbursement and support development of new metrics by industry stakeholders

# P4P: Organizational Benefits

- Reposition AMCP as a leading voice on pharmacy performance measures
- Demonstrate to CMS that AMCP is a go-to source for expertise on pharmacy performance metrics
- Educate members, allies, and opponents about the relationship between DIR fees and value-based care
- Realign relationships with external stakeholders beyond traditional pharmacy to include managed care stakeholders
- Increase awareness for value of managed care strategies

# P4P: Success Factors

- Building and maintaining relationships with key officials at CMS
- Responding to and neutralizing anti-managed care narrative
- Organizational willingness to bring clarity and focus to AMCP's role in elevating managed care
- Ongoing investment of resources

# P4P: Early Potential Tactics

- Research health plan-created metrics (i.e., Humana, CVS)
- Educate/brief relevant staff on policy principles and plan moving forward
- Develop series of educational materials for AMCP members
- Create glossary on performance-based reimbursement
- Conduct research on federal and state legislators who support value-based care

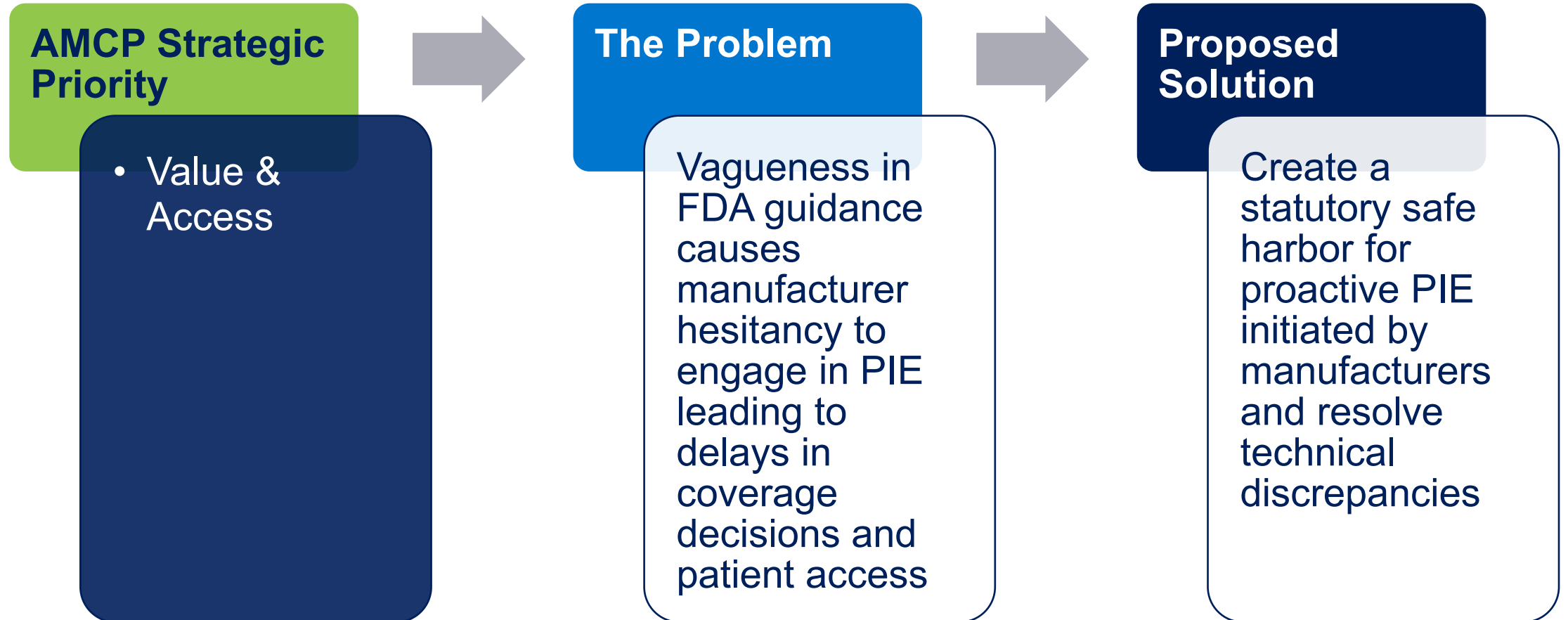
# P4P: Early Potential Tactics (cont.)

- Contract for independent study or literature review on the value of managed care pharmacy practices, tools, and strategies
- Conduct focus groups (and potential polling) around developing the counter-narrative to anti-managed care rhetoric
- Distribute mailers to policymakers on value of managed care pharmacy
- Develop toolkit for AMCP members to frame value component
- Briefing for allies (potentially another for opponents)



# **Pre-Approval Information Exchange (PIE)**

# Pre-Approval Information Exchange



# PIE: Goals

## Short-Term: In 2022:

- Work with Rep. Guthrie's office to attach uncompromised PIE to PDUFA VII (H.R. 7008 intro'd March 9)
- Strengthen support within FDA to provide TA to Congress
- Find at least 1 Democratic and 10 Republican cosponsors for uncompromised PIE
- Educate potential allies on both sides of the aisle on the Hill
- Identify potential Senate champions for introduction



# PIE: Goals

Mid-Term: Depending on House majority in 118<sup>th</sup> Congress, make new legislative push in 2023

- If R majority reintroduce, build co-sponsorship, and pass
- If D majority find a Democratic champion
- Work with bipartisan Senate champions to introduce

Long-Term: Within 5 years, codify the authority for proactive Pre-approval Information Exchange (PIE)

# PIE

## Organizational Benefits

- Reaffirm AMCP as a leading voice on PIE
- Demonstrate to Congress & FDA that AMCP is a go-to source for PIE expertise
- Increase AMCP member enthusiasm for advocacy and strengthen AMCP's Legislative Day program
- Educate opponents on the value and safety of PIE
- Educate allies on the need for codification
- Realign relationships with external stakeholders beyond traditional pharmacy to include managed care stakeholders

## Success Factors

- Educate and align manufacturers on the need for codification
- Overcome institutional knowledge loss within FDA and manufacturers

# PIE: Early Potential Tactics

- Strengthen AMCP's case for why PIE is needed
- Review AMCP's available data, including Format Executive Committee, Accelerated Approval Partnership Forum, Xcenda
- Refine Congressional targets and develop relationships with potential bipartisan champions
- Investigate current FDA position on PIE
- Reactivate PIE Coalition once PIE Act introduced

# PIE: Early Potential Tactics (cont.)

- Secure adequate 2023 campaign budget
- Include PIE in 2022 Legislative Day (May 18) + 2023 Legislative Day
- Conduct 2023 Congressional PIE briefing
- Raise PIE awareness using Op-Eds, AMCP blog posts, and Thank You ads for PIE Act sponsors
- Sign-on letters



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**Questions?**