Employer Playbook on Biosimilars

National Alliance
of Healthcare Purchaser Coalitions
Driving Health, Equity and Value

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Overview of Biosimilars

"Acceptance and use of biosimilars are key to preserving economic competition in the drug marketplace, especially after patent expiration of FDA-approved reference products."

Employer/purchaser plan sponsors have been grappling with how best to integrate biologics into their health and pharmacy benefit plans. Without consistent strategies among companies, employees and their families must often navigate these new drug options with no clear guidance. Many employers tell coalition partners that they receive inconsistent recommendations from advisors, health plans, and vendors such as, "Biosimilars are just another type of specialty drug," or "Biosimilars are more expensive and do not need to be part of the formulary."

Employers/purchasers want to develop benefit designs that best support their workforces while keeping costs down and achieving consistent outcomes. The National Alliance has developed this playbook to help employers navigate the challenges of managing drugs on the medical and pharmacy sides of their benefit plans and better understand innovative and emerging treatments. This playbook will also provide clear information to support discussions with plans and other vendor partners.

Biosimilars are one category of the class of drugs that are biological or derived from living organisms. Biosimilars are composed of macromolecules—in contrast to most chemically derived small-molecule drugs—with complex manufacturing processes and regulatory requirements.

Following are some key points to keep in mind.

Biosimilars

A biosimilar is a biological product that may be sold in pill or liquid form.

FDA-approved biosimilars have been compared to an FDA-approved biologic, known as the reference product (Biosimilars | FDA). Reference and biosimilar products are:

- Large and generally complex molecules.
- Produced from living organisms.
- Carefully monitored to ensure consistent quality.

A biosimilar is highly similar to a reference product:

- For approval, the structure and function of an approved biosimilar are compared to a reference product.
- Data from these comparisons must show the biosimilar is highly similar to the reference product in key characteristics, such as:
  - Purity.
  - Molecular structure.
  - Bioactivity (effect on the body).

A biosimilar has no clinically meaningful differences from a reference product:

- Studies were performed to show the biosimilar has no clinically meaningful differences in safety, purity or potency (effectiveness) compared to the reference product. These studies, whether conducted independently or combined, include:
  - Pharmacokinetic and, if needed, pharmacodynamic studies.
  - Immunogenicity assessment.
  - Additional clinical studies as needed.

A biosimilar is approved by FDA after rigorous evaluation and testing by the applicant:

The rapidly evolving biosimilars market can be confusing. Be sure to see "Where Do I Start?" on page 13.

- Prescribers and patients should have no concerns about using these medications instead of reference products because biosimilars:
  - Meet FDA's rigorous standards for approval.
  - Are manufactured in FDA-licensed facilities.
  - Are tracked as part of post-market surveillance to ensure continued safety.

Generally, a biosimilar is like a lower-cost generic version of a patented/branded drug. Unlike the branded product, biosimilars are not usually accompanied by rebates, due to their competitive pricing. The chart on the next page compares the regulatory requirements for generics and biosimilars.

If vendor partners say the price of these products is higher than the reference (branded/patented) drug, ask why. It doesn't make economic sense to manufacture a biosimilar drug and charge more for it when competition between drugs is no longer stifled by patent protection.

PARAMETERS	GENERICS	BIOSIMILAR
Drug characteristics	▶ Small molecules (< 5kDa) ▶ Low molecular weight and complexity	▶ Complex macromolecules (5 kDa - 500 kDa) ▶ High molecular weight, complex 3-D structure
Manufacturing process	▶ Type of production: Chemical synthesis, simple microbial fermentations or simple analytical process ▶ Not very sensitive to production process changes ▶ Reproducibility is easy to establish ▶ Very low manufacturing cost	▶ Type of production: Genetically modifies cell lines, fermentation and purification complex procedures, or complex analytical methods ▶ Reproducibility is difficult to establish relative to generics; however, less difficult compared with originators ▶ Sensitive to production process changes and manufacturing changes ▶ High manufacturing cost
Non-clinical development	None	▶ In-vitro/in-vivo comparative assays, pharmacokinetic/pharmacodynamic analysis, immunogenicity and toxicity
Clinical studies	Limited clinical activities, often only Phase I trials	Only Phase I and III trials required excluding Phase II studies, however, pharmacovigilance and periodic safety updates after launch are needed
No. of patients	20–50 patients	~500 patients
Time to market	2–3 years	7–8 years
Development costs	US$ 2–3 million	US$100–150 million
Success probability	90–99%	50%
Regulatory process requirements	▶ To be approved as a generic, a drug must have the same active ingredient, strength, dosage form, and route of administration as the reference drug; furthermore, it needs to demonstrate bioequivalence with the reference medicinal product through appropriate bioavailability studies ▶ Automatic substitution allowed ▶ Abbreviated registration procedures in EU and US	▶ Biologics Price Competition and Innovation Act, 2009 in the US: • II dimensions of approval: biosimilarity and interchangeability • Market exclusivity for reference product for 12 years • Market exclusivity for first biosimilar product for 12 months for interchangeable product only • Interchangeable product can be substituted without authorization from healthcare providers ▶ Regulatory pathway is defined in the US ▶ Automatic substitution intended if there is interchangeability ▶ Needs to demonstrate “comparability”

Courtesy of EY

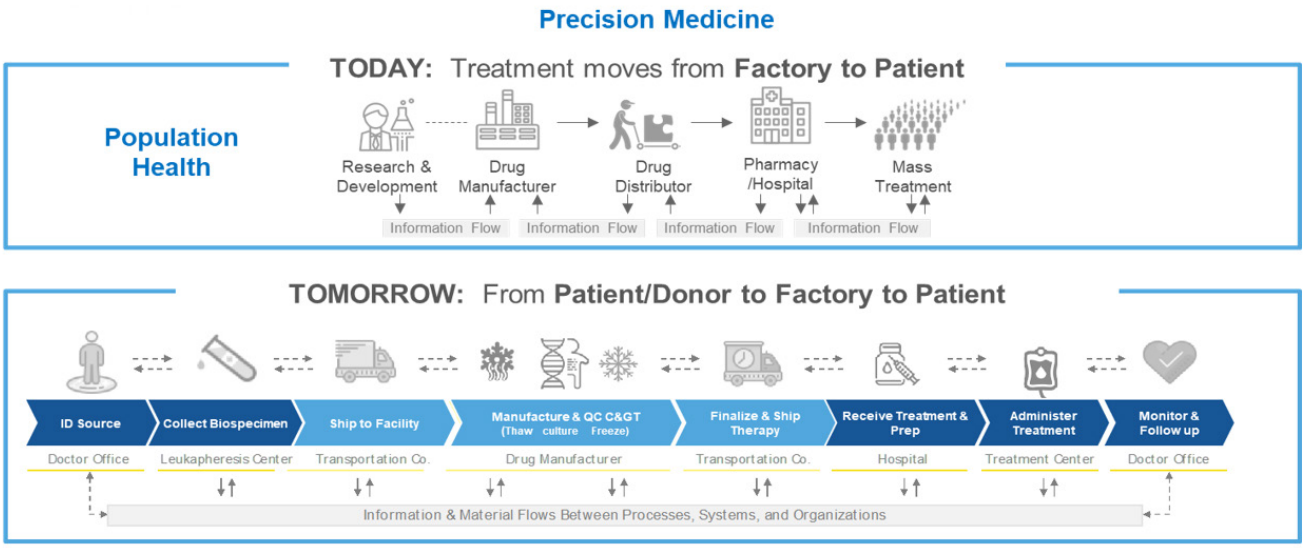
Drug Management Strategies: Key Areas to Address for Biosimilars

Plan Design

Most current plan designs for pharmacy coverage are simple three- or four-tier copay plans coupled with high deductibles. In earlier discussions, many employers indicated these are the designs consultants and pharmacy benefit managers (PBMs) promote. However, employers can reshape these designs to better fit workforce needs, making any changes the data suggests will improve health outcomes.

Including biosimilar and cell and gene therapies in a benefit plan is not difficult. Every organization must consider the coverage and cost-sharing that will work sustainably in its particular circumstances. It is generally advisable to include biosimilars and cell and gene therapies as covered benefits for several reasons beyond cost.

These treatments undergo higher clinical scrutiny and demonstrate greater efficacy than standard medications. They are subject to intense review in clinical trials because of their potential to harm a patient, and they often are used to treat serious and rare diseases and conditions. Rather than addressing general population health, these drugs and therapies are part of the expansion of "precision medicine."



Courtesy of EY

Patients generally are not prescribed biologic or biosimilar treatments unless they face chronic, serious or life-threatening—and high-cost—conditions. So excluding these drugs from benefits coverage undermines the best interest of both patients and plan sponsors. Diseases targeted by biosimilars include rheumatoid arthritis, multiple sclerosis, Crohn's disease, ankylosing spondylitis, ulcerative colitis, hemophilia, cancer, and diabetes.

Some patients who are prescribed these treatments may be on their way to becoming, or have already become, disabled and are frequently absent or on short- or long-term disability. Monitoring their progress to ensure they receive needed care is imperative for managing costs and improving outcomes, including reducing the risk of complications, hospitalizations, readmissions and other costly health events. Limiting coverage for biosimilars or cell and gene therapies can create unintended consequences if patients are left to seek alternative, sub-optimal care. Removing barriers to sometimes costly optimal care will benefit patients and plan sponsors over time.

Suggested Strategies for Plan Design

- Implement an overall plan design that minimizes member disruption, limiting changes or grandfathering a current member's treatment cycle.
- Ensure the plan design reflects a value-based approach that includes strategies to improve high-value care. Evaluate financial tradeoffs.
- Develop a strategy for each drug class, considering market dynamics and the treatment situation. Ensure that plans communicate with physicians and members.
- Review copay tiers, consider strategies that limit a patient's cost, and use coinsurance or cap the out-of-pocket (OOP) maximum by therapy class, as well as copays/coinsurance based on drug/therapy class/high-value products.
- Carve out specialty drugs.
- Identify separate strategies for cell and gene therapies.

"Companies are spending more on employees' health insurance than ever before, and biosimilars are safe and effective treatment options to lower the cost of prescription drugs if they are accessible to the patients who need them. We urge employers to implement recommendations from this playbook and work with their PBMs to ensure their employees have access to lower cost biosimilars and are educated about them."

— JULIANA M. REED
Executive Director, The Biosimilars Forum

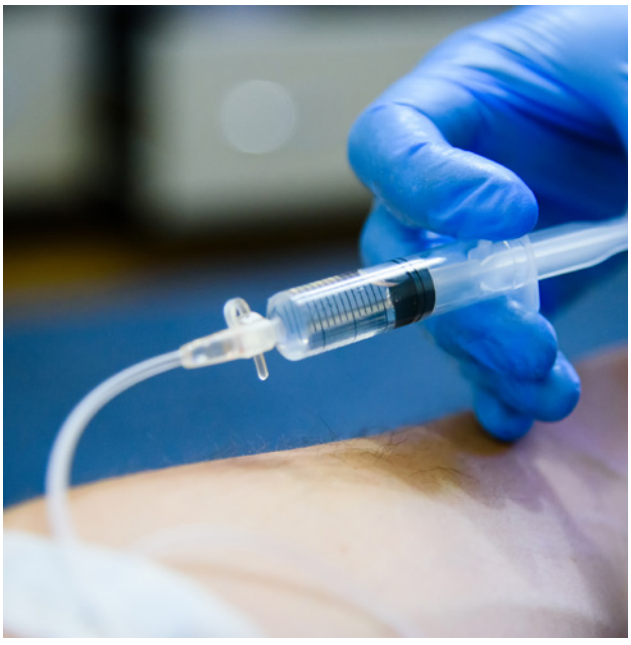
Formulary Design

Most employers cover the broad range of specialty medications approved by the FDA. Including biosimilars on the formulary should be a part of this approach.

- Biosimilars should be treated like generic drug products, not specialty products, even though they treat conditions managed by specialists. (See "Drug Pricing and Rebates" below and "How Rebates Distort Drug Prices" on page 19 for an explanation of the impact rebates have on formulary design.)
- Ensuring biosimilars are included on the drug formulary creates better access for patients, as they don't need to shop around for alternate drugs, and doctors can prescribe the most effective therapy.
- Excluding biosimilars or creating step therapy requirements creates a barrier to treatment and may result in costly unintended consequences, such as further progression of the disease, hospitalizations, disability, absence from work, or even early death.

Suggested Strategies for Formulary Design

- Consider a custom formulary design and targeted utilization management, either from administrative services only (ASO) or from a third party.
- Request an audit of the current formulary and a utilization review that includes an inpatient/outpatient drug cost comparison.
- Take control of formulary management and implement a formulary that is not rebate-driven.
- Require that all new biosimilar releases be placed in the generic tier of the formulary.
- When a new biologic comes to market, ask the ASO:
  - What is the value/logic/reasoning for or against its inclusion on the formulary and at the tier selected? Is price/cost a factor in the decision?
  - How will this affect the current formulary for drugs in the same class?
  - Will patients on a drug in the same class know about this change? If so, how? Will they be required to switch to the new drug?



Drug Pricing and Rebates

Even with biosimilars costing up to 30% less than the branded/reference product, plan sponsors are often told by PBMs and health plans that adopting biosimilars would result in a cost *increase*, due to the loss of rebates on the branded product. These economics are controversial for many reasons, and not every branded product offers rebates.

- It is a common practice by PBMs to spread rebate dollars from a specific brand manufacturer across all the branded products in the therapy class to subsidize them and to show an employer a "lower" brand price.
- These practices are under significant scrutiny by legislators at the state and federal levels and are not sustainable.

With the looming threat of a ban on rebates, plan sponsors are encouraged to investigate the use of net unit prices, rather than relying on rebates to cover costs. Rebates are unreliable and counting on them for cost savings creates a dependency on dollars that may not be available in the future.

- It is prudent to ask PBMs and health plans to show net unit prices without rebates to clarify the exact cost, rather than relying on retrospective payment information.
- Using actual drug prices to make decisions is reliable and creates an expectation that PBMs and health plans will deliver the lowest price—not the lowest subsidized price, which varies and can be manipulated.

"We've been told that adopting biosimilars can result in higher costs due to the loss of rebates. It was troubling to learn this is false!"

— LEARNING COLLABORATIVE PARTICIPANT

Suggested Strategies for Drug Pricing and Rebates

- Understand how rebates impact overall drug pricing and assess how they are positioned in the plan design. Work with an objective consultant to determine the best approach.
- Adopt a strategy to ensure the lowest net cost—without rebates—or consider a phased approach that reduces (or eliminates) rebates and other non-transparent credits or incentives.
- Ensure lower costs by posing tough questions to benefit consultants, plans and PBMs.
- Implement best practices for transparent contracting, consider hiring an expert independent pharmacy consultant, and require full pass-through in contracts.
- Do not be lured into 340B pricing plans. If wage-band health plan differentials are being explored, only consider 340B pricing for low-wage earners.
- Start over with a transparent or pass-through PBM, if necessary.

Drug Access and Availability

- The key to improving biosimilar adoption is to include all biosimilars on the formulary at the time of their launch and to avoid access barriers. Since these products are the same as the branded reference product, it makes no sense to exclude them. A better strategy may be to make them "preferred" over the brand.
- Like generics, biosimilar products are substitutes. Creating a preference in the plan design will increase adoption.
- Utilization tactics like step edits and pre-authorizations need to be revisited, too, since many biosimilar products are prescribed for serious conditions, so a delay in therapy can result in further declining health.
- Although specialty and infusion products are expensive, their unit costs pale in comparison to the medical costs incurred when treatment is delayed. Resulting expenses are hidden in the medical benefit and are not easily connected to denied or delayed prescriptions.
- Employers need to consider whether specialty pharmacy networks have easy access to the biosimilar, as these drugs are not always available without advance notice, so prescriptions may take a few days to fill.
- Many commonly prescribed biosimilars are infusible or injectable and require special transportation and storage, another reason they are not always immediately available, especially in rural locations.

Suggested Strategies for Drug Access and Availability

- Include all biosimilars on the formulary; when multiple biosimilars are available, providers might find it cost prohibitive to inventory all of them.
- Offer incentives for the use of all biosimilars in the same drug class over the reference product.
- Carve out specialty drugs and/or biosimilars with a specialty PBM or pharmacy if that option provides better outcomes.

"We have a better understanding of the 'high cost of misalignment' if we don't take action. It is important for us to continuously evaluate our vendor partners to ensure they are working on our behalf."

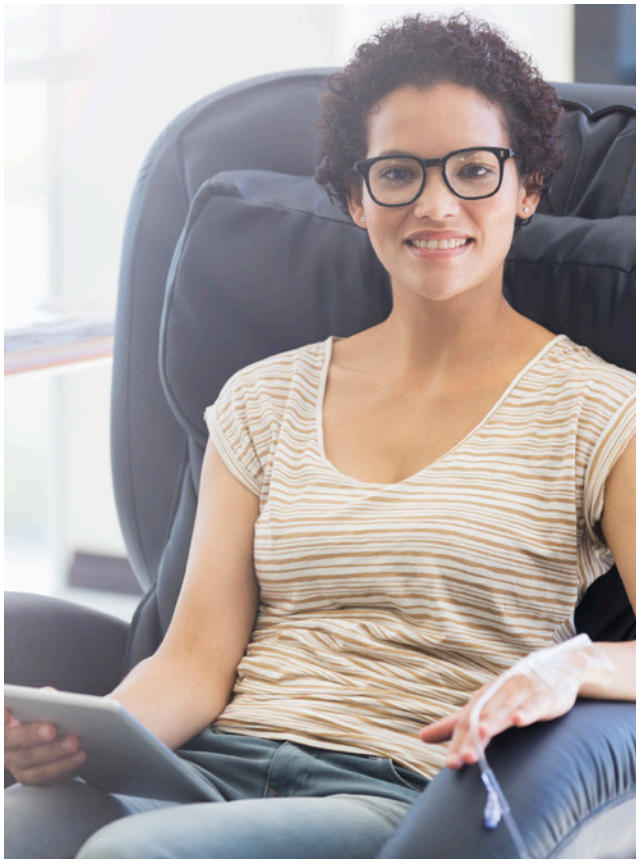
— LEARNING COLLABORATIVE PARTICIPANT

Sites of Care and Drug Administration

Because many biosimilars are infusible or injectable, there are associated costs for administration. It is crucial that employers steer patients to the lowest-cost setting for administration. Physicians often administer the drugs themselves or steer patients to an affiliated facility to capture revenue. These costs are not reflected in the pharmacy benefit, as they are billed and paid for under the medical benefit, masking the true cost of treatment.

Of course, exceptions must be made for products requiring a sterile or hospital environment, but a review of all drug-administration sites covered under the benefit plan helps create a tiered preference that lowers overall site-of-care and facility charges, as well as benefit plan costs.

The key is to encourage a shared decision-making process in which patients receive care at low-cost, high-quality sites.



Suggested Strategies for Sites of Care and Drug Administration

- Understand current health plan and PBM approaches to sites of care and drug administration.
- Consider preferred or tiered sites of care; for employers with on-site/near-site/shared-site clinics, consider on-site infusion.
- Anticipate advances in drug delivery, such as infusion or ports replacing pills, by including those options in plan designs.
- Collaborate with local health systems to identify high-value sites of care.

What Employers are doing as a Result of the Learning Collaborative

- Reviewing their data and targeting implementation for the 2023–2024 plan year.
- Exploring saving opportunities with specialty medication carve-out.
- Including the adoption of biosimilars in performance guarantees.
- Considering making biosimilars "preferred" over the brand—but confirming their availability.
- Engaging an objective pharmaceutical consultant to conduct an audit/review of prescription drug strategies, including identifying key biosimilar opportunities.
- Developing value/outcomes-based contracts that include biosimilars.
- Engaging PBMs to discuss a Humira strategy—and determining how to have biosimilars on formulary.
- Determining whether PBMs are receiving credits, incentives, discounts and/or rebates from biosimilar companies—and ensuring those will be passed on to the employer or the patient. One of the top concerns from employers is the affordability and access to biosimilars if secret agreements related to incentives, discounts and/or rebates are used to influence formulary and drug placement by PBMs.
- Implementing communication programs to increase understanding and encourage the use of biosimilars.

An Employer's Checklist to Address Biosimilars

See quick-start guide on page 13

General Pharmacy Benefit Considerations

- Once a year, review PBM contracts and vendors against performance guarantees and savings commitments. Ask for reports that measure savings from the beginning of the plan year.
- Ask your broker or pharmacy consultant to provide an update on drug company pipelines and new drug launches to determine whether new market releases will have an impact on prescriptions and prices.
- Ask for an annual market price check on all generics, using cash-pay pharmacy and other public-domain price data (e.g., Medicare/government best price) to see whether generic products would be cheaper if purchased directly with cash.
- Assess whether drug copays are reasonable, given generic cash-price levels.
- For branded drugs, including high-cost specialty and new biologics, ask for a report that shows plan utilization and prices for the most widely prescribed and highest-cost products. Ask your PBM and pharmacy consultant to do a general market benchmarking on prices.
- Evaluate quality and cost-effectiveness by reviewing publications from independent sources (i.e., ICER Press Releases | News & Insights | ICER).

Targeted Biosimilar Strategies and Considerations

- Use an independent data analytics company or request that consultants or health plans provide monthly reports to assist with monitoring and verifying drug utilization (i.e., switching, site of care), pricing, network access, and patient behavior.
- Outline a strategy that addresses pharmacy spending through the medical and PBM benefit. Evaluate medical claims separately for drug charges related to inpatient confinements for patients already on a specialty medication or those who get a new prescription because of a hospitalization; compare the price (where available) to the outpatient or cash price.
- Contract with an independent specialty pharmacy management vendor that may be better equipped to dispense specialty biosimilars and manage complex patient care. These pharmacies often buy directly from pharmaceutical companies and sometimes have better pricing.
- Determine the most cost-effective site-of-care options for patients (e.g., contracting directly with infusion center networks to eliminate access barriers and lower costs).
- Consider fixed-unit price (net price after rebates) bidding for the top specialty drugs, instead of aggregate pricing with discounts (across the entire therapy class) to avoid enabling PBM revenue streams.
- Review PBM and third-party administrator (TPA) strategy and training guidelines on handling escalated member issues (i.e., supply delays) prior to the release of a potentially high-use biosimilar.

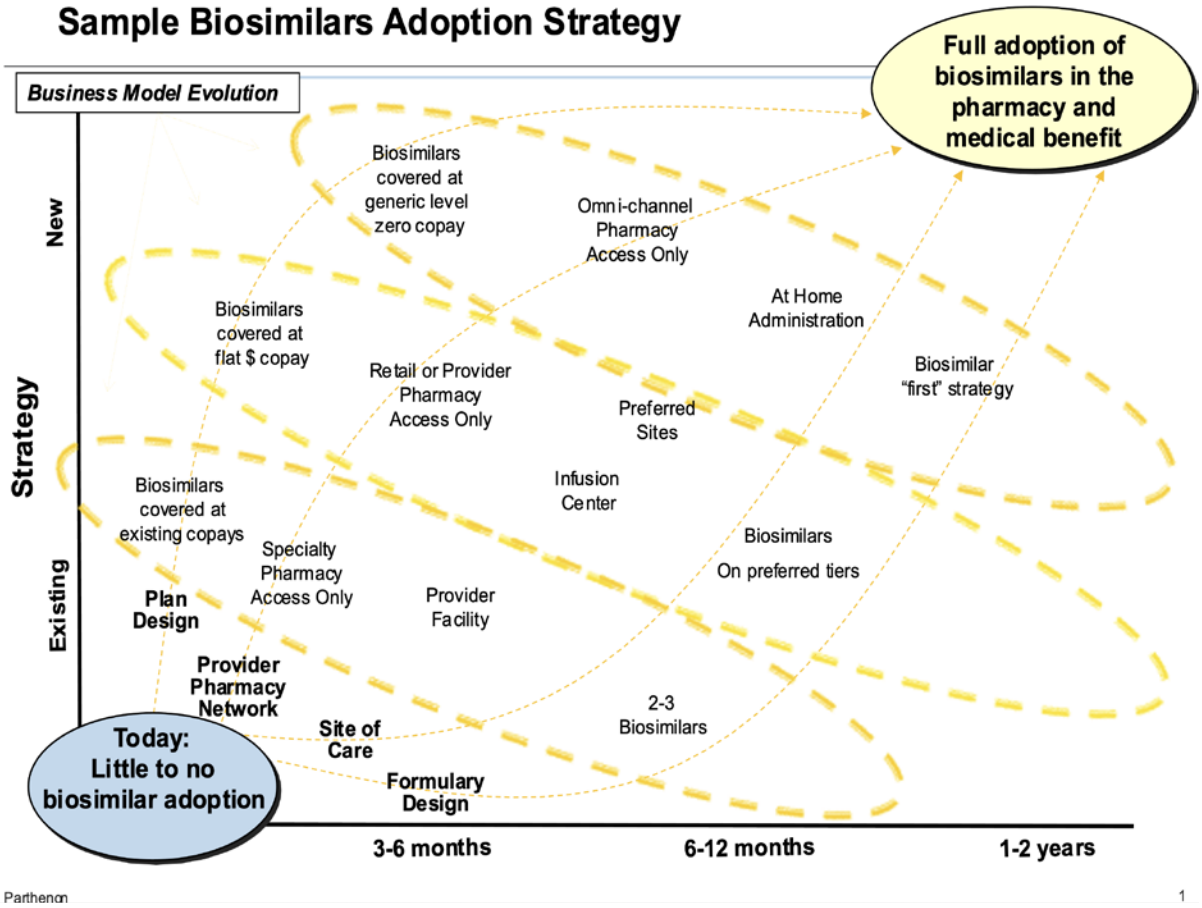
"There are several deceptive tactics being used to slow the adoption of biosimilars. This can have devastating repercussions to the longevity of biosimilars and the anticipated cost savings for patients and employers. Employers need to understand that this is happening and act against it."

Biosimilar Adoption Strategy

Biosimilar adoption first requires an understanding of the current list of products on the formulary, as well as drugs in the pipeline. Then, a general agreement can be forged among the employer, their health plan/PBMs, and other vendor partners to include biosimilars and associated treatment components (i.e., medical devices, sites of care, etc.) in the benefit plan—covered by both the pharmacy *and* the medical benefit.

It is important that employers/purchasers actively engage in the benefit design process to ensure that biosimilar products are:

- Included in the plan design as a preferred product on a generic-like tier.
- Listed on the formulary as a covered product.
- Affordable to patients with low or no copays.
- Available at pharmacies and providers or at preferred specialty pharmacies (if carved out).
- Dispensed or administered at the lowest-cost site (where necessary).
- Communicated in enrollment materials.



Where Do I Start?

A biosimilar strategy starts with a series of administrative actions:

- **Review the employer/purchaser landscape and reimbursement.** Work with PBMs and health plans to determine their biosimilar adoption strategy, when they plan to enter the market, and how they will improve access and affordability.

- **Identify appropriate patients.** Ask carriers to run reports on patients who are candidates for biosimilars to evaluate the savings.

- **Assess the payer formulary.** Determine which biosimilars are currently included on the formulary and request the adoption of a "biosimilar preferred" formulary (or create a custom/carved-out formulary).

- **Review billing requirements.** Determine whether pharmacies are changing their claim adjudication process, claim payments, and point-of-sale systems.

- **Evaluate health plan utilization management criteria.** Understand care barriers, whether they have a negative clinical impact on patient outcomes, and whether there is a true net savings for using management programs (e.g., step edits, pre-authorizations).

- **Research patient support programs.** Determine which patient support programs are offered by manufacturers. Don't dismiss available clinical support programs or patient copay assistance as "inducement." Specialty drugs are not discretionary medical treatment.

- **Develop a communication plan.** Work with vendors and PBMs to align communications with open enrollment periods. Notify affected patients about a potential switch to a biosimilar that has shown no clinically meaningful differences in terms of safety, purity and potency. Ensure appropriate communication with providers.

Sample Information Request

Employers need to understand their current adoption (utilization) of biosimilars, as well as the savings or costs. To do so, ask PBMs and health plans for a report with ***summary***-level information (no patient-level data) that includes the following variables:

- Total number of prescriptions (# of scripts) by drug (drug list with associated codes attached).
- Total average quantity (# days/units) per prescription, to get a sense of whether prescriptions are 30-, 60-, or 90-day.
- Total average unit cost (amount billed/paid) per prescription (use this information to identify high costs).
- Average employee/patient out-of-pocket cost (to analyze whether affordability is a barrier to care).

Employer Considerations for Contracting

- Obtain copies of third-party and vendor contracts from plan administrators/outsourcing vendors, insurance carriers/PBMs, and any consultants (including data analytics firms) to investigate potential savings.
- Look for language regarding data ownership and secure the rights to all data generated by the plan for any administration, including claim adjudication. Request all historical data, not just the current year.
- Look for language regarding service fees to avoid hidden fees and provisions that hinder cost recovery.
- Avoid conflicts of interest and provisions favoring the claims administrator or the carrier/PBM. Seek consultant/legal counsel for assistance.
- Proactively gather pricing and claims data from any medical plan/insurance carrier, TPA, PBM, and consultants.
- Submit a *demand letter* to your TPAs, PBMs, and consultants to receive all negotiated prices and claims data in your role as a plan fiduciary. Seek consultant/legal counsel for assistance.
- Engage a third party to reprice a year of medical and pharmacy claims data at Medicare rates.
- Engage a prescription analytics company to scrub pharmaceutical claims for potential savings. Identify and investigate overcharges, payment errors, and adjudication anomalies, then pursue recoveries.
- Renegotiate service provider contracts to align vendor performance with goals, or issue an RFP for new partners. For example, if a vendor promises savings, ask for a guarantee backed by a penalty if they fail to deliver.
- Eliminate middle players by contracting directly for fairly priced, high-quality hospitals, drugs and providers. Smaller companies can solicit other employers to participate in a group contract to gain leverage through the larger scale of an employer coalition.
- Implement a fair, transparent, reference-based pricing model; agree to pay a percentage of Medicare rates.
- Consider centers of excellence, steering employees to high-quality, lower-price providers.
- Implement a transparent, pass-through pharmacy benefit, carved out of the medical benefit. Companies like Navitus, WellDyne, GoGoMeds, and other cash-pay pharmacies for generics are many times cheaper than PBMs.
- Manage the drug formulary using waste-free drug designs, biosimilars, and single-source generic drugs (generic versions for which a manufacturer has the sole production rights for anywhere from six months to one year).
- Provide advanced primary care to lower plan costs and improve health outcomes.
- Update all plan documents and benefit designs to safeguard the purchaser's fiduciary role and eliminate non-value-added programs.
- Avoid independent foundational programs that add intermediaries for a fee, tapping funds meant for patients. (See "Patient Assistance Programs" below.)
- Biosimliar companies will likely offer patient assistance programs or copay assistance, but the extent of the program may differ from that of the originator.

Evaluate the total net cost of each drug before making changes. Companies with reference products will likely offer significant incentives to maintain market share, including increasing patient assistance programs.

Patient Assistance Programs

- Watch out for the many emerging independent foundational programs. Many of these models exploit foundational funding meant for patients with organizations collecting a fee to administer the program on behalf of the patient.
- Biosimilar companies are unlikely to offer patient assistance programs or copay assistance because, in theory, they already offer the lowest price.
- The companies with reference products will likely offer significant incentives, such as increased patient assistance programs, to keep market share, so always evaluate the total net cost of the drug before making changes.

Engaging PBMs: Point/Counterpoint

For each bolded statement below (usually what a PBM presents as a reason for *not* offering a biosimilar), the employer can ask the "counterpoint" questions that follow to clarify the facts and address issues of access, availability, etc.

Adopting biosimilars will result in a loss of rebates and a higher cost for the employer.

- The market suggests the biosimilar should cost approximately 30% less than the branded reference product. Why would it cost more?
- Are the rebates I am receiving greater than 30% of the branded price on the reference product?
- Are the rebates you receive for branded reference products subsidizing other drugs in the same therapy class or subsidizing rebate guarantees for other clients?

Switching patients from the branded reference product to a biosimilar will result in adverse outcomes.

- The FDA requires that a biosimilar, like other generic drugs, be held to the same quality, safety and efficacy standards as the branded reference product. Why would there be any potential for an adverse clinical outcome?
- If the switch is managed by a licensed provider (e.g., physician, specialist or pharmacist), don't they have protocols to ensure the patient is protected from any potential negative outcome? If not, does

your plan hold your provider network accountable for patient management, using leading clinical practices as their standard? If not, why not?

Patients will have to undergo step therapy or pre-authorization to switch to the biosimilar.

- These products are identical to the branded reference product. Why would the patient need to repeat any screening if they have already been approved for the existing product?
- For patients new to therapy, what barriers are we creating and what purpose do they serve? Would these prequalification processes require anything new from the patient and provider, and if so, why?

Pharmacies don't have access or inventory to dispense biosimilars, or you have to use OUR specialty pharmacy.

- Licensed pharmacies are protected by the "any willing provider" law and are permitted to order and dispense all products, if they follow safety guidelines and federal laws. Why would there be any issue with them getting inventory?
- Even if they experience a short delay in stocking the biosimilar, the pharmacies in our network can buy directly from the manufacturer or a wholesaler. Why wouldn't you facilitate that process? Why do I need to use your specialty pharmacy if I already have a network?
- Is there an additional cost to use your specialty pharmacy, and if so, why?

We can't add the biosimilar to the formulary unless you pay for a custom formulary, or we have elected not to cover this biosimilar.

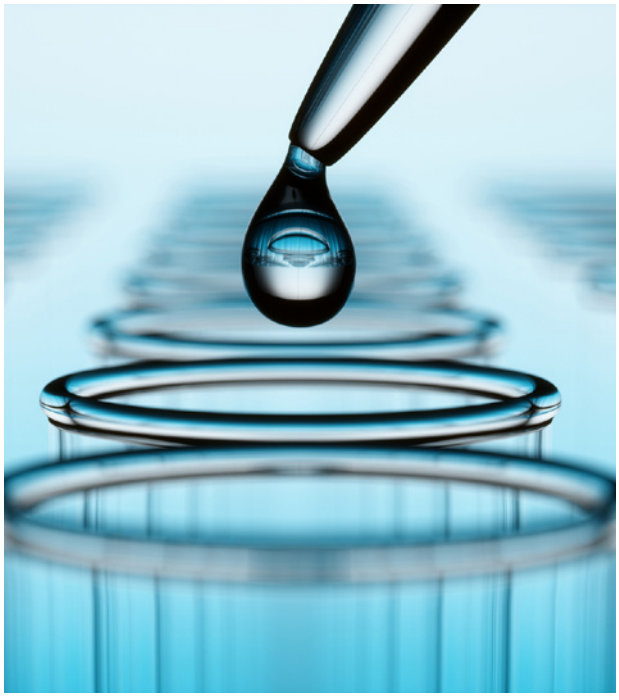
- What criteria did you use to determine not to cover a particular biosimilar?
- Why would I have to pay extra to include a product on a formulary that already covers 2,000–10,000 licensed and FDA-approved drugs? Surely one more drug isn't going to necessitate any special internal administrative changes?

Patients/employees will have a larger out-of-pocket cost.

- If these products are generic versions of the branded reference product, and they are lower priced, why should the patient/employee have a greater out-of-pocket expense if my plan design is not changing?
- Isn't the adjudication process the same for a biosimilar, and if not, why not?
- Are pharmacies charging different dispensing fees for biosimilars than for the reference product, and if so, why would you permit that?

Providers/prescribers may prefer the patient come to their office for infusions.

- If a provider is part of a specialty group or the patient's condition requires physician supervision, infusions and injections may be better suited to their office.
- Many providers are now stocking, dispensing, and administering these products directly from their practice.



Strategies and Considerations to Address Humira®

What's Likely to Happen

Following its loss of Humira's patent protection in 2023, AbbVie will try to retain market share by increasing rebates to PBMs in an attempt to remain at parity on their formularies with the new biosimilars entering the market. Current rebates are estimated to be at 40% of wholesale acquisition cost (WAC), but industry insiders think those rebates may increase to 50–60%.

Biosimilars will enter the market without rebates potentially at a 30% lower wholesale price, but their net price may remain higher than Humira until they gain market share. It may be cheaper for employers to continue Humira, as those rebates subsidize the entire therapy class of drugs; the net cost of Humira may be below the cost of the biosimilar, once you factor in the copay and other patient-assistance dollars. Keep in mind that these rebates may decline over time. Worse, if biosimilars fail to gain sufficient market share, their manufacturers may exit the market. In the absence of competition, AbbVie could then increase the price of Humira, even without patient protection.

"Employers are encouraged to ask their PBM about their formulary strategy for biosimilars and managing patients already on the drug. This includes asking about if credits, incentives, discounts and/or rebates from biosimilar companies will be passed on to the employer or the patient."

— NATIONAL ALLIANCE PROJECT TEAM

Humira Biosimilar Considerations

- Humira has lost its patent protection, so as many as three drug manufacturers may soon launch competing biosimilars.
- PBMs have said they will keep Humira on their formularies and add eligible biosimilars. AbbVie has indicated it will continue to pay rebates to maintain preferred formulary placement.
- New biosimilar companies will be:
  - Prospecting physicians to encourage them to switch patients from Humira to their product and to write new prescriptions for patients currently on other products who might now be able to afford this drug.
  - Approaching PBMs and health insurance companies to have their products added to formularies and offering credits, incentives, discounts, rebates, patient assistance, and copay discount cards to gain market access.
  - Advertising directly to patients, encouraging them to ask their providers about the new drugs.

POTENTIAL ACTION: *Ask your PBM what their formulary strategy is and how they will treat Humira biosimilars and manage patients already on the drug. Also ask whether they are receiving credits, incentives, discounts and/or rebates from biosimilar companies; ensure those will be passed on to the employer or the patient.*

Humira Biosimilar Considerations: Patients

- Patients on Humira may be switched to a biosimilar:
  - Some PBMs may require a switch if they make biosimilars preferred on the formulary.
  - Some providers may encourage the switch to a biosimilar, while others who want their patients to stay on Humira may use a "DAW" (dispense as written) prescription.
  - Patients new to therapy may also drive new prescriptions to biosimilars.

POTENTIAL ACTION: *Communicate to your employees that Humira will face competition from newly launched—and equally effective—biosimilars. Inform patients already on Humira that their provider may discuss a switch with them. If you are changing your formulary to prefer the biosimilar, alert patients that they may be switched.*

Humira Biosimilar Considerations: Ecosystem

- Wholesalers/distributors, hospitals/providers, and pharmacies will need to stock a sufficient inventory of new biosimilars, as some products require special handling and refrigeration.
- Insurance companies/PBMs, hospitals/providers, and pharmacies may try to steer patients to their network facilities or offices for injections and self-injection training if the volume of patients increases.
- Pharmacies presented with new prescriptions will have to review coverage/formulary rules and employer/plan sponsor plan designs to determine whether to dispense the new products. Pharmacies are also likely to steer patients to their own injection-training or infusion services.

POTENTIAL ACTION: *Discuss your network strategy and plan design with your vendors to ensure your employees are able to fill prescriptions everywhere you require. If you want to save money by switching your patients to biosimilars, require your PBMs to prefer them on the formulary and make sure your pharmacy networks stock them.*

How Rebates Distort Drug Prices

Company A offers a drug at a $100 price, with a rebate at the end of the year based on the revenue the company achieves:

- **A 60% rebate for revenue of $X.**
- **A 50% rebate for revenue of $Y.**
- **A 40% rebate for revenue of $Z.**

The process is opaque.

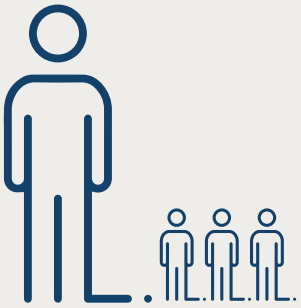
Company A never reveals what percentage of the revenue target they achieved for the year, only that rebate thresholds are based on annual sales.

Company B offers its drug at an upfront cost of $50 without rebates, because it offers the lowest price and has no patent to protect its market share.

Which do you choose?

If you don't take the offer from company A, you could miss out on a $60 rebate and a $40 final cost, which is less than Company B charges.

However, if Company A misses their revenue target, your rebate can be as low as 40%, which means you ended up paying $60 for the drug after the year-end rebate.



Most employers pick Company A and bet everyone else will, too, so Company A will meet its highest revenue target and employers will get the maximum rebate. The consequence of this action is that Company B goes out of business, so now Company A, with no competition, the next year raises its drug price to $120.

This example shows why drug prices keep rising year after year. **There's not enough competition.**

Now imagine a rebate broker negotiates that rebate for you for a fee; the broker pockets a percentage. That's what a PBM does. The more drugs sold, the more money the manufacturer makes, and the more the PBM keeps.

To further increase the likelihood of their rebate share, PBMs get to decide which drugs they add to the formulary. PBMs try to offer at least three products for each medical condition, whenever there are at least three competitors. The PBMs claim to want more competition, so they can play the drug companies against each other and drive overall prices lower. But being able to pocket a portion of the rebates makes it difficult for them to be objective.

Resources

Understanding Biosimilars

- Improving Drug Management: Employer Strategies on Biosimilars, 2022 | National Alliance
- Biosimilar Basics | Biosimilars Forum
- Overview of Biosimilar Products | FDA —Offers an overview of biosimilar products, including benefits/risks, approval process, and interchangeability.
- Biosimilar Product Information | FDA —Up-to-date list of FDA-approved biosimilar products.
- Case Study: Biosimilars 101 Webinar | Biosimilars Forum
- Awareness, Knowledge & Perceptions of Biosimilars among Specialty Physicians | Biosimilars Forum

The Economics of Biosimilars

- Biosimilars: An Obvious Solution for Lowering Medicare Part D Healthcare Costs | Biosimilars Forum
- Biosimilar Forum Review of PBM Business Practices| Biosimilars Forum—Offers a perspective on the various practices of PBMs and the impact of these practices on pharmacies and consumers.
- Biosimilars: Key regulatory considerations and similarity assessment tools | NIH Review
- Humira® Biosimilars: Reaching the Market's Cost Savings Potential | Biosimilars Forum
- Infographic: Biosimilars Economic Impact by State | Biosimilars Forum
- Saving Billions on Healthcare Costs with Biosimilars | Biosimilars Forum

Biosimilars in the News

- Arthritis Top-Seller Humira Set for U.S. Rival After $193 Billion in Sales (ABBV) | Bloomberg
- Cigna's PBM Express Scripts Latest To Put Less Pricey Biosimilars Of Abbvie's Humira On Preferred Drug List | Forbes
- FDA approves first interchangeable biosimilar insulin | Healio.com
- OptumRx to Cover Biosimilars for Humira | Modern Healthcare
- UnitedHealth To Keep AbbVie's Humira Drug Available As Biosimilar Sales Start | Bloomberg

About National Alliance

The National Alliance of Healthcare Purchaser Coalitions (National Alliance) is the only nonprofit, purchaser-led organization with a national and regional structure dedicated to driving health and healthcare value across the country. Its members represent private and public sector, nonprofit, and Taft-Hartley organizations, and more than 45 million Americans spending over $300 billion annually on healthcare. Visit nationalalliancehealth.org, and connect with us on Twitter and LinkedIn.

Project Team

Margaret Rehayem, *Project Lead*

Margaret Rehayem is vice president of the National Alliance and provides leadership for national initiatives that support member collaboration, helping coalitions leverage their regional efforts at the national level to drive health, equity and value for organizations and communities across the country. Her focus has been on health and well-being, continuous improvement frameworks, multi-stakeholder collaboratives, and the development of strategies that support system and delivery reform. With more than 20 years of experience working with employers in various areas, including overall healthcare strategic planning, Margaret oversees several grant activities in conjunction with national funding organizations such as the CDC Foundation and PCORI. She helps drive the direction of the organization's National Health Leadership Council and engages with employers through the National Purchaser Leadership Council (NPLC). Margaret is a national speaker on healthcare topics, including business performance and leadership, health benefits, medical and pharmacy drugs, biosimilars, employee engagement, organizational culture, and the impact of health and well-being on organizations.

Alex Jung, *Facilitator*

Alex Jung is a former partner at EY Parthenon and is known as an expert on business strategy and economic modeling. She has more than 30 years of experience with strategic growth and risk mitigation and has developed corporate and growth strategies for several Fortune 500 companies, including the top healthcare payers, PBMs, pharmaceutical companies, and pharmacies. Additionally, she has worked with major private equity firms on their portfolio mergers and acquisition strategy and commercial due diligence. She is a regular speaker at events such as the JPMorgan Annual Healthcare Conference, BIO and BIO International, ASCO, AHIP, Assembia, OPPM of India, World Healthcare Congress, Crain's Annual Health Care Conference, and Northwestern and Yale Universities' annual Healthcare Conferences. She has been quoted in numerous articles in Kennedy Research, Forrester, *Forbes, The Chicago Tribune, Business Insurance, Workforce, Crain's Chicago Business,* and other industry publications.

Christina Bell

Christina Bell is director of healthcare strategy at the National Alliance, with 15-plus years of experience focusing on program and project administration in a healthcare environment. She leads strategic initiatives that address healthcare system challenges, issues and opportunities in delivery and system reform, health equity, and total person health and well-being. As a former vice president of the Pittsburgh Business Group on Health (PBGH), Christina held responsibilities for implementing of PBGH's overall strategic direction. She served as the architect for educational programming, projects and business development framework to improve understanding and aid decision-making about

equitable access, healthcare quality, cost containment, and employer choice in the PBGH market region and nationally. Christina serves on the PCORI HIIP Advisory Board, Heinz Endowment Economic Security Investment Advisory Council, and the Professional Women's Network Advisory Board.

She is a Certified Project Management Professional (PMP) and a Certified Health Value Advisor, and she holds a bachelor's degree in public administration and a master's degree in health administration.

Amanda Green

Amanda Green is the National Alliance's manager of healthcare initiatives and is responsible for supporting strategic initiatives that address issues and opportunities in health system reform and health and well-being.

Amanda's work has been published in several healthcare journals, notably the *Journal of Managed Care Pharmacy*. Before joining the National Alliance, Amanda was a research associate at the National Pharmaceutical Council (NPC). In this role, she was responsible for leading and supporting research projects related to the essential role of biopharmaceuticals in the healthcare delivery system. She also worked for the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, in the Epidemiology Workforce Branch and gained community-based intervention experience working at the Florida Department of Health.

She holds a master's of science in public health from the University of Miami Miller School of Medicine, and dual bachelor's degrees in public health and international relations from the University of Miami.

Participating Coalitions

Economic Alliance for Michigan: EAM comprises businesses and labor organizations representing more than 900,000 covered lives working together and serving as a trusted source for employers and health benefit professionals who are searching for solutions to better manage the costs of benefits and provide access to quality care to their covered populations. Contact: Bret Jackson, president; website: eamonline.org

Florida Alliance for Healthcare Value: The Florida Alliance is an employer-led research and education organization that brings together benefits leaders and healthcare stakeholders to develop and implement innovative improvements in healthcare cost, quality, transparency and safety in Florida. Contact: Karen van Caulil, PhD, president & CEO, Ashley Tait-Dinger, vice president; website: flhealthvalue.org

Washington Health Alliance: The Washington Health Alliance leads health system improvement, bringing together those who get, give and pay for healthcare to create a high-quality, affordable system for the people of Washington state. Contact: Denise Giambalvo, Director, Member Engagement & Business Strategy; website: wahealthalliance.org

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