

Part III: The Biden Administration, US Healthcare and the Next 4 Years Supplemental materials



February 2021

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# Providers are likely to face continued reimbursement pressure and incentives to deliver value, but could benefit from policies aimed at improving access to care

DIRECTIONAL **Providers Provider impacts** Hospitals Physician groups Government preparation for the next Protect future procedure volumes via access to PPE/related resources infectious disease event Reversing Trump exec. orders on ACA and Limited expected impact women's health Increasing access to telehealth/behavioral Increased payments per patient for telehealth and behavioral health Policy developments during health a Biden administration are Larger providers with the capability to track costs and outcomes are most likely to lead to: Supporting value-based innovation better positioned to benefit Lower reimbursement Lowering prescription drug prices Depends on if extended to Part B drugs per unit volume Lower reimbursement due to price competition, particularly for providers Increasing healthcare price transparency or systems providing "shoppable" procedures such as MRIs, etc. Greater focus on valuebased care **Enabling importation of FDA-approved** Limited expected impact foreign drugs Shift toward digitally Increased healthcare antitrust scrutiny Limits on mergers are expected to increase health system competition enabled access points (e.g., telehealth and Depends on if extended to all persons 60+ (reduced reimbursement) or Lower Medicare age to 60 only uninsured/Medicaid beneficiaries (reduced uncompensated care) virtual care enablement) Public option + ACA subsidy financial Increased coverage could reduce prevalence of uncompensated care support ACA invalidation Reduced coverage could lead to increases in uncompensated care Positive Net stakeholder impact Negative Neutral © 2021 L.E.K. Consulting LLC

## Providers should prioritize efforts to shift to lower-cost sites of care and develop internal infrastructure to support patient-centered models of care

**Providers** 

DIRECTIONAL

#### Strategic priorities

### **Policy implications**



Lower reimbursement per unit volume

- ✓ Lower total cost of care by developing office-based alternatives to Hospital Outpatient Department care, and be price competitive where price transparency is mandated
- ✓ Counter revenue declines by **expanding attractive services or service lines** including, but not limited to, telehealth and behavioral health



Greater focus on valuebased care  Adopt evidence-based protocols to reduce clinical variation, and measure patient experience and outcomes to enable value-based contracting (VBC)



Shift toward digitally enabled access points

- ✓ Develop telehealth infrastructure or partner with leading platform vendors
- ✓ Double down on **expanding behavioral health services**, which are expected to get increased attention and reimbursement

### Downward pressures on reimbursement that are expected to challenge providers are conversely expected to benefit commercial payers

DIRECTIONAL Commercial payers **Commercial payer impacts** Government preparation for the next Limited additional impact infectious disease event Executive orders may require coverage of additional services but overall Reversing Trump exec. orders on ACA and are expected to stabilize individual marketplaces women's health Increasing access to telehealth/behavioral Expected to require reimbursement for additional services such as Policy developments during health payment parity for telehealth and behavioral health services a Biden administration are most likely to lead to: Supporting value-based innovation Value-based innovation is expected to lower total cost of care Focus on controlling Lowering prescription drug prices Depends on if regulations are extended to commercial payers spend/driving value Increasing healthcare price transparency Price competition will benefit payers in contract negotiations Additions to required benefits (e.g., telehealth, **Enabling importation of FDA-approved** Drug importation has the potential to **lower drug costs for payers** foreign drugs behavioral health) Increased provider competition will benefit payers in contract Increased healthcare antitrust scrutiny negotiations Efforts to stabilize and expand individual Increased Medicare coverage could reduce commercial lives if Lower Medicare age to 60 extended to all persons 60+ (possible to only extend to Medicaid/unins.) marketplace enrollment Public option + ACA subsidy financial An attractive public option could reduce commercial lives, though this could be offset by expanded individual marketplace enrollment support Invalidation of the law, or of elements of the law related to individual **ACA** invalidation coverage, could reduce commercial lives Neutral Positive Net stakeholder impact Negative © 2021 L.E.K. Consulting LLC

Source: L.E.K. research and analysis

# Commercial payers should engage in targeted negotiations for 'shoppable' services, and partner with providers to control costs of new service offerings

Commercial payers

DIRECTIONAL

#### **Policy implications**



Focus on controlling spend/driving value



Additions to required benefits (e.g., telehealth)



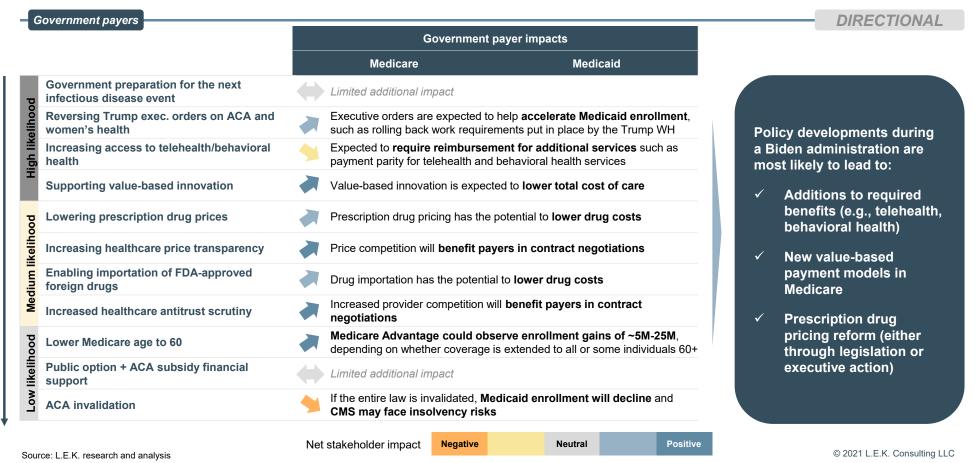
Stabilization of individual marketplace

#### Strategic priorities

- Engage in targeted re-contracting efforts with providers, particularly on "shoppable" procedures such as MRIs or laboratory and pathology services
- ✓ Develop capabilities to track outcomes and cost as value-based models are introduced
- ✓ **Proactively manage drug formularies** if drug pricing reform and reimportation take effect
- Consider vertically integrating or partnering with leading telehealth and behavioral health providers to control costs and utilization as their popularity increases

 Reassess or develop new individual plan offerings in response to Biden administration executive actions

# Government payers are more likely than commercial payers to benefit from enrollment increases or new payment models due to executive pathways for action



# Government payers should prioritize developing capabilities to participate in value-based care demonstrations and to lower prescription drug costs

Government payers

**DIRECTIONAL** 

#### **Policy implications**



Additions to required benefits (e.g., telehealth)

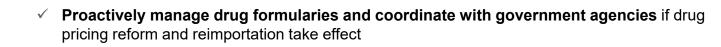
#### Strategic priorities

Consider vertically integrating or partnering with leading telehealth and behavioral health providers to control costs and utilization as their popularity increases



New value-based payment models in Medicare

- ✓ Develop capabilities to track outcomes/costs required to participate in value-based care demonstrations via CMMI\*
- ✓ Conduct **targeted re-contracting efforts** with providers, particularly on "shoppable" procedures such as MRIs or laboratory and pathology services





Prescription drug pricing reform

<sup>\*</sup>Center for Medicare and Medicaid Innovation Source: L.E.K. research and analysis

# Stakeholders in the healthcare supply chain are likely to face multiple headwinds from increased logistical requirements and downward pressures on unit revenues

HC supply chain DIRECTIONAL Healthcare supply chain impacts Government preparation for the next Government initiatives are likely to result in increased funding and infectious disease event support for supply chain infrastructure and capacity Reversing Trump exec. orders on ACA and Limited expected impact women's health Policy developments during a Increasing access to telehealth/behavioral Biden administration are most Limited expected impact health likely to lead to: Efforts targeted at drug pricing (e.g., value-based purchasing, Supporting value-based innovation international pricing index) could lower unit revenues Increased infrastructure Prescription drug pricing reform could reduce unit revenues, albeit investments in light of Lowering prescription drug prices primarily for branded drugs, with net lower margins for distributors pandemic readiness Increasing healthcare price transparency Limited expected impact, as targeted to shoppable services Indirect impact of effort to control drug costs in the **Enabling importation of FDA-approved** Drug importation could impose additional logistical costs and burdens foreign drugs form of lower revenue Several distributors hold ~90%+ market share: antitrust scrutinv is Increased healthcare antitrust scrutiny expected to focus on providers, but could affect distributors Potential new requirements of drug Lower Medicare age to 60 Expanded health insurance coverage could increase sales volumes reimportation (lower Public option + ACA subsidy financial likelihood) Expanded health insurance coverage could increase sales volumes support If the entire law is invalidated, fewer insured persons could lead to **ACA** invalidation reduced sales volumes Neutral Positive Net stakeholder impact Negative © 2021 L.E.K. Consulting LLC Source: L.E.K. research and analysis

# Healthcare distributors should focus on necessary changes to warehousing and shipping capacity, and shifting sales mix toward higher-margin generics

HC supply chain

DIRECTIONAL

### **Policy implications**



Expanded pandemic response capabilities



Lower revenue due to drug pricing reform



Higher costs from drug reimportation oversight

#### Strategic priorities

- ✓ Develop warehousing and shipping capacity to distribute COVID-19 vaccines
- ✓ **Pursue opportunities** to develop supply chain infrastructure and participate in government programs that enhance U.S. pandemic readiness
- ✓ **Develop new initiatives to expand utilization of generics**, which are higher-margin than branded drugs, to counter revenue pressures imposed by drug pricing reform
- ✓ Proactively engage government agencies in the design of models such as international pricing indices to protect distributor margins

✓ Should drug reimportation be realized, **identify potential overseas supplier relationships** 

# Several policies are expected to help pharmacies expand services provided and increase market power vis-à-vis distributors and PBMs

DIRECTIONAL **Pharmacies** Pharmacy impacts Government preparation for the next Pharmacies may need to adapt inventory and supply chain infectious disease event Reversing Trump exec. orders on ACA and Marginal growth in contraceptives sales may stem from exec. orders women's health Policy developments during a Increasing access to telehealth/behavioral Telehealth and broader initiatives to increase access to care may present Biden administration are most health opportunities for pharmacies to provide additional services likely to lead to: Supporting value-based innovation Value-based purchasing models may lead to **lower reimbursement** Better protection and Could rein in direct and indirect remuneration (DIR) fees and increase Lowering prescription drug prices expanded bargaining access, but lower revenue may also be passed on to pharmacies power vis-à-vis PBMs May require PBMs to disclose generics pricing, reducing the likelihood Increasing healthcare price transparency that pharmacies are reimbursed less than acquisition cost **Potentially lower Enabling importation of FDA-approved** Impact depends on whether savings from drug importation are required to reimbursement due to foreign drugs be passed along to pharmacies and consumers value-based purchasing Antitrust scrutiny may give pharmacies more bargaining power relative Increased healthcare antitrust scrutiny to distributors and PBMs Expanded role of Lower Medicare age to 60 Expanded health insurance coverage could increase sales volumes pharmacies in healthcare delivery Public option + ACA subsidy financial Expanded health insurance coverage could increase sales volumes support If the entire law is invalidated, fewer insured persons could lead to **ACA** invalidation reduced sales volumes Neutral Positive Net stakeholder impact Negative Source: L.E.K. research and analysis © 2021 L.E.K. Consulting LLC

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### Pharmacies should focus on opportunities to diversify care offerings to counter lower reimbursement and take advantage of initiatives to expand access to care

**Pharmacies** 

DIRECTIONAL

### **Policy implications**



Increased leverage vis-àvis distributors/PBMs

### **Strategic priorities**

✓ **Identify opportunities for fairer generics reimbursement** as price transparency requirements provide greater visibility into PBM payment methodologies



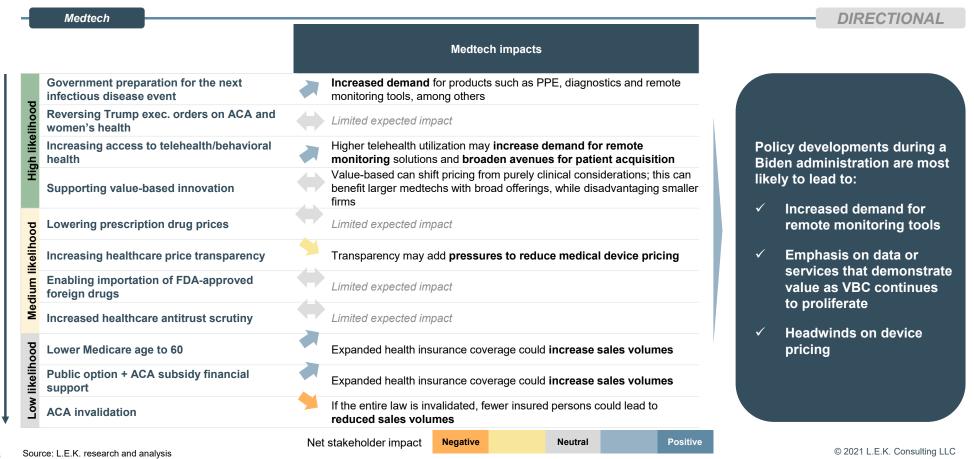
✓ Counter lower per-prescription reimbursement through **tailored approaches to right-sizing revenue** (e.g., **front-of-store sales** growth, increasing **patient acquisition** in the community, expanding into **additional healthcare services**)



**Expanded role of pharmacies in HC delivery** 

✓ **Double down on technological and personnel investments** as initiatives to expand care accessibility present opportunities for pharmacies

# Under a Biden administration, initiatives to enhance pandemic readiness and telehealth access are expected to drive demand for remote monitoring solutions



# Targeted expansion of remote monitoring and digital patient engagement tools can help medical device companies demonstrate value and acquire patients

Medtech

DIRECTIONAL

### **Policy implications**



Increased demand for remote monitoring

#### Strategic priorities

✓ Prioritize disease areas in which to develop remote monitoring tools based on complication rates, total cost of care and retrospective analysis of procedure volumes during the COVID-19 pandemic



Emphasis on data and services that support VBC

- ✓ Leverage remote monitoring tools to help providers collect information on outcomes and coordinate care
- ✓ **Develop digital patient engagement tools** to help educate patients, connect them with providers and enhance timing of procedures in order to reduce cost of care



✓ As VBC upends traditional models for increasing prices (i.e., purely clinical outcomes), focus on **expanding patient acquisition** (e.g., **via digital patient engagement tools** and other mechanisms) to counter margin erosion with increased revenues

### Healthcare IT stands to benefit from most policy outcomes over the next 4 years, particularly due to continued expansion of telehealth reimbursement

DIRECTIONAL Healthcare IT **Healthcare IT impacts** Government preparation for the next Expanded role for healthcare IT in public health via tools that use deinfectious disease event identified patient information to trace virus transmission, testing, treatment Reversing Trump exec. orders on ACA and Support for individual marketplaces may expand opportunities for women's health vendors that support digital sales in ACA marketplaces Policy developments during a Increasing access to telehealth/behavioral Permanent support for telehealth will lead to increased vendor revenue Biden administration are most health likely to lead to: Supporting value-based innovation Increases in healthcare IT utilization to help track costs and outcomes Significant and sustained Lowering prescription drug prices Limited expected impact increase in telehealth utilization Providers may need point-of-care tools that inform patients of Increasing healthcare price transparency insurance coverage/financial responsibility for procedures/services Continued emphasis on Potential opportunity for healthcare IT vendors to play a role in **tracking Enabling importation of FDA-approved** tools that track cost. foreign drugs program administration and quality quality and outcomes Increased healthcare antitrust scrutiny Limited expected impact **Expanded role of** Increased health insurance coverage may increase healthcare utilization Lower Medicare age to 60 healthcare IT in public and reliance on health IT solutions (i.e., EHR\*, telehealth) health Public option + ACA subsidy financial Increased health insurance coverage may increase healthcare utilization support and reliance on health IT solutions (i.e., EHR\*, telehealth) Reduced requirements to track quality and outcomes may reduce **ACA** invalidation demand for healthcare IT, though these requirements span multiple laws Neutral Positive Net stakeholder impact Negative \*Electronic health record

# Healthcare IT can seize on tailwinds by partnering with providers on telehealth and engaging government stakeholders on public health and VBC initiatives

Healthcare IT

DIRECTIONAL

#### **Policy implications**



Significant and sustained increase in telehealth util.



Growing need to track cost, quality/outcomes



Expanded role of HCIT in public health

#### Strategic priorities

- ✓ **Develop partnerships with health systems** to develop telehealth offerings and gain access to rendering providers
- ✓ **Build security functionality to address patient privacy requirements**, which were waived in the height of the COVID-19 pandemic but may reemerge in the long term
- ✓ As multiple measures increase the need for price transparency (e.g., executive orders), vendors should articulate the value of healthcare IT solutions in helping patients and providers understand cost
- ✓ Coordinate tool development with CMS/other federal agencies to ensure healthcare IT tools can provide timely support to new value-based demonstrations
- ✓ **Engage federal, state and local governments** to provide support in tracking COVID-19 spread, testing and ultimate vaccination/treatment
- ✓ Leverage COVID-19 experience to **launch a longer-term dialogue with governments about the role of HCIT** in public health as future pandemic readiness plans are developed

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Source: L.E.K. research and analysis

# While biopharma is unlikely to encounter significant change during the Biden administration, investment in infectious disease research is likely to expand

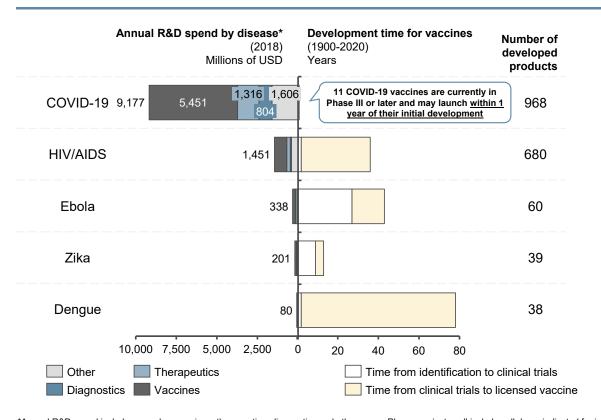
	Passable via exec order		Life sciences impact		
Government preparation for the next infectious disease event	✓		Government agencies are likely to continue placing greater emphasis on investments in vaccines and therapeutics for infectious diseases		
Reversing Trump exec. orders on ACA and women's health	✓	<b>\</b>	Limited expected impact		
Increasing access to telehealth/ behavioral health	✓	$\Leftrightarrow$	Limited expected impact	Policy developments during a Biden administration are most likely to lead to:  ✓ Moderate pressure on prescription drug pricing ✓ Increased spend on infectious disease preparation ✓ Potential for increased competition if the importation of foreign drugs is approved	
Supporting value-based innovation	✓	$\Leftrightarrow$	Neutral impact on life sciences due to increased emphasis on value- based purchasing (VBP)*		
Lowering prescription drug prices		<b>1</b>	Lowering of prescription drug prices may reduce overall spend by patients and payers but impact is not expected to be significant		
Increasing healthcare price transparency	✓		Increased price transparency will likely create negative public sentiment and pricing pressure		
Enabling importation of FDA- approved foreign drugs	✓		Drug importation has the potential to <b>lower overall drug spend</b> and <b>increase pressure</b> from payers; large-scale importation is unlikely		
Increased healthcare antitrust scrutiny	✓	$\Leftrightarrow$	Limited expected impact		
Lower Medicare age to 60			Lowering the Medicare age to 60 will <b>increase the number of covered lives</b> eligible for therapeutics		importation of foreign
Lower Medicare age to 60  Public option + ACA subsidy financial support			Public option + ACA subsidy financial support will <b>increase the number of covered lives</b> eligible for therapeutics		drugs is approved
ACA invalidation		<b>1</b>	ACA invalidation will <b>decrease the number of covered lives</b> and therefore reduce the number of lives eliqible for therapeutics		

Net stakeholder impact

Negative

Neutral

## The investment, speed and success of COVID-19 R&D has shattered historic norms for infectious disease and vaccine development



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- Previous vaccine development timelines have been shattered by the rapid development of COVID-19 vaccines and therapeutics
  - While previous infectious diseases required decades of R&D, COVID-19 vaccines with >90% efficacy have been produced and sent to the clinic in less than a year
- The combination of unprecedented R&D spend and accelerated development timeline may disrupt the way biopharma engages with infectious disease research
  - Pharma companies should explore opportunities to invest given global need and policy/government investment tailwinds

<sup>\*</sup>Annual R&D spend includes spend on vaccines, therapeutics, diagnostics and other areas; Pharmaprojects pull includes all drugs indicated for infection/prophylaxis and related complications Source: Pharmaprojects; L.E.K. research and analysis

# Presidents may utilize an executive order (EO) to implement policy without congressional approval; federal courts hold power to strike down EOs

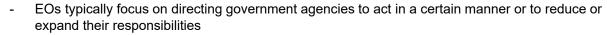
#### **Executive orders and healthcare implications**



 EOs are federal directives by the president of the United States that carry the force of law but are not considered pieces of legislation as they do not require approval from Congress



EOs may be utilized as an effective way of **enacting policy during times of distress or a legislative gridlock**, but may be undone by future administrations



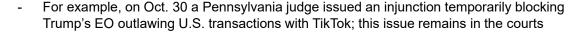


• The number of EOs issued by a president can vary considerably

- Since President Reagan, the **average number of EOs issued yearly is 43\*** and has been trending downward since President Franklin Roosevelt



Congress and federal courts can **strike down EOs that are viewed as unconstitutional**, though this rarely happens





● Of the ~6,200 EOs\*\* issued between 1937 and 2013, **18% were amended, 8% were superseded and 25% have been revoked, with the rest remaining unchanged**; on average it takes five years for an EO to be changed and 13 years for revocation

## **Executive orders have created significant and lasting impact within the healthcare industry**

DIRECTIONAL

### Example executive orders impacting the healthcare industry

Historically, presidents have utilized executive orders to accelerate improvements within areas of healthcare (e.g., HIV care, mental health for veterans) that could benefit from swift and concentrated change without congressional approval



#### Legislated into law

 $\bigcirc$ 

#### Maintained



## Revoked Executive Order 13435



#### **Superseded**

Executive Order 13237 (G.W. Bush, 2001)

#### Executive Order 13676 (Obama, 2014)

- Enacted to create a streamlined plan to prepare for antibioticresistant bacteria
  - Directed federal agencies to use coordinated action, forming the U.S. National Strategy for Combating Antibiotic-Resistant Bacteria
  - Congress recently passed an act\* which transferred PACCARB's\*\* legal basis from EO to law

### Executive Order 13155 (Clinton, 2000)

- Established that the U.S. would not challenge intellectual property laws in sub-Saharan African countries for HIV/AIDS treatments
  - Pharmaceutical/medtech companies would not be able to seek traditional intellectual property rights for HIV/AIDS treatments
  - This EO has been maintained and is frequently cited in healthcare IP cases in sub-Saharan Africa

### (G.W. Bush, 2007) Limited federal funding for

stem cell line experiments
Obama signed EO 13505 in 2009, which revoked EO 13435 and its associated limitations on

research

federal funding of stem cell

- Established an advisory body<sup>^</sup> for the president on bioethical topics
  - In 2009, EO 13521 (Obama) superseded EO 13727 and terminated the council
  - Obama replaced the council with a group focused on "practical policy options" rather than philosophical debate

<sup>\*</sup>All-Hazards Preparedness and Advancing Innovation Act of 2019

<sup>\*\*</sup>Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

<sup>^</sup>President's Council on Bioethics

## Given likely policy developments, L.E.K. has identified a few near- to midterm priorities for life sciences stakeholders

DIRECTIONAL

#### Strategic priorities for life sciences stakeholders



## Focus on development of internal capabilities

- Reduced biopharma price growth and/or other price compression should be carefully looked at from a portfolio planning and FP&A\* basis
- ✓ Upgrading internal capabilities within asset life cycle value demonstration, portfolio planning and marketing budget impact will be key to navigating the years ahead

## Reevaluate infectious disease investment strategy

- ✓ Government budgets will likely favor infectious disease R&D in future years given COVID-19
- ✓ Review infectious disease investment strategy to assess potential areas of investment given R&D drivers



## Proactively prepare for value-based pricing

- Opportunity to coordinate with payers and/or providers to design new models of value-based care/pricing
- ✓ Explore proactive integration of **valuebased pilots** into R&D planning

<sup>\*</sup>Financial planning & analysis Source: L.E.K. research and analysis

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