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Post-Election Outlook: Issues to Watch for Pharmacy Industry Stakeholders

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The 2024 election results will create significant tailwinds for Republican legislative and regulatory priorities in US Congress, federal agencies, and state houses across the country. This *On the Subject* considers the outlook for pharmacy regulation under the second incoming Trump administration and a unified Republican Congress, as well as state-level pharmacy policies that may advance as Republican public policy momentum builds.

In Depth

In its second term, the Trump administration is likely to pursue many of the priorities left unfinished at the end of its first term. With respect to pharmacy regulation, during President-elect Trump's first term, Congress enacted the Know the Lowest Price Act and the Patients' Right to Know Drug Prices Act. These two acts prohibited "gag clauses" in agreements between pharmacies and pharmacy benefit managers, removing a potential barrier for pharmacists to disclose less expensive drug options to consumers. The legislation sought to increase transparency and reduce patient out-of-pocket costs.

Despite these legislative achievements, several pharmacy priorities discussed in the Trump administration's American Patients First blueprint remained unfulfilled at the conclusion of the first Trump term. The second Trump administration and Republican-led state houses and administrative agencies will also look to conservative think tanks, such as the America First Policy Institute, the Heritage Foundation, and the Paragon Health Institute, for recommendations on legislative and regulatory strategies to further Republican priorities. Tellingly, in January 2018, the Heritage

Foundation reported that President-elect Trump's first administration had adopted almost two-thirds of its policy recommendations.

DRUG PRICE TRANSPARENCY

The Trump administration, along with the broader Republican Party, considers transparency and natural market dynamics to be a key pathway to reducing healthcare costs. During the first Trump term, President-elect Trump's administration implemented several price transparency measures, including a Transparency in Coverage (TiC) Rule that cobbled together several statutory authorities to require certain group health plans and issuers to disclose patient cost-sharing information, in-network provider negotiated rates, and drug pricing information.

On August 20, 2021, the Biden administration determined to defer enforcement of the TiC Rule's requirement that plans and issuers publish machine-readable files related to prescription drugs. On April 19, 2022, the Biden administration issued a temporary "safe harbor" for circumstances where compliance was "not possible," but on September 27, 2023, the Biden administration withdrew the safe harbor and announced a "case-by-case" enforcement approach.

In its second term, the Trump administration may look to unwind the flexibilities of the Biden administration and take a stronger stance in enforcing the TiC Rule as applicable to prescription drugs. Many states have passed prescription drug transparency laws, although these laws are most commonly focused on transparency of wholesale acquisition costs, as opposed to consumer out-of-pocket costs that are likely to influence patient choice. Focus by the Trump administration and statehouses on greater consumer access to cost-sharing obligations at the pharmacy counter may affect both prescribing and dispensing trends for prescription drugs.

BIOSIMILAR PRODUCTS

President-elect Trump's American Patients First blueprint reasoned that improving the availability, competitiveness, and adoption of biosimilars as "affordable alternatives to branded biologics" can promote innovation and competition for biologics, thereby bringing down prices. The American Patients First plan called for the US Food and Drug Administration (FDA) to continue to educate clinicians, patients, and payors about biosimilar and interchangeable products and asked for suggestions on resources and tools for the FDA to improve the efficiency of the biosimilar and interchangeable product development and approval processes. The blueprint asked for additional suggestions on how to improve the interchangeability of biosimilars and the potential effects on prescribing, dispensing, and coverage of biosimilar and interchangeable products. An interchangeable product may be substituted for its reference product without the intervention of the healthcare provider who prescribed the reference product.

In June 2024, the Biden administration issued draft guidance updating the 2019 Guidance for Industry entitled, "Considerations in Demonstrating Interchangeability With a Reference Product." According to the new draft guidance, experience has shown that for products approved as biosimilars, the risk in terms of safety or diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product. The FDA acknowledged that its scientific approach to when a switching study or studies may be necessary to support a demonstration of interchangeability "has evolved." The FDA's draft guidance would allow applicants to provide an assessment of why the data otherwise provided to the FDA for biosimilar approval supports the switching standard absent data from a switching study or studies. Finalizing this guidance would be consistent with the Trump administration's historic interest in improving access to

interchangeable biosimilars.

The American Patients First blueprint also indicated a need to give each biosimilar a unique billing and payment code under Medicare Part B, which would incentivize the development of additional lower-cost biosimilars. The blueprint stated that the current approach to biosimilar coding and payment creates a “race to the bottom” of biosimilar pricing while leaving the branded product “untouched,” making the biosimilar market unviable and one “that few would want to enter.” Because HCPCS Level II coding for biosimilars is largely unbound by statutory or regulatory requirements, the Trump administration’s Centers for Medicare and Medicaid Services may revisit the HCPCS Level II coding policies to establish a more diversified code set for biosimilars.

VACCINES

President-elect Trump has announced he will nominate Robert F. Kennedy Jr. (RFK) to be the Secretary of the US Department of Health and Human Services (HHS). He also has chosen Dr. Marty Makary to be the US Food and Drug Administration (FDA) Commissioner, Dr. Jay Bhattacharya to lead the National Institutes of Health (NIH), and Representative Dave Weldon to lead the Centers for Disease Control and Prevention (CDC).

RFK has made several statements questioning the safety and efficacy of certain vaccines purchased and administered by pharmacies across the country. If confirmed by the US Senate and appointed, RFK would oversee the FDA Commissioner, who in turn has the authority to approve vaccine applications. The Secretary also selects the director of the HHS National Vaccine Program, which coordinates with the NIH, the CDC, the FDA, and the US Department of Defense to provide direction for research on vaccinations and adverse events related to vaccines. The Secretary can also influence certain health plan, Medicare Part D, and Medicaid coverage of vaccines through oversight of the Advisory Committee on Immunization Practice and the CDC. Medicare Part B coverage of certain vaccines (pneumococcal, influenza, COVID-19, and hepatitis B) is established by statute, but coverage for other vaccines is subject to the Medicare Part B “reasonable and necessary” coverage requirement.

Any action that restricts the development and introduction of new vaccines, the approval of currently available vaccines, or reimbursement for vaccines may disrupt pharmacy vaccine service delivery. Such actions are likely to be challenged in federal court and subject to judicial scrutiny under the interpretive framework of *Loper Bright v. Raimondo* and the Administrative Procedure Act, as applicable.

PHARMACIST SCOPE OF PRACTICE

Support for expanding the scope of practice of pharmacists has continued to gain momentum in recent years, heralded by the Cicero Institute as a potential solution to primary care shortages. Many states have expanded pharmacist scope of practice beyond dispensing medications to include administering immunizations and long-acting injectable medications, prescribing hormonal contraceptives, prescribing antivirals for influenza and COVID-19, counseling on tobacco cessation, and providing point-of-care diagnostic testing services. Several states have enacted statutes defining pharmacist scope of practice based on a “standard of care” model, where pharmacists must act consistently with their education, training, and experience and within the accepted standard of care provided in a similar setting by a reasonable and prudent pharmacist.

Reimbursement for an expanded scope of pharmacist services is also gaining traction in Congress,

where the Equitable Community Access to Pharmacist Services Act has collected almost 150 bipartisan cosponsors in the US House of Representatives and 28 bipartisan cosponsors in the Senate as of the time of publication. The legislation would create a new Medicare Part B benefit category for pharmacist services and services furnished incident to the service of a pharmacist. Covered services would include the evaluation and management of patients for testing or treatment of COVID-19, influenza, respiratory syncytial virus, or streptococcal pharyngitis. Medicare Part B would reimburse pharmacist services through the Medicare Physician Fee Schedule as a percentage of physician reimbursement.

Given its potential to reduce the costs of certain types of care and federal healthcare program expenditures, expanding the scope of practice for pharmacists may gain additional momentum with the new federal administration and in state houses. However, scope of practice reforms have historically encountered challenges in Congress and faced considerable political obstacles.

KEY TAKEAWAYS

- Pharmacy and pharmacy-adjacent regulation is very likely to undergo a period of moderate disruption as the incoming Trump administration takes actions to transition from the outgoing Biden administration, potentially affecting various aspects of healthcare policy, regulatory frameworks, and industry practices.
- Pharmacy and pharmacy-adjacent laws, regulations, and guidance oriented toward transparency, competition, and reduced out-of-pocket costs may benefit from tailwinds from the incoming Trump administration and more conservative state houses.
- Pharmacies and pharmacy stakeholders should consider engaging with federal and state government representatives and regulators on proposed legislation, regulations, and subregulatory guidance that may advance or hinder their strategic interests.
- Several areas of legislation, regulation, and administrative action appear ripe for movement following the 2024 elections. These include drug price transparency, biosimilar interchangeability approval and reimbursement, vaccine approval and reimbursement, and pharmacist scope of practice.

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