

President-Elect Biden's Potential Executive Actions: A Health Care & Life Sciences Perspective

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President-elect Biden's agenda and approach for his first 100 days in office will depend to a large degree on which party controls the United States Senate. Many of the incoming President's major campaign promises—such as comprehensive climate solutions, sweeping immigration reform, infrastructure spending and tax reforms—would only be possible with a Democratic majority in both the House and Senate. As a result, if Republicans win either of the run-off elections in Georgia and maintain control in the Senate, President-elect Biden's first 100 days in office likely will focus on a considerable number of executive actions and a less far-reaching legislative agenda.¹

We catalogue below the executive actions the Biden Administration is likely to take within the first few months related to health care and life sciences matters.²

COVID-19

Confronting the global pandemic will undoubtedly be President-elect Biden's top priority. The extent to which the two parties are able to find common ground in response to the ongoing pandemic—and how quickly—will be the telling measures regarding whether executive actions become the most direct and expedient way for Democrats to move forward portions of their pandemic response agenda.

- President-elect Biden has indicated he will immediately reverse President Trump's decision to withdraw from the World Health Organization (WHO).³ The Trump Administration recently submitted a formal notification of the U.S.' intent to withdraw from the organization, effective July 6, 2021.
- President-elect Biden plans to restore the White House National Security Council Directorate for Global Health Security and Biodefense, which was established by the Obama Administration and eliminated by the Trump Administration in 2018.⁴
- The President-elect has stated that he will use authorities under the Defense Production Act (DPA) to increase production of masks, face shields and other personal protective equipment (PPE) to ensure current needs are met and stockpiles are fully replenished.⁵

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- President-elect Biden plans to establish a “pandemic testing board” to focus on increasing testing, building out more drive-through testing sites and hiring at least 100,000 contract tracers.⁶
- In the absence of legal authority to issue a national mask mandate via executive order, President-elect Biden is expected to increase mask wearing by requiring masks on all federal property and “all interstate transportation.”⁷

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The Affordable Care Act

If Republicans retain control of the Senate, significant Affordable Care Act (ACA) expansions are unlikely. Instead, look to a Biden Administration to reverse or revise ACA-related regulations and executive orders advanced by the Trump Administration.

- The Biden Administration is expected to repeal promptly President Trump’s executive order directing the Department of Health and Human Services (HHS) and other relevant agencies to take action to “waive, defer, grant exemptions from, or delay the implementation of any [ACA] provision or requirement” that imposes a fiscal or regulatory burden.⁸The Biden Administration will likely direct agencies to ensure the viability and success of the ACA through various policies.⁹
- President-elect Biden is also likely to repeal Trump’s executive order instructing various agencies to consider regulations and/or guidance to expand the use of: (1) association health plans; (2) short-term, limited duration insurance; and (3) health reimbursement arrangements, all of which undermine the framework of the ACA exchanges.¹⁰
- President-elect Biden is expected to roll back the Trump Administration’s Section 1332 guidance, which gives states additional flexibility to waive ACA insurance requirements, including activities that promote the sale of, and apply subsidies to, ACA noncompliant policies.¹¹
- President-elect Biden will likely direct HHS to restore the Obama Administration’s broad interpretation of Section 1557, which prohibited discrimination based on race, color, national origin, sex, gender-identity, age, and disability in health programs and activities receiving federal financial assistance.¹²
- President-elect Biden may make operational changes through executive order to encourage marketplace participation, such as implementing a special enrollment period for the federal marketplace to address gaps in insurance coverage for those who may have lost employment and benefits due to the economic downturn associated with the pandemic, and promoting access to nonprofit plan navigators.¹³

Health Care

Medicare

- If Republicans retain control of the Senate, significant changes to the Medicare program are unlikely. In that event, President-elect Biden is likely to signal a commitment to protecting Medicare by rescinding Trump’s August memorandum on deferring payroll tax obligations.¹⁴
- President-elect Biden has reiterated a desire to provide a public option modeled on Medicare.¹⁵ He is likely to rescind, at least in part, Trump’s executive order criticizing “Medicare for All” and placing increased emphasis on privatized Medicare plans.¹⁶

Medicaid

- President-elect Biden has made clear that he supports expanding Medicaid eligibility to more Americans.¹⁷To this end, he is likely to reverse Trump's executive order that promotes the use of work requirements to qualify for Medicaid¹⁸and to repeal Trump era sub-regulatory guidance on Medicaid block grants¹⁹and community engagement requirements.²⁰ President-elect Biden also could issue a policy statement via an executive order in support of stated Medicaid expansion efforts.

Health Equity

- A key focus of the Biden Administration's COVID-19 response will be racial health disparities.²¹ President-elect Biden could issue an executive order to create a task force addressing such issues.

Health Care Market Concentration

- President-elect Biden supports aggressively enforcing existing antitrust laws against corporations in the health care sector.²²He may use executive order authority to direct more robust enforcement.

Drug Pricing

- President-elect Biden has proposed directing HHS to establish an independent review board to assess the value of specialty drugs. He may move to accomplish this through executive order. The goal is to have the board recommend a reasonable price for certain drugs, which will determine what Medicare (and any public option) will pay.²³
- President-elect Biden has indicated a continued commitment to importing prescription drugs from other countries, so long as HHS has certified that they are safe.²⁴ He may rescind Trump's executive order on drug importation and institute his own.²⁵

Opioids

- The Biden Administration will likely direct the Drug Enforcement Administration (DEA) to take stronger action against pharmaceutical companies for their role in the opioid crisis, including by prohibiting certain drug shipments, better policing over the failure to monitor shipments, increasing penalties, and improving data collection.²⁶

Nursing Homes and Long-Term Care Facilities

- President-elect Biden will likely direct HHS to reverse Trump-era rules that reduced training requirements for nursing home staff and permit forced arbitration agreements.²⁷
- During the course of the COVID-19 pandemic, President-elect Biden intends to direct the Occupational Safety and Health Administration (OSHA) to enforce an Emergency Temporary Standard to ensure safe nursing home workplaces. He has stated that he will also require facilities to meet with residents and family members to share information and to allow the State Long-Term Care Ombudsman entry during visitation restrictions.²⁸

- Look for President-elect Biden to provide spending oversight by directing the Office of Inspector General (OIG) to audit nursing home cost reports and ownership data.²⁹

Gag Rules

- President-elect Biden plans to direct the reissuance of guidance stating that states cannot refuse Medicaid funding for Planned Parenthood. He also plans to rescind Trump-era rules preventing Planned Parenthood and family planning programs from obtaining Title X funding.³⁰
- It is expected that President-elect Biden will rescind the Mexico City Policy, which prohibits the U.S. federal government from funding nongovernmental organizations (NGOs) that provide abortion counseling/referrals, advocate to decriminalize abortion, or provide abortion services.³¹

Cannabis

- Under the Biden Administration, the new Attorney General could quickly reinstate the Cole Memorandum, a Department of Justice (DOJ) policy of noninterference with state-legal marijuana activity. The Cole Memorandum was issued in 2013³² and rescinded by Attorney General Jeff Sessions in 2018.³³

¹ The President can take executive action through an executive order, presidential memoranda, or proclamation. The distinction among these options is more so a matter of form than substance since each can be used to direct and govern the actions of government officials and agencies. The only technical difference is that executive orders and proclamations must be published in the Federal Register, while presidential memoranda are published only when the President determines that they have "general applicability and legal effect." 44 U.S.C. §1505.

² The President's authority to issue executive actions does not include a grant of power to implement policy decisions that are not otherwise authorized by law.

³ Biden for President, Beat COVID-19, <https://joebiden.com/covid19/> (last accessed Nov. 23, 2020).

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ Reuters, President-elect Biden says he would if elected mandate masks in interstate transportation (Oct. 23, 2020), <https://www.reuters.com/article/us-usa-election-biden-masks/biden-says-he-would-if-elected-mandate-masks-in-interstate-transportation-idUSKBN2782P6>

⁸ Executive Order 13765, Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, 82 Fed. Reg. 8,351 (Jan. 24, 2017), <https://www.govinfo.gov/content/pkg/FR-2017-01-24/pdf/2017-01799.pdf>.

⁹ Biden for President, Health Care, <https://joebiden.com/healthcare/> (last accessed Nov. 23, 2020).

¹⁰ Executive Order 13813, Promoting Healthcare Choice and Competition Across the U.S., 82 Fed. Reg. 48,385 (Oct. 17, 2017), <https://www.govinfo.gov/content/pkg/FR-2017-10-17/pdf/2017-22677.pdf>.

¹¹ Centers for Medicare & Medicaid Services, State Relief and Empowerment Waivers, Guidance, 83 Fed. Reg. 53,575 (Oct. 24, 2018), <https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf>.

¹² Kaiser Family Foundation, The Trump Administration's Final Rule on Section 1557 Nondiscrimination Regulations Under the ACA and Current Status (Sept. 18, 2020), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/the-trump-administrations-final-rule-on-section-1557-nondiscrimination-regulations-under-the-aca-and-current-status/>.

¹³ See NPR, President-Elect Biden Has A Plan To Combat COVID-19. Here's What's In It (Nov. 8, 2020), <https://www.npr.org/sections/health-shots/2020/11/08/930887069/hold-president-elect-biden-has-a-plan-to-combat-covid-19-heres-what-s-in-it>.

¹⁴ Memorandum on Deferring Payroll Tax Obligations in Light of the Ongoing COVID-19 Disaster, 85 Fed. Reg. 49,587 (Aug. 8, 2020), <https://www.federalregister.gov/documents/2020/08/13/2020-17899/deferring-payroll-tax-obligations-in-light-of-the-ongoing-covid-19-disaster>.

¹⁵ Biden for President, Health Care, <https://joebiden.com/healthcare/> (last accessed Nov. 23, 2020).

¹⁶ Executive Order 13890, Protecting and Improving Medicare for Our Nation's Seniors, 84 Fed. Reg. 53,573 (Oct. 3, 2019), <https://www.federalregister.gov/documents/2019/10/08/2019-22073/protecting-and-improving-medicare-for-our-nations-seniors>.

¹⁷ Biden for President, Health Care, <https://joebiden.com/healthcare/> (last accessed Nov. 23, 2020).

¹⁸ Executive Order 13828, Reducing Poverty in America by Promoting Opportunity and Economic Mobility, 83 Fed. Reg. 15,941 (Apr. 10, 2018), <https://www.govinfo.gov/content/pkg/FR-2018-04-13/pdf/2018-07874.pdf>.

¹⁹ Centers for Medicare & Medicaid Services, State Medicaid Director Letter SMD 20-001, RE: Healthy Adult Opportunity (Jan. 30, 2020), <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf>.

²⁰ Centers for Medicare & Medicaid Services, State Medicaid Director Letter SMD 18-002, RE: Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries (Jan. 11, 2018), <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf>.

²¹ See NPR, Biden Advisory Board Co-Chair Says Addressing Health Disparities Will Be A Key Focus (Nov. 13, 2020), <https://www.npr.org/2020/11/13/934718160/biden-advisory-board-co-chair-says-addressing-health-disparities-will-be-a-key-f>.

²² Biden for President, Health Care, <https://joebiden.com/healthcare/> (last accessed Nov. 23, 2020).

²³ *Id.*

²⁴ *Id.*

²⁵ Executive Order 13938, Increasing Drug Importation To Lower Prices for American Patients, 85 Fed. Reg. 45,757 (July 24, 2020), <https://www.federalregister.gov/documents/2020/07/29/2020-16624/increasing-drug-importation-to-lower-prices-for-american-patients>.

²⁶ Biden for President, Opioid Crisis, <https://joebiden.com/opioidcrisis/> (last accessed Nov. 23, 2020).

²⁷ Biden for President, Biden-Harris Plan to Make Nursing Homes and Long-Term Care Facilities Safe, <https://joebiden.com/covid-nursing-homes/> (last accessed Nov. 23, 2020).

²⁸ *Id.*

²⁹ *Id.*

³⁰ Biden for President, Health Care, <https://joebiden.com/healthcare/> (last accessed Nov. 23, 2020).

³¹ *Id.*

³² James M. Cole, Memorandum: Guidance Regarding Marijuana Enforcement (Aug. 29, 2013), <https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

³³ Jefferson B. Sessions, Memorandum: Marijuana Enforcement (Jan. 4, 2018), <https://www.justice.gov/opa/press-release/file/1022196/download>.

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