



## **B Lab Statement on Phlow Corporation - B Corp Requirements for Pharmaceutical Companies**

B Lab's independent Standards Advisory Council has rendered the following decision and guidance regarding eligibility for B Corp Certification for companies in the pharmaceutical industry:

*"B Lab and its independent Standards Advisory Council have determined that companies with clients on or within the pharmaceutical companies are eligible for B Corp Certification if they have not engaged in specific prohibited practices in the last five years AND are meeting additional industry specific practice requirements outlined below..."*

Phlow Corporation is required to disclose a summary of how it complies with these industry requirements as a part of its B Corp Certification. For more information on the specific requirements, please refer to B Lab's position statement on Pharmaceutical Industry [here](#).

### **About Phlow Corporation**

Phlow Corp (Phlow) is a U.S.-based company that develops and domestically manufactures Active Pharmaceutical Ingredients (APIs) and distributes private labeled finished pharmaceutical products. Phlow has four facilities to include: Phlow's Research & Development lab located at the Advanced Pharmaceutical Development Center in Richmond, Virginia; a Kilo-Scale cGMP Facility and a Metric Ton-Scale cGMP Facility in Petersburg, Virginia; and the country's first Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) in an undisclosed location.

Phlow currently has a team of approximately 50 employees in functional areas including Process Chemistry/Manufacturing Science & Technology, Regulatory, Quality, Supply Chain/Procurement, Project Management, Business Development, Marketing & Senior Leadership. Phlow's revenue is primarily derived from a cost-plus fixed fee contract with the U.S. Government for the development and manufacture of APIs of essential medications; their contract development and manufacturing services for pharmaceutical and biotech companies; and from the sale of private labeled drug products to the members of the Children's Hospital Coalition.

The company worked in partnership with the U.S. Government to deliver over two million doses of essential generic medicines used to treat COVID-19 patients to the U.S. Strategic National Stockpile, including medicines used for sedation to help patients requiring ventilator support, medicines for pain management, and certain essential antibiotics. As a Public Benefit Corporation, Phlow is focused on a triple bottom line of environmental, social, and financial performance.



## Phlow's Disclosure on Prohibited Practices

*Pharmaceutical companies engaged in the following practices in the last five years, as demonstrated through company disclosures or through material, justified, and unresolved stakeholder concerns, are currently ineligible for B Corp Certification:*

- *Companies engaged in any form of lobbying or policy advocacy that endangers consumer safety, promote an anti-competitive environment (e.g. by opposing increased transparency measures), inhibit affordable pricing, or limit equitable access to medicine. This includes membership, Board involvement, or funding of industry associations that engage in such lobbying activities.*
- *Companies utilizing intellectual property strategies for branded products to influence an unjustified delay to the introduction of an authorized generic product to the market (e.g. "evergreening" patents).*
- *Companies engaged in price gouging as evidenced by significant and unjustified year-over-year price increases to their products.*

Phlow has been reviewed in accordance with B Corp Certification's Disclosure Questionnaire and background check requirements, including disclosure of its involvement in lobbying and advocacy activities, intellectual property strategies, and price changes in order to verify if it is meeting the above requirements regarding prohibited industry practices. The company's approach to managing these material topics in the industry is further detailed below.

## Phlow's Disclosure on Required Best Practices

*In order to be eligible, pharmaceutical companies must be able to demonstrate that they have the following practices in place and disclose them on their B Corp Profile:*

1. *Adherence to credible national and/or international standards of safety, quality, and efficacy covering all relevant stages of the drug life cycle (i.e. drug development, supply chain, manufacturing, and distribution), which should include explicit systems to manage the risk of substandard medicines.*

In order to ensure the quality and safety of its products, Phlow implemented a quality management system (QMS) designed to meet or exceed legal and regulatory requirements as well as industry expectations for the manufacture and supply of essential medicines. Phlow's QMS defines the control criteria/systems and steps that will be performed to ensure product safety and quality. All currently applicable state and federal regulatory standards (i.e., 21 CFR Part 210-211) were met or exceeded in 2020. Once operational, compliance with cGMPs will be assured and confirmed during all product lifecycle stages.



Phlow is currently licensed by the Commonwealth of Virginia Board of Pharmacy as a Pharmaceutical Wholesaler and Distributor. Phlow has been inspected and found to be in compliance with all applicable state and federal laws and regulations including 18-VAC-50-10. Phlow initiated distribution from inventory held for the USG in 2023. Phlow is performing this activity in compliance with all applicable laws and regulations, including 21 CFR part 210-211 and relevant cGMPs.

Additionally, in 2021 Phlow initiated distribution of pharmaceutical products in compliance with the applicable criteria stated in the DSCSA (Drug Supply Chain Security Act) prior to the federally mandated implementation date of November 2023.

Phlow's QMS, including company policies and procedures, is applicable to all employees, contractors, and/or consultants acting on behalf or under contract with Phlow. Phlow has invested in newer technologies than are typical for domestic drug substance production. The technologies employed by Phlow for internal production are designed to significantly reduce the environmental impact and waste that is typical of drug substance production worldwide.

*2. A Code of Ethics and/or other policies applicable to all company employees and critical third parties that establish minimum expectations with regard to anti-corruption and bribery, lobbying and advocacy activities, company interactions with healthcare professionals/organizations, and ethical marketing (where applicable). The company must also have clear processes to enforce the Code, including an accessible whistleblowing channel, and regular training of staff and third parties on the Code.*

Phlow has established a [Business Code of Conduct](#) to ensure that each associate will conduct Phlow's business with integrity and comply with all applicable laws in a manner that exudes trustworthiness and reliability and also excludes considerations of personal advantage or gain.

Phlow's Business Code of Conduct is applicable to all employees. All third parties with whom Phlow engages are bound contractually to adhere to [Phlow's Supplier Code of Conduct](#) and are provided a link to that code.

Phlow's Business Code of Conduct addresses the following topics in the listed sections.

- Anti-corruption and bribery
  - Anti-Kickback Policy // Gifts, Gratuities, and Business Courtesies //Meals, Refreshments, and Entertainment //Accepting Gifts // Human Trafficking Policy // Responsible Labor Practices Policy // Whistleblower Policy
- Lobbying and advocacy activities

- Anti-Kickback Policy // Gifts, Gratuities, and Business Courtesies //Meals, Refreshments, and Entertainment // Whistleblower Policy
- Company interactions with healthcare professionals/organizations
  - Anti-Kickback Policy // Gifts, Gratuities, and Business Courtesies //Meals, Refreshments, and Entertainment // Whistleblower Policy // Protecting Confidential Information // Conflicts of Interest
- Ethical marketing
  - Truth in Negotiations Act (TINA) // Anti-Kickback Policy // Gifts, Gratuities, and Business Courtesies //Meals, Refreshments, and Entertainment // Whistleblower Policy // Protecting Confidential Information // Conflicts of Interest

Phlow ensures adherence to the above policies in the following ways:

- Phlow trains its employees on the Code, posts the Code online, and provides a copy of the code to all new hires.
- Phlow provides annual required training for employees on Ethics, the Code, and the reporting process.
- Phlow conducts proper due diligence in selecting a third party and provides written contracts that outline compliance and responsibilities of all parties.

3. *Public disclosure detailing the company's approach to government affairs, inclusive of lobbying/advocacy and political activities. This should include disclosure of the material issues that the company lobbies/advocates for, their trade associations, and the controls they have in place in regards to political contributions, lobbying/advocacy on the company's behalf, revolving door policy, political contributions, and donations.*

The company's political advocacy is in accordance with laws of the jurisdictions where they engage in these activities. All political and lobbying activities as well as meetings with government officials are coordinated and aligned with the company's internal Government Affairs Policy. Employees receive onboarding training upon hire and undertake an annual Lobbying Disclosure Act of 1995 (LDA) attestation process. Starting in 2024, all employees will receive annual training on Government Affairs/Advocacy. In the interest of transparency and in accordance with the LDA, Phlow publicly discloses all lobbying activities on a quarterly basis. Phlow's lobbying disclosures are online at: <https://disclosurespreview.house.gov/>. Phlow similarly follows all lobbying disclosure requirements in the state of Virginia and any other state jurisdictions in which we are engaged.

Phlow's advocacy is dedicated to supporting its programs and the manufacturing of essential medications in the U.S. The company has engaged in the appropriations process supporting



key programs at multiple agencies seeking to address supply chain security and drug shortages. Additionally, Phlow has been engaged as a subject matter expert on legislative proposals by congressional policy makers over the past several years. At the state level, its advocacy efforts have been focused on supporting regional economic development. Phlow played an advocacy role in securing funding through Virginia for Petersburg wastewater infrastructure and supported the Alliance for Building Better Medicines recent grant award of \$53M from the U.S. EDA.

Phlow's political advocacy is currently entirely policy based. The company does not currently have a Political Action Committee or participate in political giving as a company. Individual employees may still exercise their right to civic participation but are educated annually on clearly defined parameters around private engagement versus advocacy on behalf of Phlow.

*4. For companies involved in research & development, public disclosure of its R&D and intellectual property strategies and disclosure of annual resources invested in both internal and collaborative R&D activities.*

Phlow's Research & Development structure includes salaries, laboratory supplies, consultants, and subcontractors, including external organizations, and other expenses associated with the Company's process development, manufacturing, regulatory and quality assurance activities.

In the last fiscal year, Phlow invested approximately 25.7% of its revenue in research and development activities. Phlow protects its intellectual property related to its R&D activities through a combination of trade secrets and patents.

*5. For companies involved in research & development for priority diseases, conditions, and pathogens identified in the Access To Medicine Index, R&D processes for both internal and collaborative R&D activities must include a framework to develop equitable access plans for such projects. Access plans must be project-specific and include detailed commitments and strategies to improve access to such products in low- and middle-income countries (LMICs).*

Phlow is not currently involved in research & development for priority diseases, conditions, and pathogens identified in the Access To Medicine Index. Phlow is focused on essential generic medications necessary to sustain life and conquer disease, including R&D for APIs that help treat diseases listed in the Access to Medicine Index.

*6. For companies involved in sales, public disclosure of its approach to pricing which, at a minimum, utilizes pricing instruments that are generally accepted by public health agencies to set prices in all markets (such as internal reference pricing, external reference pricing,*

*and value-based pricing). Additionally, for sales in LMICs<sup>1</sup>, pricing strategies must prioritize the payer's ability to pay across different segments of a country's population and aim to improve access to those in need.*

Phlow's business practices, including its pricing policy, are aligned with its mission and guiding principles of providing accessibility, transparency, and value across the portfolio of products and services it brings to market.

The company states:

- They are committed to providing ongoing accessibility by pricing their products in a consistent, affordable, fair manner based on the value provided across their portfolio and reflective of the value of their innovation;
- They provide their customers with open insight and transparency into how their prices are determined and how they are maintained on an ongoing basis;
- Their pricing practices are designed to offer a competitive and consistent market price that can be sustained while ensuring ongoing product supply, provision of services, and price predictability. They provide long-term value and reliability for their partners as well as for the caregivers and patients they serve;
- When determining product pricing, they consider internal reference pricing by benchmarking against available US product analogues and value-based pricing by considering the value their products deliver to patients and the healthcare systems;
- As they adhere to their guiding principles of accessibility, transparency, and value, they believe that their organization and their shareholders will achieve a fair return across their portfolio of products, services, and businesses;
- They are a public benefit corporation whose Officers and Board are committed to a "triple bottom line". They balance social responsibility, environmental sustainability, and financial performance throughout their decision-making and go-to market decisions.

Phlow's full pricing philosophy is publicly available on their website at: <https://www.phlow-usa.com/pricing-policy/>.

*7. For companies involved in sales, companies have financial incentive structures for sales agents/teams designed to encourage responsible sales practices and minimize the risk of overselling (for example, by decoupling bonuses from sales volume).*

Phlow does not have financial incentive structures for sales agents/teams and ensures that all its business practices are consistent with its mission to supply affordable, high-quality medicines and with its Code of Conduct.

---

<sup>1</sup> Defined as the 106 countries included in the geographic scope of the [Access to Medicine Index](#).