



## CBSA End-of-Session Report 2021 Legislative Session

### A Letter from CBSA's President & CEO

Colorado Life Sciences Ecosystem:

CBSA leads **Policy + Advocacy** efforts to support a collaborative, pro-innovation environment for life sciences in Colorado. We work to advance state and federal policies that support the companies in our ecosystem and the patients they serve.

The First Regular Session of the 73rd General Assembly marked the third year of Democratic control of state government. It was an unprecedented session that started during the height of the COVID-19 pandemic and ended as restrictions were being lifted. Due to the month-long break at the beginning, the session stretched into the summer. Legislators ultimately wrapped up the session a few days before their hard deadline to adjourn. The Democratic majorities in the House and Senate stayed within party lines to deliver on the Governor's priorities, including a public health insurance option, drug pricing, and data privacy.

During the session, CBSA worked tirelessly to promote and champion legislation that would advance Colorado's health innovation ecosystem. Our Policy + Advocacy team built a coalition to counter legislation that would undermine Colorado's innovation ecosystem and make it harder for our life sciences companies to advance new technologies and treatments for patients.

We could not do this work without you, our members, the leadership of our board, the CBSA Policy Committee, the lobbying team of Colorado Legislative Strategies, and the team at the Colorado BioScience Association. Thank you to everyone who dedicates their time to advocate for our life sciences community and educate legislators on the impacts and unintended consequences of policy decisions.

A handwritten signature in blue ink that reads 'Jennifer Jones Paton'. The signature is fluid and cursive, with the first name 'Jennifer' being the most prominent.

Jennifer Jones Paton  
President & CEO  
Colorado BioScience Association

## Summary

During the 2021 legislative session, Colorado BioScience Association weighed in on eight bills and reviewed countless more. This report provides an overview of several areas of engagement focused on CBSA's **Policy Priorities**:

- Protect Patient Access to Health Innovation
- Strengthen Incentives for Innovation
- Increase Capital and Growth
- Promote a Supportive Tax and Regulatory Environment
- Cultivate an Educated Workforce
- Advance Ecosystem Priorities Within the Colorado State Budget
- Promote Strategies to Improve Public Health

## The State Budget

One main storyline from this legislative session was recovery. Recovering from the public health emergency presented by COVID-19, recovering from the economic fallout, and recovering from the deep budget cuts last session. During the 2020 session, the state was forced to cut \$3.3 billion from the state budget. Many of those cuts were reversed this session due to state and federal stimulus spending.

The budget funding restoration provides support for vulnerable Coloradans and makes investments to enhance Colorado's resiliency. Budget highlights include:

- Restored funding to state programs and services impacted by the 2020 budget cuts
- Investments to support vulnerable Coloradans and enhance Colorado's resiliency
- A set aside of \$800 million for the **legislative stimulus package**, which includes funding for agricultural communities, infrastructure, rural economic development, school investment, and job creation.

The cash flow has given Colorado one of the strongest state budgets to date, and Governor Jared Polis has additionally earmarked \$1.3 billion to ensure a healthy budget moving forward.

## Protecting the Advanced Industries Accelerator Grant Program

The **Advanced Industries Accelerator Grant Program** supports the growth and development of the life sciences ecosystem in Colorado. That program, along with many others, faced serious budget cuts during the 2020 session and lost \$10 million in funding. CBSA led the fight to preserve partial program funding. Early in this legislative session, CBSA and our partners worked on the passage of **Senate Bill 42**, which restored program funding. The dollars came through a supplemental budget appropriation. Governor Polis signed the bill in March.

This was a major victory following last legislative session's significant cuts. The CBSA Policy + Advocacy team worked closely with the Office of Economic Development and International Trade (OEDIT) to educate members of the General Assembly about the importance of the Advanced Industries Accelerator Grant Program to our life sciences community.

The Advanced Industries Accelerator Grant Program is a critical source of non-dilutive funding for Colorado life sciences companies and organizations. It demonstrates a significant return on investment, delivering value back to the state through company creation and high-paying jobs.

Since inception, the program's success metrics for life sciences alone include:

- 500+ grants
- 1,022 jobs
- 82 new companies
- \$1 billion in follow-on capital

CBSA is grateful to our members and partners for their support and engagement to protect the Advanced Industries Accelerator Grant Program. We know the outreach and stories of innovation made a difference. We also thank our partners at the Office of Economic Development and International Trade (OEDIT) for their commitment and support of this successful program.

## **Prescription Drug Affordability Review Board (SB21 – 175) Amendments Accepted**

Governor Polis has made healthcare legislation a top priority for this legislative session and he, along with his allies in the legislature, pushed ahead on a bill that negatively impacts the Colorado Life Sciences Ecosystem, [Senate Bill 175](#) (Prescription Drug Affordability Review Board or PDAB). The bill, which ultimately passed and was signed by the Governor, creates a prescription drug review board in Colorado that is charged with collecting prescription drug pricing information and determining which drugs must undergo an affordability review. If the board determines that a drug is unaffordable for Colorado consumers, they have the authority to set an upper payment limit (UPL) on all payments and reimbursements for the drug in the state.

While CBSA shares the goal of improving healthcare affordability, we remain very concerned that this bill will adversely impact healthcare providers in the state and as a result, limit patient access to the very medicines subjected to the UPL. These state mandated UPLs would diminish the ability of Colorado's life sciences companies to raise needed capital to fund R&D and the commercialization of new therapies.

CBSA worked very closely with our members and partners to advocate for changes to the bill. We thank our lobbyists and coalition partners for the incredibly hard work to negotiate 12 amendments. Five of them passed, which represent important policy wins for our life sciences community.

Negotiations yielded important concessions. After much dispute, a five-year sunset amendment made it onto the bill. This sunset provision is a measure to ensure that the law will cease to have effect after five years, unless further legislative action is taken to extend the law. Thanks to Minority Leader Hugh McKean, along with the life sciences coalition, legislators agreed to several amendments that will require the board to solicit more information from patients, caregivers, providers, and scientists. Additionally, the board will have to request input from the drug manufacturers about the feasibility of setting an upper payment limit.

CBSA led the way on another important change to the bill. As introduced, the legislation would have allowed upper payment limits on any drug when the price rose more than \$3,000 per year. However, that was changed to only allow such an action when a price goes up more than 10 percent in a year. These changes, along with protecting the five-year sunset, were significant changes to protect health innovation in Colorado. All changes include:

- Amend trigger threshold from \$3,000 to 10%
- Ask for additional input to the PDAB from patients, caregivers, providers, and scientists
- Request additional input to the PDAB from manufacturers

CBSA policy team will continue to prioritize the fight and advocating for the life sciences ecosystem.

## **Insulin Access and Pricing Legislation (HB21-1307)**

The other significant bill impacting the life sciences ecosystem is [House Bill 1307](#), which requires insulin manufacturers to give free insulin to certain patients. While CBSA wants to find impactful ways to get medicines those most in need, CBSA was opposed to this bill as it sets a dangerous precedent by forcing manufacturers to give up their product without compensation.

## **Plastics (HB21-1162) Amendment Allows CBSA to be Neutral on Legislation**

CBSA took an amend and then neutral [position on House Bill 1162](#), which creates new regulations for the use or sale of single-use plastics. It also prohibits stores and retail food establishments from providing single-use plastic carryout bags to customers and distributing expanded polystyrene products for to-go food. CBSA advocated for amendment L.001, which creates a statewide exemption for medical products. CBSA's concern with this legislation was the repeal of preemption and the potential for local municipalities to implement their own plastics regulations impacting medical products.

We don't think a local municipality would intentionally create a regulation that limits plastics used in medical products or supplies, but without this exemption, there is concern that it could be overlooked. These products are highly regulated by the U.S. Food and Drug Administration (FDA) and have rigorous requirements to ensure each product and its individual components are safe, reliable, and maintain integrity. This amendment ensured local regulations won't impact these products or create confusion for those involved in their research, development and manufacturing.

Ultimately, the bill was passed with the amendment, L.001 which allowed CBSA to be neutral on the legislation. During the next legislative session, CBSA plans to work with stakeholders on a clarifying bill to explicitly state that the FDA exemption remains in place.

## Final CBSA Positions on Legislation Impacting Life Sciences

### HB21-1162, Management of Plastic Products

CBSA Position	Bill Description
Neutral	<p>House Bill 1162 repeals language that prohibits local governments from regulating the use or sale of single use plastics. It also prohibits stores and retail food establishments from providing single-use plastic carryout bags to customers and distributing expanded polystyrene products for to-go food. Local governments may enact regulations that are more stringent than the statewide requirements.</p> <p>CBSA's concern with the bill was the repeal of preemption and the potential for local governments to enact their own plastics regulations that impact medical products.</p> <p><b>CBSA Engagement:</b> CBSA testified in the House Energy &amp; Environment Committee and urged legislators to vote in favor of an amendment that exempts medical products and supplies. The amendment was adopted without any opposition, and as a result, CBSA moved to a neutral position. During the next legislative session, CBSA plans to work with stakeholders on a clarifying bill to explicitly state that the U.S. FDA exemption remains in place.</p>
Outcome	House Bill 1162 was signed by Governor Polis on July 6, 2021.

### HB21-1199, Consumer Digital Repair Bill of Rights

CBSA Position	Bill Description
Oppose	<p>House Bill 1199 mandates original equipment manufacturers (OEMs) of digital electronic equipment provide independent repair providers with diagnostic and repair information, software, tools, and parts. It exempts some medical device manufacturers, but the requirements apply to electric wheelchairs.</p> <p>CBSA opposes HB 1199 because it requires manufacturers to disclose proprietary information without any contractual safeguards. We are also concerned that it specifically targets electric wheelchairs, Class II medical devices that are regulated by the U.S. FDA. Wheelchairs are designed, manufactured, and serviced according to requirements that support device quality, patient safety, and system security. This bill conflicts with those regulatory requirements and creates unnecessary patient safety risks.</p> <p><b>CBSA Engagement:</b> CBSA submitted written testimony in opposition to the bill for the hearing in House Business Affairs &amp; Labor.</p>
Outcome	House Bill 1199 was postponed indefinitely.

## HB21-1307, Prescription Insulin Pricing and Access

CBSA Position	Bill Description
Oppose	<p>House Bill 1307 provides eligible individuals access to one emergency prescription insulin supply within a 12-month period at a cost not to exceed \$35 for a 30-day supply. It also creates the insulin affordability program in the division of insurance through which eligible individuals may obtain prescription insulin for 12 months at a cost not more than \$50 for a 30-day supply. Insulin manufacturers must reimburse the pharmacy or send the pharmacy a replacement supply of the same insulin.</p> <p>CBSA opposes this bill and believes it sets a dangerous precedent by forcing manufacturers to give up their product without compensation.</p> <p><b>CBSA Engagement:</b> CBSA submitted written testimony in opposition to the bill for the hearing in House Business Affairs &amp; Labor.</p>
Outcome	House Bill 1301 was signed by Governor Polis on July 6, 2021.

## SB21-042, Department of Governor, Lt. Governor and OSPB Supplemental

CBSA Position	Bill Description
Support	<p>Senate Bill 042 includes a one-time \$10 million infusion for the Advanced Industries Accelerator Grant Program.</p> <p>CBSA supports this bill. The Advanced Industries Accelerator Grant Program is a top priority for CBSA and our members. The program provides a critical source of non-dilutive funding for our companies and institutions and has proven to be a strong economic driver for Colorado. Last year, the legislature had to make budget cuts to the program. This one-time appropriation will help backfill those cuts.</p> <p><b>CBSA Engagement:</b> CBSA was very active in advocating support on this piece of legislation.</p>
Outcome	Senate Bill 042 was passed and signed by Governor Polis on March 21, 2021.

## SB21-080, Protections for Entities During COVID-19

CBSA Position	Bill Description
Support	<p>Senate Bill 080 would provide liability protections for businesses that comply with public health guidelines related to COVID-19.</p> <p>Public health guidelines for the safety and health of employees are very important to companies in the life sciences ecosystem especially during COVID-19, but the increased liability that comes with this is a concern. Senate Bill 080 offers reasonable protections for businesses, as long as they are following appropriate guidelines to ensure safe operations during the pandemic. For these reasons CBSA supported Senate Bill 080.</p>
Outcome	Senate Bill 080 was postponed indefinitely.

### SB21-106, Concerning Successful High School Transitions

CBSA Position	Bill Description
Support	<p>Senate Bill 106 expands the high school innovative learning pilot program and creates greater flexibility around requirements that students learn within the walls of the traditional classroom, allowing a wider range of career and postsecondary opportunities. It also creates a fourth-year innovation pilot program that would provide state funding for eligible students who complete high school in three years to take full-time college courses or participate in career training in their fourth year of high school.</p> <p>CBSA supports workforce development initiatives and educational pathways that cultivate a strong talent pipeline for life sciences. This bill advances our workforce priorities by expanding career-connected learning, benefitting both employers and students. Life sciences employers who invest in offering internship and apprenticeship opportunities benefit from the innovative ideas that students provide and build a pipeline for their business. This bill makes it easier for students to take advantage of those opportunities and connects them to high quality pathways to careers and other postsecondary opportunities.</p>
Outcome	Senate Bill 106 was signed by the speaker of the House on June 11, 2021.

### SB21-123, Expand Canadian RX Import Program

CBSA Position	Bill Description
Oppose	<p>Senate Bill 123 expands the Canadian drug importation program to other countries beyond Canada, if allowed under federal law.</p> <p>CBSA opposes proposals to import prescription drugs from foreign countries because importation programs will increase risks to patient safety and are unlikely to result in savings for Colorado consumers. Additionally, the state has already spent millions of dollars on the Canadian importation program, and it still has not been operationalized. It is premature to pass legislation to expand a program that may not even work or be sustainable.</p> <p><b>CBSA Engagement:</b> CBSA submitted written testimony in opposition to the bill in committee hearings in both the House and Senate.</p>
Outcome	Senate Bill 123 passed both chambers and was signed by Governor Polis on April 26, 2021.

## SB21-175, Prescription Drug Affordability Review Board

CBSA Position	Bill Description
Oppose	<p>Senate Bill 175 creates a five-person prescription drug affordability review board in Colorado, appointed by the Governor. The board is charged with identifying prescription drugs that meet specific pricing thresholds and determining whether the drug(s) are unaffordable for Colorado consumers. If the board determines a drug is unaffordable, the board has the authority to set an upper payment limit (UPL) on any purchase or payer reimbursement for the drug dispensed to an individual in Colorado.</p> <p>The bill requires health insurers and PBMs to report certain information to the Division of Insurance for all prescription drugs dispensed at a pharmacy and paid for by that carrier in the preceding year. The board may also request drug pricing information from a manufacturer, insurer, or PBM. Any entity that violates an upper payment limit may be fined up to \$1,000 per violation. Any manufacturer that intends to withdraw a drug with an upper payment limit from sale or distribution in Colorado must provide notice 180 days in advance or be subject to a fine of up to \$500,000.</p> <p>The bill directs the Department of Health Care Policy &amp; Financing (HCPF) to collect, analyze, and report prescription drug costs for the 20 highest-cost drugs per course of therapy and the 20 highest-cost drugs based on total spending by each state department. CBSA opposed the bill because it would have created an administrative burden for drug manufacturers and would do nothing to lower out-of-pocket costs for patients or improve patient access. We also objected to the specific information companies would have been required to report under the bill, including items like R&amp;D and manufacturing costs for a single drug, which is not feasible. CBSA testified in opposition to the bill in the Senate Health &amp; Human Services Committee and worked with our members and industry partners on amendments to improve protections for reported information.</p> <p>CBSA shares the goal of improving the affordability of medicines, but we are concerned about the board's power to set upper payment limits (UPLs) for drugs. This could make it harder for Colorado life sciences companies to raise capital to fund the research, development, and commercialization of new therapies and reduce the availability of medicines in Colorado.</p> <p><b>CBSA Engagement:</b> CBSA sent an opposition letter to the Senate Health &amp; Human Services Committee and testified during the committee hearing. Several CBSA members have also participated in legislator meetings, submitted letters of opposition, and testified in committee.</p> <p>CBSA worked very closely with our members and partners to advocate for changes to the bill and thanks our lobbyists and partners for the incredibly hard work to negotiate 12 amendments. Five of them passed, which represent important policy wins for our life sciences community.</p>
Outcome	Senate Bill 175 was signed by Governor Polis on June 16, 2021.