WILLIAM G. BUSH, IV
STATE REPRESENTATIVE
29th District

HOUSE OF REPRESENTATIVES
STATE OF DELAWARE
411 LEGISLATIVE AVENUE
DOVER, DELAWARE 19901

COMMITTEES

Economic Development/Banking/Insurance & Commerce, Chair
Agriculture, Vice Chair
Capital Infrastructure, Member
Gaming & Parimutuels, Member
Public Safety & Homeland Security, Member

House Economic Development, Banking, Insurance & Commerce Committee Minutes

Date: 5.14.2024

House Committee Meeting

Chair Bush called the meeting to order at 12:04 p.m.

Members present:
Representative William Bush, Chair
Representative William J. Carson, Vice Chair
Representative Paul S. Baumbach
Representative Ron Gray
Representative Krista Griffith
Representative Larry Lambert
Representative Michael Smith
Representative Jeffrey Spiegelman
Representative Sherry Dorsey Walker
Representative Daniel B. Short
Representative Kevin Hensley
Representative Matthews

Chair Bush introduced **SB 232 AN ACT TO AMEND TITLE 18 OF THE DELAWARE CODE RELATING TO INSURANCE COVERAGE FOR CONTRACEPTIVES.** *Time Stamp: 12:06*

Rep. Heffernan stated that considering the Federal Drug Administration's recent approval of over-the-counter non-emergency contraceptive pills, this bill expands the contraceptive coverage laws to include over-the-counter non-emergency contraceptive pills.

Chair Bush opened the floor to public comment. *Time Stamp: 12:08*

Robert Overmiller, Member of the Public, Melanie Ross Levin, Office of Women's Advancement and Advocacy, Sarah Stowens, Christiana Care, Mara Gorman, Planned Parenthood of Delaware, spoke in favor of the legislation.

Chris Haas, Department of Insurance, appreciated the committee considering the bill.

A motion to release was made by Rep. Baumbach and seconded by Rep. Dorsey-Walker to release SB 232; motion carried. Yes = 10 (Baumbach, Carson, Bush, Dorsey Walker, Griffith, Lambert, Spiegelman, Hensley, Gray, Smith). No=0. Not Voting = 1 (Short). Absent = 2 (Wilson-Anton and Matthews). Motion carried with F = 3, M = 7, U = 0.

Rep. Short commented that he was not voting because it is a great idea but Delaware as a state has passed over 40 mandates. He shared that the state is struggling with healthcare expenses and until they decide what they will or will not cover, and how they are going to pay for it, he will continue to vote not voting.

Chair Bush introduced **HB 383 AN ACT TO AMEND TITLES 18 AND 24 OF THE DELAWARE CODE RELATING TO PROHIBITING DISCRIMINATION AGAINST 340B DRUGS AND COVERED ENTITIES BY MANUFACTURERS AND PHARMACY BENEFITS MANAGERS.** *Time Stamp: 12:17*

Rep. Harris stated that Section 1 of this Act prohibits discrimination against 340B drug distribution by manufacturers, repackagers, third-party logistics providers, and wholesalers. Violations are deemed an unlawful practice enforceable by the Consumer Protection Unit of the Department of Justice. The Department of Justice has authority to promulgate regulations under this section. The Board of Pharmacy may take disciplinary action against licensees based on the outcome of investigations or proceedings brought by the Department of Justice. Section 2 of this Act prohibits discrimination by pharmacy benefits managers against 340B covered entities. Violations are deemed unfair practices in the insurance business. Contracts purporting to include provisions in violation of this Act are deemed void and unenforceable. Section 3 of this Act contains severability language in the event that any provision or the application of the Act to a person or circumstance is deemed to be invalid. Section 4 of this Act contains non-preemption language to ensure that the Act can be read and interpreted to not conflict with other State or federal law. The threats to 340B program are not unique to Delaware.

Rep. Baumbach asked how hospital systems have misuse, however, the 340B program.
Rep. Harris confirmed there is misuse however, the amount is a small percentage. Specifically, between one to five percent nationwide and not one example shared happened in the state of Delaware.

Rep. Smith shared that he read that 83 percent of 340B hospitals are below the national average for charity care levels. He asked how this goes into the bill if it is not a Delaware issue, could this create a bigger problem for the hospitals.

Rep. Harris called Mark Ogunsusi, Powers Law, as a witness.

Mr. Ogunsusi noted that he does not believe that the passage of the bill will cause any impact of hospitals ability to provide the charity care they currently provide. In 2020, Delaware hospitals, which are primarily 340B hospitals, provided approximately $978 million in charity underfunded services in Delaware. He continued that 340B is facilitating a vast amount of uncompensated and undercompensated services at no cost to taxpayers.

Rep. Smith shared that they legislature is dealing with another major bill in regard to hospitals and that he appreciated his response. He asked should this be happening at the national level.

Rep. Harris responded that during stakeholder meetings with PBM's and FQHC's they all spoke about delayed action at the federal level and the impact it has had on all the entities. Rep. Harris shared that she is presenting the bill because when there is in-action at the federal level we cannot let Delawares state budget and constituents fail.

Rep. Smith asked for a broad overview of the 340B program and how this bill will solve this.

Mr. Ogunsusi responded that the program was established 30 years ago for two purposes. One was to combat the cost of drugs and to provide critical support to safety net providers. The program works by drug manufactures offering 340B discounts that are purchased by safety net providers. In exchange for the drug manufactures products there is coverage under Medicare and Medicaid. 340B is essentially a taxpayer relief program. The 340 statue regulates drug pricing and purchasing, but currently the statue is silent on the delivery and distribution of drugs, nor does it mention pharmacies by design. This bill will fill a gap in the federal statute that does not regulate distribution and protects the delivery of discounted drugs.

Rep. Smith asked does 340B closely define the way Medicaid works or does it need to be better defined in terms of the patient and access.

Mr. Ogunsusi responded that what limits the drugs a safety net provider can purchase is if it is a patient of a safety net provider, which is clearly regulated and defined. In terms of Medicaid, Delaware does not allow 340B drugs to be used for Medicaid, safety net providers are not using 340B for Medicaid in Delaware.

Rep. Smith appreciated his comments from a consumer standpoint as he was on a PBM taskforce regarding this issue. He shared that he has seen how Amazon and Mark Cuban are trying to get into the market of drug delivery. Rep. Smith expressed that he is still unsure whether this can be fixed on a state-by-state basis or should if it be federally regulated. He asked why this is a problem.

Mr. Ogunsusi responded that there are 30 to 31 states that have enacted PBM 340B laws. There is a state-by-state protection of safety net providers. With contract pharmacy, the federal statue does not regulate pharmacies from distribution drugs. States are free to enact bills to protect public health within their borders.

Rep. Griffith asked specifically how this bill will help Delawareans for its intended purpose and how to prevent abuses.

Rep. Harris introduced Chris Fraser, Westside Family Healthcare. Mr. Fraser stated that clinicians and nurses over the years have had to move people off their regiments because the medications are not available. He shared that individuals have tried to find the medications at a discount all over the state.

Rep. Griffith asked again how the bill will impact what he just described.

Mr. Fraser said that it will open the drugs going back to the pharmacies where patients are used to getting those medicines. There clinicians will get them the best drugs instead of having to change them to something else that might not be as effective.

Rep. Griffith noted that research and development (R&D) is something they want the companies to continuing pursuing and that this will impact them.

Rep. Harris stated that she has had conversations with pharmacists and small manufacturers on this and they all have described why things should be different. In discussion with stakeholders nearly fifty percent of their revenues goes back into R&D where the larger manufacturers are at five to ten percent according to their numbers. In trying to help the small organizations that put a lot into R&D they opted out trying to change the language to make sure they were protected.

Mr. Ogunsusi also added that R&D is subsidized by the government.

Rep. Smith added that it is important to not stifle innovation in any way. Life science companies do a good job of pouring most of that money back into R&D. Another concern Mr. Smith had within the 340B programs is that the rebates are going to out of state folks due to proximity.

Rep. Harris shared that there are folks here who have different opinions on that if the committee would like to hear both sides.

Rep. Harris introduced Kristen Party, Pharmaceutical Research.

Rep. Smith asked why this program seems to be a problem now when it was not for so long.

Ms. Party responded that the program is still incredibly important, and that her company is still committed to it. She stated that this program needs systemic reform at the federal program. 340B started as a safety net program to fill the gap but the program expanded every couple of years to the point where today it is about two-thirds of the hospitals in Delaware. Contract pharmacies, large-chain pharmacies, and pharmacy benefit managers all are benefiting financially off the program. The state has seen something around 8,000 percent growth in contract pharmacies.

With this growth there comes a lack of transparency that is not benefiting the patient. 1.4 percent of the discount passes directly to the patient when they fill a script.

Rep. Smith stated that we want to support our federally qualified health centers. He asked can this be solved on a state-by-state basis or will it require federal action.

Ms. Party firmly agreed that this needs federal action. It can only be changed at the federal level because it needs such authorized reform, and the states can address an issue they see is important, but it can only be fixed by going after the program from 1992. They need to re-visit 340B given that a lot has changed since then. Ms. Party continued by stating that she has worked at the state level her whole life and those that do tend to be more cynical of federal action, however, that we are seeing a change now. Her company is a part of a coalition with the community health centers and other groups; there's also bipartisan legislation that is being discussed with a draft forthcoming. Everybody involved wants Congress to act.

Rep. Smith asked who is benefiting the most from the program.

Ms. Party shared that a lot are. What we have seen with this growth is a movement towards contract pharmacies, large-chain pharmacies, and pharmacy benefit managers that are getting a piece. It is not a requirement to pass down the difference between what they receive in a discount and what they charge for the actual patient. Because of this, different stakeholders and industries have an interest because it has been financially beneficial, but not to the patient.

Rep. Smith asked then who is making the profit if the patient is not seeing much difference off the rebate.

Ms. Party responded that it is divided. The hospitals and grantees of the health centers. Contract pharmacy is not within the statue, that is relatively a new thing that has increased. This bill is not changing anything, all manufacturers are shipping, that is the requirement of the law. There are huge financial incentives for contract pharmacies. The law is not patient focused, and it needs to get back to that.

Rep. Smith noted that one thing he was reading explained that 340B entities in North Carolina were overcharging for cancer drugs to state employees. All of his questions are leaning at the recent hospital bill in general.

Rep. Harris asked what the greatest concern is and what is the biggest impact on pharmaceutical manufacturers.

Ms. Party explained that right now when a patient receives a script, they can fill it at the covered entity of the hospital or contract pharmacies. The patient is not receiving the discount on the point of sale which is not required by law and is the greatest challenge along with a lack of transparency.

Rep. Harris needed clarification for which groups were taking the largest portion of funds. Rep. Harris asked if it was FQHC's.

Ms. Party responded that it is mostly hospitals.

Rep. Harris asked how one becomes a 340B entity.

Ms. Party explained that in order to qualify as a 340B entity you must have roughly a 11.5 percent Medicaid population, but it was expanded by the Affordable Care Act to include other hospitals.

Rep. Harris stated that the revenues that come from this go back to community benefits through the hospitals. Maybe patients do not get the access at the point of receiving their prescription, but they do get it other ways.

Ms. Party stated that this is a possibility. Charity Care nationally is about 2.4 percent for hospitals and at the state level it could be smaller than that. She stated that you would think that there might be more direct benefits to each patient, although that is not a requirement.

Rep. Harris asked what would happen to the patients if the healthcare centers were the only community healthcare centers and the access to care was not also at the hospital level.

Ms. Party shared that they are there for a reason and that there should perhaps be some guiderails for hospitals, exactly what they look like and how they use it unlike the grantees that do not have a requirement.

Rep. Harris clarified then that people need hospitals and community healthcare centers as well.

Ms. Party reassured that they are absolutely both beneficial and that they would like for it to become patient focused. It is an entity-based system.

Rep. Harris has heard over and again from all stakeholders this measure is needed. Rep. Harris believed that it requires safety nets until the federal government moves.

Chair Bush opened the floor to public comment. *Time Stamp: 1:05*

Robert Overmiller, Member of the Public, Chris Lundy, INCYTE CORP., are opposed to the legislation.

Chris Haas, Department of Insurance, stated working with the sponsor on addressing regulation of medically related PBM engagement and that this industry is prone to litigation.

Dr. Yvette Gbemudu, Henrietta Johnson Medical Center, supported the legislation.

Rachel Hersh, La Red Health Center, shared the importance of 340B to the patients they serve.

Tom Stephens, Westside Family Healthcare, supported the legislation.

Chris Fraser, Westside Family Healthcare, shared that they depend on contract pharmacies and adhere to strict federal regulations in order to provide their services.

Nicole Freedman, Member of the Public, shared a personal story along with her daughter Amelia about the benefits of 340B.

Shay Scott, Henrietta Johnson Medical Center, shared that their goal is to contract to pharmacies, so that their patients can pick the most convenient pharmacy.

Steven LePage shared his support but notes that there is a lot of problems in the bill.

Mike Fleming, Delaware BioScience Association, is opposed to the bill.

Kelly Memphis, Healthcare Distribution Alliance, opposes the inclusion of distributors within the bill.

A motion was made by Rep. Baumbach and was seconded by Rep. Dorsey Walker Yes = 11 (Bush, Baumbach, Carson, Dorsey Walker, Griffith, Gray, Hensley, Short, Smith, Spiegelman, Lambert). No= 1 (Matthews). Absent = 1 (Wilson-Anton). The bill passed with F = 0, M = 6, U = 1.

Chair Bush adjourned. *Time Stamp: 1:33*

Respectfully submitted by Tyron Herring.

Attendee list:

- Chris Fraser, Westside Family Healthcare
- Mark Ogunsusi, Powers Law
- Dr. Yvette Gbemudu, Henrietta Johnson Medical Center
- Rachel Hersh, La Red Health Center
- Tom Stephens, Westside Family Healthcare
- Paul Ruggiero, NKS
- Steve Tegario, Slaudard*
- John Aiello, Southern Glazers
- Robert Overmiller, Member of the Public
- Alexis Nunan, Harvest Ridge Winery
- Citucn Nuha, Delaware Wilmington Association*
- Chris Lundy/Marc Stanislawczyk, INCYTE CORP.
- Terri Beirne/Sames Dechen, Wine Institute
- Chris Haas, Department of Insurance
- Melanie Ross Levin, Office of Women’s Advancement and Advocacy
- Sarah Stowens, Christiana Care
- Bob Trostal, Breakthru Beverage
- Mara Gorman, Planned Parenthood of Delaware

- Nicole Freedman, Member of the Public
- Shay Scott, Henrietta Johnson Medical Center
- Kristen Party, Pharmaceutical Research.

TRINIDAD NAVARRO
COMMISSIONER

STATE OF DELAWARE
DEPARTMENT OF INSURANCE

May 14, 2024

Members of the House Economic Development/Banking/Insurance and Commerce

Re: HB 383

Representatives:

On behalf of Insurance Commissioner Trinidad Navarro, the Delaware Department of Insurance, and our Office of Value-Based Health Care Delivery, I thank you for the opportunity to comment on this legislation. We continue to support efforts to regulate Pharmacy Benefit Managers (PBMs), the multi-billion-dollar intermediaries who have driven up costs and driven independent pharmacies out of our communities. These are one of the most profitable components of the health care industry, yet they provide no direct product or service to consumers. We have been proud to achieve substantial progress in this work, completing the nation's first investigatory examinations of these companies (press release attached).

We appreciate Majority Whip Harris bring this legislation forward. Federally-designated 340B entities were established by Congress more than three decades ago to lower pharmaceutical costs in provider locations typically serving economically- and access-disadvantaged populations, such as Federally Qualified Health Centers. 340Bs are highly regulated, subject to registration, regular recertification, federal audits, and strong guardrails regarding the use of the dollars they save on pharmaceutical drugs. At least 22 states now prohibit PBMs from refusing to contract with 340Bs, reimbursing them at a lower amount, imposing different fees, and other forms of discriminatory practices. We support Delaware taking a similar position, both as it relates to the department's regulatory activities, as well as the state's own contracts with such entities.

The General Assembly has seen fit in the past to ensure regulatory authority can protect certain entities from PBM discrimination, and it is important to continue to identify where more protection may be needed. We have met with Majority Whip Harris, who has been understanding of our need to discuss in detail some of the particulars of the legislation, which may require amendment. As this remains an industry prone to litigation, we want to be sure the final language is clear, firm, and limited to appropriate jurisdiction. Should the department be required to legally defend this legislative mandate, we would expect payment from the Litigation Fund -- PBM regulation does not come without cost, and we received no funding when taking on the legislative mandate to do so.

Sincerely,
Chris Haas
Senior Policy Advisor to Insurance Commissioner Trinidad Navarro
Delaware Department of Insurance

NAVARRO ANNOUNCES COMPLETION OF FIRST PHARMACY BENEFIT MANAGER EXAMS

Efforts to protect consumers and independent pharmacies, and lower pharmaceutical costs continue

DOVER, DE (May 7, 2024) – Following the unanimous passage of legislation in 2021, the Delaware Department of Insurance was given regulatory authority over Pharmacy Benefit Managers (PBMs) and has been building an investigation and enforcement program in order to address the multi-billion-dollar industry that has played a key role in increasing total cost of care and consolidating the pharmacy market. Today, Insurance Commissioner Trinidad Navarro announced the department has completed some of the nation's first examinations of PBMs, with more exams in progress.

"Protecting consumers from unjustified pharmaceutical costs and pharmacy monopolies is a key method of addressing the rising total cost of care in Delaware, and across the country. Creating transparency and accountability around PBMs is vital, and we are working hard to investigate and improve compliance with Delaware law," said **Commissioner Navarro**.

PBMs act as intermediaries for prescription drug plans, influencing what medications will be covered and the costs of those drugs for both consumers and pharmacies. These companies bring in billions through manufacturer rebates, limiting generic drug offerings, and retaining negotiated savings, while costs for consumers continue to rise. The largest PBMs operate their own pharmacy chains, and their consolidated market power has allowed them to pay unaffiliated pharmacies unsustainably low reimbursement rates – rates lower than it costs the pharmacy to dispense the drug to a consumer. PBMs' movement toward monopolization has contributed to waves of independent pharmacy closures across the nation, especially in rural, inner city, and under-served areas that already crave access. When implementation of PBM enforcement began, baseline data showed that net of rebates, Delaware prescription spending increased annually an average of 4.9% per insured person, and an average of 5.5% per prescription. Rebates paid by the state's largest PBMs to insurers or plan sponsors equaled nearly 23.5% of the cost per prescription, indicative of the cyclical nature of this issue.

The department has regulatory authority over any PBM entity operating in the state for any claim or pharmacy transaction that is dispensed or delivered to a patient in this state, regardless of the pharmacy's location. Several PBMs have incorrectly argued regulation does not apply to their Delaware business and limiting the application of the law by excluding certain contracts, locations, chain pharmacies, mail order pharmacies, and specialty pharmacy claims. In turn, these entities have been found to be not compliant with the law.

As expected, exam reports uncovered a variety of issues regarding the operations of PBMs, and their effect on pharmacies and consumers. Issues regarding limited access and unequal treatment of pharmacies are common findings, including imposing inappropriate credentialing requirements. These direct violations of the law have severely limited the ability of pharmacies in Delaware to dispense commonly prescribed medications, and adversely affect the operations of these pharmacies, especially independent and regional establishments, by pushing consumers to fill prescriptions for maintenance, short-term, and non-specialty drugs via PBM mail order, affiliates, or specialty pharmacies.

Further, as part of their influence and control of drug formularies and preferred drug lists, the department has found that PBMs and carriers have included many drugs on formularies and insurer-owned Specialty Drug Lists to restrict their dispensation to affiliated pharmacies, when these drugs should be available to, and dispensed by, all retail pharmacies. Restrictive dispensing criteria that are unrelated to FDA labeling or other specialty manufacturing limitations significantly hamper the ability of Delaware pharmacies to operate under the full scope of their licenses.

Although restricted access for pharmacies to dispense commonly prescribed medications to consumers

has had the most significant negative impact on pharmacies operating in Delaware, several other concerns and noncompliant activities have been identified through the exams, including: use of the Maximum Allowable Cost ("MAC," a reimbursement model developed by a PBM versus a single unmodified pricing source), appeals, PBM pharmacy fees and charges, pharmacy audits, network enrollment and credentialing, spread pricing, and pharmacy reimbursement issues.

The department continues to work with PBMs to ensure all pharmacies operating in Delaware are accessible and are treated fairly even when not an entity owned by a PBM or their related companies. Pharmacies operating in Delaware are encouraged to contact the Delaware Department of Insurance if they suspect or have been a victim of a PBM violation pursuant to Title 18 Chapter 33A.

In market conduct examinations under new regulatory authority, the department first completes an introductory exam where required corrections are noted but the entity does not receive financial penalties. These examinations began in 2021 often take more than 6 months to complete due to their in-depth nature. Exams occur on a regular schedule but also can be initiated outside of that schedule due to consumer or entity reports of noncompliance, and PBMs who have completed their exams will be re-examined in short order to ensure they have complied with mandated corrections. Future exams noting noncompliance will result in financial penalties, which go into the state's General Funds. Expenses of exams are paid by the entities.

To date, there are currently 42 active PBMs registered in Delaware. 3 large examinations have been fully completed, and 5 exams are currently in progress.

The department's Office of Value-Based Health Care Delivery also monitors and reports on prescription drug spending and rebates in Delaware, including a baseline report published publicly in 2022 and reported to various groups like the Delaware Health Care Commission and the Primary Care Reform Collaborative.

View this press release on Delaware.gov

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TRINIDAD NAVARRO
COMMISSIONER

STATE OF DELAWARE
DEPARTMENT OF INSURANCE

May 14, 2024

Members of the House Economic Development/Banking/Insurance and Commerce

Re: SB 232

Representatives:

On behalf of Insurance Commissioner Trinidad Navarro and the Delaware Department of Insurance, thank you for the opportunity to comment on SB 232. This consumer-friendly legislation is intended to address the recent FDA approval of over-the-counter contraceptive medications, and their release for public sale. Under the Affordable Care Act and our Delaware Insurance Code, residents can access prescribed contraceptives without incurring personal expenses like copayments or coinsurance.

However, with an over-the-counter product coming to market, we want to be sure that consumers are not inadvertently paying out of pocket for something otherwise covered at no cost to them. This is similar to the protections legislatively put into place for over-the-counter emergency contraceptives.

Additionally, the finalization of the legislatively-mandated statewide standing order effectively prescribes contraceptives to all people, meaning all people on relevant insurance plans can have their non-condom contraceptives covered. Within the bill we are codifying nonprescription access to over-the-counter medication as well, though we hope and expect the standing order to be permanent.

Finally, as enactment occurs, Department of Insurance will be working to communicate with consumers about the easiest methods by which they can apply their insurance to this over-the-counter purchase, such as encouraging pharmacy-counter purchases. We do feel that insurers will be able to produce the relevant reimbursement models as they did with COVID tests purchased at various sellers.

The coverage proposed in this bill is subject to all other limitations currently in law, including medical management, counseling, and utilization review practices, and has been thoroughly reviewed by insurance industry stakeholders. It is not a new coverage mandate, it is just adding a covered method of purchase for already-covered forms of medication.

Thank you for your time and consideration.

Sincerely,
Chris Haas
Senior Policy Advisor to Insurance Commissioner Trinidad Navarro
Delaware Department of Insurance

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Delaware Section

House Economic Development/Banking/Insurance & Commerce Meeting

May 14, 2024

Dear Committee Members,

The Delaware Section of the American College of Obstetricians and Gynecologists (ACOG) requests that you refer Senate Bill 232 out of committee. As soon as the FDA approved the over-the-counter progesterone only contraceptive pill, "Opill," ACOG released a Practice Advisory affirming its safety and furthermore pointed out that:

> For those concerned about confidentiality or who may be a victim of contraceptive coercion, an over-the-counter purchase allows the user to bypass insurance and avoid potential disclosure from itemized explanation of benefits statements. The over-the-counter POP may be a good option for those in between contraceptive methods or who do not have immediate access to a clinician or prescription refills.

Regarding access and cost, the Practice Advisory goes on to say:

> Cost is a common barrier to accessing contraception. While having a user-dependent hormonal method available over the counter is a key step toward increasing access to family planning, if consumers cannot afford to purchase it (in person or online), including buying multiple packs at once, then the method is not truly accessible. Historically, high out-of-pocket costs, deductibles, and copayments for contraception have limited contraceptive access, even for those with private health insurance. A switch to over-the-counter access should not add yet another barrier for someone who desires contraception. While insurers are not required to cover over-the-counter contraceptives without an accompanying prescription, several states have passed laws requiring state-regulated private health plans to cover certain over-the-counter methods (eg, emergency contraception and condoms) without a prescription and without cost-sharing . To address disparities in reproductive health, policies for over-the-counter contraception should cover Opill without a prescription requirement and at no up-front cost to the user, regardless of payer.

Thank you for your attention to this important public policy matter for the citizens of Delaware.

Sincerely,

Margaret R. Chou, MD, FACOG
Legislative Co-Chair Delaware Section
American College of Obstetricians and Gynecologists

Michael Fleming
President and CEO, Delaware BioScience Association
Testimony
Delaware House of Representatives Economic Development/Banking/Insurance & Commerce Committee
May 14, 2024

Re: House Bill 383: AN ACT TO AMEND TITLES 18 AND 24 OF THE DELAWARE CODE RELATING TO PROHIBITING DISCRIMINATION AGAINST 340B DRUGS AND COVERED ENTITIES BY MANUFACTURERS AND PHARMACY BENEFITS MANAGERS.

Thank you Chairman Bush, Rep. Harris and members of the committee. My name is Michael Fleming, I am president and CEO of the Delaware BioScience Association – and I am sorry I could not be with you in person today due to long-planned travel.

Delaware Bio serves biotech, pharmaceutical and biomedical research and manufacturing companies, academic research centers and educational institutions that make up our state's thriving life science ecosystem. Our 170+ member organizations of are every size, from global leaders to small start-ups – the largest and fastest growing segment of our membership – representing more than 11,000 direct jobs vital to Delaware economic future and the world's public health.

I speak today in opposition to HB 383.

The 340B program was created in 1992 with the support of the biopharmaceutical industry to help eligible hospitals and safety-net providers serve low-income, uninsured, vulnerable patients in underserved or rural communities. Fast forward to today the 340B program has expanded well beyond the scope of this noble intent into the second-largest federal prescription drug program in the nation. Unfortunately, that rapid growth has NOT been accompanied by expanded care for those in need – instead, it has led to ballooning profits for large pharmacy chains leveraging mark ups on the discounted pricing they receive through 340B.

Not surprisingly, since 2010, the number of contract pharmacies has grown by over 8000 percent!

This troubling, Frankenstonian program drift is why bipartisan efforts are actively underway at the federal level to investigate 340B failures and bring much needed reform.

That includes addressing the serious lack of transparency and oversight of where these sprawling 340B discounts are actually going.

Studies have shown the program does not lower patients' out-of-pocket costs and makes it more difficult for states, payers, and manufacturers to identify illegal duplicate discounts and diversion (and waste in the system).

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A new report by the North Carolina State Health Plan for Teachers and State Employees showed that "North Carolina providers used the safety-net 340B Drug Pricing Program to overcharge cancer patients, state employees, and taxpayers for oncology drugs. Although the 340B program was intended to subsidize care for impoverished patients, some [*providers]* pursued higher profits by expanding into wealthier neighborhoods with higher rates of health insurance."

The report continues: "Theoretically, 340B hospitals would share [these] discounts with patients or reinvest the savings in vulnerable communities — but they face no legal requirement to do so."

"Too many [providers] have converted the 340B drug discount program into a profit center at the expense of state employees, cancer patients, and taxpayers. The North Carolina State Health Plan cannot afford to pay such exorbitant price markups, particularly when existing evidence suggests that impoverished patients are not the primary beneficiaries of the 340B program."

Here in Delaware, according to the agency that runs the 340B program, the Health Resources & Services Administration (HRSA):

Only 50% of contract pharmacies are located in medically underserved areas and Delaware 340B providers have nearly 50 contracts with pharmacies outside the state in faraway places such as Arizona, Hawaii, Texas and California.

All of this unchecked, unintended and wasteful profiteering comes at the expense of the patients 340B was designed to serve but also the scientists and entrepreneurs of Delaware Bio who spend their lives – and great personal and financial expense – working on innovative new treatments and cures for the most deadly, debilitating and costly medical conditions and diseases.

Waste and profiteering from middlemen raise health care costs for us all and take funds directly out of investment in innovative research right here in Delaware.

Please do not compound this unfairness and waste by expanding this deeply flawed – and clearly extraordinarily complex – program through HB 383.

Thank you.

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DISTILLED SPIRITS COUNCIL
OF THE UNITED STATES

May 10, 2024

Hon. William Bush, Chair
Hon. William Carson, Vice Chair
Delaware House Economic Development, Banking
Insurance & Commerce Committee
411 Legislative Avenue
Dover DE, 19901

Dear Representative Bush and Representative Carson:

This letter is submitted on behalf of the Distilled Spirits Council of the United States, a national trade association representing producers and marketers of distilled spirits and importers of wines sold in the United States regarding HB 262 entitled "*An Act to Amend Title 4 of the Delaware Code Relating to Direct Purchasing and Shipment of Wine.*" As you know, this legislation would only allow the direct-to-consumer shipment of wine products to consumers in Delaware, while maintaining the prohibition on direct-to-consumer shipment of spirits. As one of the few remaining states without a direct shipment law, Delaware has a unique opportunity to pass a comprehensive shipping law that meets consumer demand for responsible access to the spirits, wine, and beer they want. Any legislation dealing with this important consumer convenience and market access issue should treat beverage alcohol products equally.

Modern-day consumers want enhanced convenience when it comes to purchasing their favorite beverage alcohol products, whether that is wine, distilled spirits, or beer, produced in-state or out-of-state. In fact, **80 percent of consumers believe distillers should be allowed to direct ship spirits** (Source: IWSR, 2021). In the past few years, the world of commerce has changed and will continue to change dramatically – particularly in the wake of the COVID-19 pandemic – and markets must adapt to meet consumer demand. Allowing the direct shipment of beverage alcohol to consumers would help meet this consumer demand while acting as a complement to the current three-tier sales system for beverage alcohol. However, there is no scientific, public safety or public policy reason for restricting those privileges only to wine.

In the last 15 years, the number of distilleries across the country has increased from 70 to more than 2,300 nationwide. Increasingly, consumers want to have access to the new and exciting spirits products that often may not be available in their state. Importantly, expanding distillers' ability to direct ship to consumers will also introduce more consumers to Delaware craft distiller brands and products. Consumers may be able to obtain limited-release products and club offerings, or to ship products home from a distillery visit in the same manner that they often ask to have wine shipped home.

Eleven states plus the District of Columbia currently allow direct-to-consumer shipping of spirits, and six others allowed in-state shipping during the COVID-19 pandemic. Distillers in these states recognize that the ability to ship their spirits products directly to their customers has been and continues to be another way to rebuild their businesses after distillery tasting rooms and tours were shut down due to the pandemic.

Distilled Spirits Council of the United States (DISCUS)
1250 Eye Street NW, Suite 400
Washington, DC 20005

Adopting legislation that will permanently allow distilleries to ship to consumers creates a more convenient marketplace by responding to consumers' demands for increased choice and variety. Direct-to-consumer shipping will lead to small producer growth and allow distillers to test new products directly with consumers and determine if there is a strong enough consumer demand and product viability for more traditional sales.

Research shows that direct ship consumers for wine or spirits are not the average consumer; they are more discriminating and are in search of more distinctive products that they are willing to pay a higher price to obtain. These are not the spirits products that are found on every shelf across the country or in every store. Further, these are brands that will perhaps never make their way to a Delaware retail shelf due to the state's market size, production levels or any one of a number of other variables.

After 20-plus years of being allowed to direct ship to consumers, the direct ship wine market only accounts for approximately 3% of wine sales. Or in the inverse, 97% of all wine continues to move through the traditional sales system in a growing market. We believe it will take a long time for spirits to achieve anything close to the wine sales level so the suggestion that direct ship of spirits would replace the traditional three-tier system is unfounded and not backed up by any data.

All of the same requirements in the proposed language for shipping wine in HB 262 regarding package labeling, licensing, tax payments, reporting, etc. should also apply to the shipment of spirits. The Distilled Spirits Council and the spirits industry are fully committed to responsible consumption and encourage moderation for adults who choose to drink alcohol. Spirits have been successfully direct shipped in other states for many years following well established and appropriate measures to restrict minors from illegally accessing beverage alcohol. There is no reason spirits should be precluded from market access channels that may be granted to the wine industry.

We believe this general policy change – direct shipment to consumers of beverage alcohol – is appropriate. However, we disagree that it should be limited to wine products only. We urge the Committee to amend the HB 262 language to include spirits. The Distilled Spirits Council of the United States remains committed to continuing to work with legislators, ABC and distilleries of all sizes to develop legislation that meets consumer demand for responsible access to the distilled spirits products they want.

Thank you for your consideration.

Sincerely,

Emily Smith
Vice President of State Public Policy

CC: Members of the Delaware House Economic Development, Banking
Insurance & Commerce Committee

WOMEN'S ADVANCEMENT & ADVOCACY
DELAWARE

May 14, 2024

The Honorable William Bush
Chair, House Economic Development/Banking/Insurance & Commerce Services Committee
411 Legislative Ave.
Dover, DE 19901

Re: SB 232– Support

Dear Chair and Members of the Committee:

I am writing to express my wholehearted support for Senate Bill 232, which seeks to expand contraceptive coverage laws to include over-the-counter (OTC) non-emergency contraceptive pills. As a constituent deeply committed to advancing women's health and reproductive rights, I urge you to champion this crucial legislation for the benefit of individuals across our state.

There are several key reasons why I believe it is imperative to support SB 232:

Effectiveness and Safety: OTC oral contraceptive pills have demonstrated high effectiveness in preventing pregnancy when used correctly, with a failure rate of less than 1%. Moreover, research affirms the safety of progestin-only pills, making them suitable for a wide range of individuals with minimal risk of serious side effects or contraindications.

Accessibility: By removing the prescription requirement for oral contraceptives, SB 232 will significantly enhance accessibility for individuals across our state. This measure will eliminate barriers related to travel, doctor's appointments, and time away from work, ultimately empowering individuals to take control of their reproductive health.

Public Support: The findings of the 2022 KFF Women's Health Survey underscore widespread public support for OTC access to birth control pills. With 77% of female respondents ages 18-64 favoring this initiative and 39% expressing intent to utilize FDA-approved OTC birth control pills, it is evident that there is a strong demand for expanded access to contraception.

Insurance Coverage: The requirement for a prescription to obtain insurance coverage for OTC medications often creates unnecessary hurdles for individuals seeking access to contraception. By enacting SB 232, we can ensure that private health insurance plans cover OTC contraception without cost-sharing, thereby promoting affordability and equitable access.

State Initiatives: Building upon existing state initiatives, such as Delaware's coverage of OTC emergency contraception through private health insurance plans, SB 232 represents a progressive step towards improving reproductive health access for all individuals in our state.

Furthermore, I am pleased to inform you that the Office of Statewide Benefits has confirmed that there are no fiscal or administrative impacts to the Government Health Insurance Program (GHIP) to implement this bill.

In conclusion, Senate Bill 232 presents a critical opportunity to advance women's health and reproductive rights by expanding access to safe and effective contraception. I urge you to support the bill and stand with the women of Delaware in ensuring their access to essential healthcare services.

Thank you for your attention to this important matter.

Sincerely,

Melanie Ross Levin
Director, Office of Women's Advancement and Advocacy
Melanie.RossLevin@delaware.gov
(302) 603-5102