

# **SB 539 PUBLIC HEARING**

**MINUTES**

**May 31, 2018**

**11:00 a.m.**

The Department of Health and Human Services (DHHS) held a public hearing on May 31, 2018 to consider amendments to the Nevada Administrative Code (NAC) Chapter 439 at the following locations:

**Location of hearing:**

Nevada Legislative Counsel Bureau  
401 S. Carson St  
Room 3138  
Carson City, NV 89701

**Via Videoconference:**

Nevada Legislative Counsel Bureau  
555 E. Washington Ave. #5100  
Room 4412E  
Las Vegas, NV 89101

**DHHS STAFF PRESENT:**

**Carson City Location:**

Dr. Julie Kotchevar, Administrator, Division of Public and Behavioral Health (DPBH)  
Margot Chappel, Deputy Administrator, DPBH  
Scott Jones, Manager, Primary Care Office (PCO), DPBH  
Veronica Sheldon, Management Analyst I, Primary Care and Health Workforce Development Office, DPBH  
Heather Mitchell, Management Analyst I, Division of Health Care Financing and Policy (DHCFP)

**Las Vegas Location:**

Joseph Tucker, Health Resource Analyst II, PCO, DPBH

Dr. Julie Kotchevar, DPBH Administrator, opened the Public Hearing for LCB File No. R042-18, Notice of Intent to Act Upon a Regulation for provisions related to drug transparency at 11:01 a.m. She stated that before public comments were heard, she would provide some guidance. Several public comments were submitted in writing prior to the public hearing; those will be incorporated into the public record.

**1. Public Comment**

Dr. Kotchevar opened the hearing for public comment, requesting that comments be limited to three (3) minutes.

In Carson City, Paul Young with R & R Partners, representing Pharmaceutical Care Management Associates (PCMA), thanked DHHS for being a pleasure to work with through the regulatory process. He also stated he submitted public comment in writing, on behalf of PCMA, which included some proposed amendments and brief rationale for the proposed amendments. He concluded by offering that he would be available for any further questions.

Dr. Kotchevar asked if there was anyone that would like to make public comment in Las Vegas. No public comment was provided in Las Vegas. She then asked if there was any other public comment in Carson City.

In Carson City, Barry Smith stated that he was Director of the Nevada Press Association (NPA), which represents newspapers around the State. Mr. Smith stated that the NPA has continually been interested in anything that has been or is an exception to the Nevada Public Records Act, which NPA perceives this proposed regulation to be. Based on his understanding of the regulation, Mr. Smith said that NPA is interested in trying to understand what may be an example of an exception that would become a trade secret. He has seen definitions, and references to the Federal exception, which he stated covers quite a bit of ground. In his stated opinion, the definition of an exception that would be a trade secret is rather subjective in a lot of subjects and areas: this is why he wanted to raise this matter at the public hearing to determine what kind of information the State might receive. Mr. Smith concluded by stating: "You are asking for pricing information, and so that's what I am looking for pricing information, the kind of thing that might be considered a trade secret, and that might not be accessible and become an exception to the Public Records Act." He offered that he would be available for any further questions.

Dr. Kotchevar asked if there were any other public comments in Carson City or Las Vegas. No additional public comments were provided. Dr. Kotchevar closed the public comment section of the agenda. She stated, "We take public comment very seriously, and we would really like to thank everyone who participated in this process."

Dr. Kotchevar stated that on behalf of the Department of Health and Human Services (DHHS), DHHS would be adopting R042-18 as previously approved by the Legislative Commission. She concluded with the statement, "We believe these regulations are sufficient as written in order to meet the deadline in the bill, but we will consider the Public Comment submitted for future revisions or clarification needed in the regulation".

Dr. Kotchevar closed the hearing.

## **2. Adjournment**

The meeting adjourned at 11:05AM.

Public comment  
received for  
SB 539  
Public Hearing

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Las Vegas

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Paul L. More (CA, NV, MA)  
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*Via electronic mail and U.S. Mail*

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**Re: Culinary Health Fund’s Comments on Proposed Regulations of  
the Department of Health and Human Services,  
LCB File No. R042-18**

To the Nevada Department of Health and Human Services and the Legislative  
Counsel Bureau:

We represent the Culinary Health Fund. The Culinary Health Fund strongly objects to the proposed regulations promulgated by the Nevada Department of Health & Human Services (“NDHHS”) on SB 539 (LCB File No. R042-18, hereinafter, the “proposed regulations”). The proposed regulations are at odds with SB 539 and so are beyond NDHHS’s authority to adopt. They rely on an interpretation of the federal Defend Trade Secrets Act (“DTSA”), 18 U.S.C. § 1836 *et seq.*, that is contrary to that federal statute’s plain text and has not been adopted by any court. The proposed regulation would have NDHHS look to federal law under the Freedom of Information Act (“FOIA”) in applying Nevada law, even though the structure of FOIA is significantly different. And the proposed regulation would amend Nevada’s Public Records Act by permitting NDHHS to withhold documents that it concluded are not confidential while a drug manufacturer litigated its objections.





In short, the proposed regulations exceed NDHHS’s authority under the relevant statute, are based on a fundamental misinterpretation of federal law, and unlawfully amend the Nevada Public Records Act.

## BACKGROUND

SB 539 amended the definition of a “trade secret” in NRS 600A.030(5) to exempt from that definition information that a drug manufacturer or pharmacy benefit manager is required to provide to NSDHHS and that NDHHS is required to disclose. This includes critical information such as the rebates that pharmacy benefits managers have negotiated with drug manufacturers, certain basic information about drug manufacturers’ pricing of essential diabetes drugs, and the factors leading to large increases in the wholesale acquisition cost of such drugs. Making this information transparent is SB 539’s entire purpose. SB 539 achieves this transparency by exempting the information from trade-secret protection under Nevada law. The Legislature included this exemption in order to ensure that the information made available to the public under SB 539’s reporting requirements would be meaningful.

The proposed regulation, however, would authorize NDHHS to keep this information secret if NDHHS “reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836.” The proposed regulations also would permit NDHHS to withhold from disclosure documents that it had concluded were not confidential while the drug manufacturer or pharmacy benefit manager pursued a court case seeking to prove otherwise, even if the lawsuit had no merit.

## OBJECTIONS

### 1. The proposed regulations exceed NDHHS’s authority under the enabling statute.

While SB 539 exempts information that drug manufacturers and pharmacy benefit managers are required to provide to NDHHS from Nevada trade-secret protection, the proposed regulations would permit NDHHS to withhold the information if it “reasonably believes” that public disclosure would “constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016[.]” This regulation—which runs directly counter to the trade-secret treatment that the Nevada Legislature prescribed for information submitted under SB 539—is based entirely on NDHHS’s belief that a state government may “misappropriate” a trade secret under the DTSA and that the DTSA “preempts” SB 539’s approach. But the DTSA only creates federal jurisdiction over civil claims of trade-secret misappropriation. By its clear terms and every indicator of legislative intent, it does not preempt a state government’s decision that certain information should be publicly available.

The DTSA is part of the federal Trade Secrets Act, 18 U.S.C. Chapter 90. The DTSA did not disturb 18 U.S.C. § 1833(a)(1), which states that “[t]his chapter does not prohibit or create a private right of action for—any otherwise lawful activity conducted by a governmental entity of



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the United States, a State, or a political subdivision of a State.” The DTSA does not prohibit NDHSS from disclosing information provided to it when that course of action is lawful under—and indeed mandated by—SB 539. Disclosing this information pursuant to SB 539 (and Nevada’s Public Records Act) is “otherwise lawful activity conducted by a governmental entity of . . . a State.” 18 U.S.C. § 1833(a)(1). *See, e.g., Brand Energy & Infrastructure Servs., Inc. v. Irex Contracting Grp.*, No. CV 16-2499, 2017 WL 1105648, at \*7 (E.D. Pa. Mar. 24, 2017) (“Congress went out of its way to make clear that the DTSA does not preempt state trade secret laws.”).

Congress made clear that it did not intend to preempt state law when it enacted the DTSA. This is clear both from its decision to include an express anti-preemption provision, 18 U.S.C. § 1838,<sup>1</sup> and from Congress’s own description of its actions. Here is how the House Judiciary Committee described the DTSA:

Consistent with the overall intent of the Defend Trade Secret Act and, in particular, § (2)(f), which provides that the bill does not “preempt any other provision of law,” the remedies provided in § (3)(A)(i)(1)(I) are intended to coexist with, and not to preempt, influence, or modify applicable State law governing when an injunction should issue in a trade secret misappropriation matter.

H. Rep. No. 114-529 (2016) (House Judiciary Committee Report), at 11-12; *id.* at 6 (“Carefully balanced to ensure an effective and efficient remedy for trade secret owners whose intellectual property has been stolen, the legislation is designed to avoid disruption of legitimate businesses, without preempting State law.”); *id.* at 14 (“ . . . State trade secret laws are not preempted or affected by this Act.”); S. Rep. 114-220 (2016) (Senate Judiciary Committee Report), at 14-15 (“Carefully balanced to ensure an effective and efficient remedy for trade secret owners whose intellectual property has been stolen, the legislation is designed to avoid disruption of legitimate business, without preempting State law.”).<sup>2</sup>

NDHHS cannot cite a single case adopting its view that a plaintiff may bring a trade-secret misappropriation case against a state agency that is lawfully acting to disclose information pursuant to state law. The DTSA’s plain text and the clear legislative history foreclose this interpretation. In fact, adopting it would call into question the many state statutes mandating that particular forms of business information be disclosed to the public, including information about

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<sup>1</sup> “[T]his chapter shall not be construed to preempt or displace any other remedies, whether civil or criminal, provided by United States Federal, State, commonwealth, possession, or territory law for the misappropriation of a trade secret.” 18 U.S.C. § 1838.

<sup>2</sup> These House and Senate reports are available, respectively, at: <https://www.congress.gov/114/crpt/hrpt529/CRPT-114hrpt529.pdf> and <https://www.congress.gov/114/crpt/srpt220/CRPT-114srpt220.pdf>.



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auto emissions, pesticide use, and, in this case, pharmaceutical drug pricing information. There is no basis for ascribing this effect to the DTSA.

Because the regulations contradict SB 539's clear mandate on the trade-secret treatment of information submitted by drug manufacturers and pharmacy benefit managers, and because such deviation from the enabling statute has no basis in federal law, the proposed regulations are beyond NDHHS's authority.

**2. The proposed regulations adopt federal FOIA law that is incompatible with the SB 539.**

The proposed regulations would require that NDHHS undertake an "initial review" to determine whether the Department reasonably believes that public disclosure "would constitute misappropriation of a trade secret" under the DTSA. The proposed regulation states that in undertaking this review, the "Department will consider, as persuasive authority, the interpretation and application given to the term 'trade secrets' in Exemption 4 of the federal Freedom of Information Act[.]" Proposed Regulation, Section 3(3)(b).

But even if NDHHS had authority to adopt regulations permitting it to look to the DTSA in determining whether to disclose documents, the definition of a "trade secret" under FOIA Exemption 4 is different from the definition of a trade secret under the DTSA. And none of information that a drug manufacturer or pharmacy benefit manager must submit to NDHHS under SB 539 is a trade secret under FOIA Exemption 4.

Exemption 4 excludes from FOIA disclosure "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4). The courts take a narrow view of what constitutes a "trade secret" under Exception 4. That term applies only to documents that are directly related to the production of a trade commodity. *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 704 F.2d 1280, 1288 (D.C. Cir. 1983) (defining "trade secret, solely for the purpose of FOIA Exemption 4, as a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 244 F.3d 144, 150-51 (D.C. Cir. 2001) (emphasizing that Exemption 4 "narrowly cabins trade secrets to information relating to the 'productive process' itself").

SB 539 does not require drug manufacturers or pharmacy benefit managers to submit information directly related to any productive process to NDHHS. The law does not require either to submit drug formulas, production methods, ingredients, or similar information directly related to the manner in which any pharmaceutical drug is manufactured. It requires that they submit only information related to their pricing of (or, in the case of pharmacy benefit managers, rebates from) essential diabetes drugs.



Moreover, FOIA Exemption 4’s definition of a “trade secret” is different from the DTSA’s definition of a trade secret, which does not limit a trade secret to a plan or formula directly related to the productive process. *Compare Pub. Citizen Health Research Grp.*, 704 F.2d at 1288, *with* 18 U.S.C. § 1839(3). Even if the DTSA applied to otherwise lawful public disclosure by a state agency, which it does not, it would make no sense for NDHHS to look to FOIA Exemption 4’s definition of a “trade secret” in determining whether information submitted pursuant to SB 539 could run afoul of the DTSA.

**3. The proposed regulations seek to amend the Nevada Public Records Act.**

The Nevada Public Records Act, NRS chapter 239, applies to every “institution, board, commission, bureau, council, department, division, authority or other unit of government of this State, including, without limitation, an agency of the Executive Department,” and applies to NDHHS. The Public Records Act sets forth the procedures that Nevada public agencies must follow when they receive a public-record request. NRS 239.0107. Under the Public Records Act, not later than the fifth business day after receiving the request, the public agency must do one of the following: (1) allow the requestor to inspect or copy the document; (2) notify the requester that the public agency does not have custody of the documents requested and inform the requester of the identity of the government entity that does have custody, if known; (3) inform the requester that the public agency is not able to provide the documents for copy or inspection within five business days and inform the requester of the date and time on which the documents will be available for inspection or copying; or (4) deny the requester’s request “because the public book or record, or a part thereof, is confidential.” NRS 239.0107(1)(a)-(d).

The proposed regulations, however, would adopt new NDHHS procedures for public-records requests for information supplied pursuant to SB 539. These procedures are contrary to the Public Records Act and so are beyond NDHHS’s authority to adopt.

The proposed regulations would permit NDHHS to deny a requester information that NDHHS concludes is not confidential while a drug manufacturer or pharmacy benefit manager that supplied the information brought a court action to prevent disclosure. Proposed Regulations, Section 3(5). Moreover, the proposed regulations would permit NDHHS to withhold these public records until a “final resolution of the action,” including all appeals. Thus, even if NDHHS concluded that the documents were public records, even if the drug manufacturer failed to obtain a preliminary injunction preventing disclosure, and even if all trial and appellate courts agreed, NDHHS would withhold the documents for the months and years that the drug manufacturer or pharmacy benefit manager took to exhaust its legal appeals. The Nevada Public Records Act does not permit NDHHS to take this approach.

NDHHS may not justify this amendment to the Nevada Public Records Act based on the language of NRS 239.0107(1)(c), as it has purported to do. Proposed Regulation, Section 3(5)(a). That portion of the Public Records Act states that if the government entity is “unable to



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make the public book or record available by the end of the fifth business day” after the request, it will so inform the requester and advise the requester of the date and time when the records “will be available.” NRS 239.0107(1)(c) is intended to address situations in which a request is too voluminous for the government entity to make copies available within five business days, or where the records are in a location or locations that make such copying within five business days impossible. A government entity that determines that records are not confidential but that faces a legal action arguing that the records are confidential is not “unable” to provide copies of the records. NRS 239.0107(c)(1) does not permit NDHHS to withhold documents that it has determined are discloseable public records while a private party pursues legal action. *Comstock Residents Ass’n v. Lyon Cty. Bd. of Commissioners*, 134 Nev. Adv. Op. 19, 414 P.3d 318, 321 (2018) (Nevada Public Records Act “allows five business days for a governmental entity to resolve a public records request.”).

### CONCLUSION

The proposed regulations exceed NDHHS’s authority under SB 539, are based on a misinterpretation of federal law, and unlawfully seek to amend the Nevada Public Records Act. The Culinary Health Fund strongly objects to them and requests that they be withdrawn.

Respectfully submitted,



Paul L. More

cc: Bobbette Bond

**From:** Paul Young  
**To:** [Drug Transparency](#)  
**Subject:** PCMA's technical comments  
**Date:** Monday, May 14, 2018 12:36:18 PM  
**Attachments:** [R042-18P-539 Reg.pdf](#)

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Hey Veronica,

Below are PCMA's technical comments to the SB 539 reg:

- There is a concern that the proposed rule may rely on an incorrect standard of the federal Defend Trade Secrets Act. The term "misappropriation," while used in the DTSA, may not be appropriate in this context, because it appears that the state would have to be violating the law for the protections to kick in (which they wouldn't, since state law allows them to). We think the underlying concern that the Dept. shares here is that the public release of the information would cause competitive harm, and think that the language should reflect that concerns.
- Re: Section 3(5)(b) – The Notice to the PBM that the public information request will be fulfilled barring any exceptions should be concurrent with the notification to the requester, since the clock starts ticking as soon as the Dept. sends the notification to the requester.
- Re: Section 4(1) – I think the goal here is that the data is truly aggregated, which helps prevent the numbers from getting "backed into," but to be sure of that, the data shouldn't be identifiable by plan, either. We'd want a bit stronger protection against individually-identifiable (by drug, manufacturer, plan or PBM) information from being exposed.

Thank you,  
Paul



Paul Young

Deputy Director, Government Affairs

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## **Amendment Proposals and Brief Rationale**

**Sections 3(1), 3(2)(b), 3(3)(b), and 3(4)** Delete “~~would constitute misappropriation~~” from all of these sections and replace with “could cause competitive harm or qualifies as a disclosure”

**Section 3(5):** Delete “~~constitute misappropriation~~” and replace with “cause competitive harm or does not qualify as a disclosure”

**Section 3(6)(a) & (b):** Delete from both (a) and (b) “~~the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended~~” and replace with “this regulation”

**Rationale:** We are requesting the above amendments because we do not believe the proposed rule relies on the appropriate standard for seeking relief under the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836 (DTSA). The term “misappropriation” implies that the Department would be committing some type of malfeasance relating to improper acquisition or use of the data provided to them. This is not the case as the Department would be acting pursuant to the law. The concern here is about the potential for competitive harm that would occur at the point of disclosure. Thus, we are suggesting that the standard for seeking relief for PBMs to meet under the DTSA that would allow for the protection against disclosure should be any information that could cause competitive harm or information that qualifies as disclosure of a trade secret under the DTSA. The amendments above would make this change consistent throughout the proposed rule.

### **Section 3(3)(b): Delete all**

**Rationale:** We are requesting the deletion of this entire subsection because it incorrectly assumes that Exemption 4 of the federal Freedom of Information Act, 5 U.S.C. § 552(b)(4), as amended, defines the term “trade secrets”. **In fact, neither the federal Freedom of Information Act, 5 U.S.C. § 552(b)(4), nor Exemption 4 defines the term.** Additionally, this section also references “misappropriation of a trade secret,” which as we have discussed earlier, is not the appropriate standard here.

**Section 3(5)(b):** Delete “~~As soon as reasonably practicable after~~” and replace with “Concurrent with”

**Rationale:** We are requesting this amendment because the PBM should be provided notice at the same time as the requester. As drafted, the 30-day clock would start running for the PBM to potentially protect their data, if need be, before the PBM even gets notice of the Department’s intent to disclose.

### **Section 4(1): Amend as follows:**

“1. Only aggregated data of all manufacturers combined or all pharmacy benefit managers combined, as applicable, and that does not disclose or allow for the determination of the identity of any drug, manufacturer, plan or pharmacy benefit manager; and”

**Rationale:** We are concerned that the Department may disclose the data separately by PBM. Even if those PBMs are not specifically identified, it would not be difficult for a person with knowledge of the market place and industry to put names to the de-identified, separate total numbers. If this were to occur, it would harm competition in the marketplace among drug manufacturers and has the potential to lead to increased costs for Nevada consumers. Therefore, we are requesting that the report compiled by the Department only include combined data from all the PBMs.

### **Section 2: Amend to include a new subsection (c):**

“(c) The Department shall hold all data in confidence and will release such data only as provided pursuant to these regulations.”

**Rationale:** We are requesting the above amendment because we believe it is important to state this explicitly in the rule.



May 15, 2018

**BY E-MAIL**

Nevada Department of Health and Human Services  
4150 Technology Way, Suite 300  
Carson City, NV 89703  
drugtransparency@dhhs.nv.gov

**Re: Proposed Regulations LCB File No. R042-18**

To Whom It May Concern:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) appreciates the opportunity to comment on the Department of Health and Human Services’ (“Department”) proposed regulations implementing Senate Bill 539 of the 2017 Legislative Session. PhRMA is a voluntary, non-profit association that represents the country’s leading pharmaceutical research and biotechnology companies. PhRMA members are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives, including essential diabetes medicines. Since 2000, PhRMA’s member companies have invested more than half a trillion dollars in the search for new treatments and cures, with members investing \$65.5 billion in 2016 in the discovery and development of new medicines.

PhRMA commends the Department and the Legislative Counsel Bureau for crafting regulations that acknowledge the need to ensure the confidentiality of manufacturers’ trade secrets. Although PhRMA was pleased to see that the Legislative Counsel adopted many of the suggestions PhRMA made in its earlier comments, PhRMA respectfully requests that the Legislative Commission and Department consider the legal and policy issues addressed below before adopting the proposed regulations.

**I. The Department Should Revise the Requirement That Manufacturers Explain Why Public Disclosure of Trade Secrets Would Constitute “Misappropriation” Under the Defend Trade Secrets Act (DTSA)**

Under Section 3(1) of the proposed regulations, a manufacturer may request that information be kept confidential if the manufacturer “reasonably believes that public disclosure of [the] information . . . would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended [the “DTSA”].” Proposed Regulations § 3(1). Pursuant to the regulations, not only must the manufacturer describe in detail what should be kept from public disclosure, a manufacturer’s request for confidentiality must “include an explanation of the reasons why

public disclosure of the information would constitute misappropriation of a trade secret” under the DTSA. *Id.* § 3(2)(b). If the Department then receives a public records-seeking disclosure of the information under the Nevada Public Records Act, the Department must determine whether the public disclosure of the information “would constitute misappropriation of a trade secret” under the DTSA. *Id.* § 3(3)(b). If the Department believes that public disclosure of the information would constitute misappropriation under the DTSA, then the Department must deny the request. *Id.* § 3(4). If the Department believes that public disclosure would not constitute misappropriation, then the Department will notify the manufacturer, who will then have 30 days to commence an action in a court of competent jurisdiction to enjoin the Department from disclosing the information under the DTSA.<sup>1</sup>

As drafted, these provisions are inconsistent with the confidentiality provisions of the Nevada Public Records Act. As the Legislative Counsel’s Digest acknowledges, under the Public Records Act, information is exempted from disclosure if it is “declared . . . to be confidential” under state or federal law. NRS 239.0101. Federal law declares trade secrets to be confidential. See Legislative Counsel’s Digest at 2–3. Thus, the relevant question under the Public Records Act is whether the requested information constitutes a trade secret under federal law, not whether disclosure of the information would constitute misappropriation under the DTSA.

As a practical matter, if the requested information constitutes a trade secret under federal law, then public disclosure of the information would necessarily constitute misappropriation under the DTSA. The DTSA defines “misappropriation” to include “disclosure or use of a trade secret of another without express or implied consent by a person who . . . at the time of disclosure or use, knew or had reason to know that the knowledge of the trade secret was . . . acquired under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret.” 18 U.S.C. § 1839(5)(B)(ii)(II). The public disclosure of a manufacturers’ trade secrets without permission would plainly constitute “misappropriation” under this definition. Nevertheless, the relevant question under the Nevada Public Records Act is technically not whether disclosure would constitute misappropriation, but rather simply whether the requested information constitutes a trade secret under federal law. PhRMA respectfully suggests that the final regulation be revised to remove the requirement that manufacturers explain why public disclosure of trade secrets would be a misappropriation so that the regulation is consistent with the Public Records Act.

## **II. The Department Should Not Automatically Disclose a Manufacturer’s Explanation of Why Disclosure of the Information Would Be a Misappropriation**

As noted, Section 3(2)(b) requires manufacturers who request that certain information be kept confidential submit “an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret” under the DTSA. As mentioned above PhRMA believes that this requirement should be revised so that the

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<sup>1</sup> PhRMA understands, and the Department has confirmed, that a federal court would be a court of competent jurisdiction to hear the manufacturer’s challenge.



explanation simply states why the requested information is a trade secret. In any event, the Department should revise the proposed regulations so that the manufacturer's explanation is not automatically disclosed to the public. As drafted, Section 3(2)(b) provides that "[u]pon a request for public records pursuant to NRS 239.010, the Department *will disclose* the explanation set forth in the request for confidentiality." *Id.* § 3(2)(b) (emphasis added). This is in contrast to Section 3(2)(a), which provides that the Department "will not disclose" a manufacturer's description of the information sought to be protected from public disclosure "unless the description and information and information are disclosed pursuant to subsections 5 and 6." *Id.* § 3(2)(a). For the same reasons that the Department should not automatically disclose the manufacturer's description of the information it seeks to protect, the Department should not automatically disclose the manufacturer's explanation as to why that information constitutes a trade secret. In either case, the manufacturer's submission to the Department will likely itself implicate trade secrets and thus should not automatically be disclosed.

Indeed, the Nevada Public Records Act requires an analysis of whether the requested information is "declared by law to be confidential" whenever a governmental entity receives a request for information. NRS 239.0101. Accordingly, PhRMA requests that the Department strike the portion of Section 3(2)(b) that *requires* disclosure of a manufacturer's explanation of why disclosure is a misappropriation, so that the Department may, consistent with the Public Records Act, consider each request for information on a case-by-case basis to determine whether the information requested is declared by law to be confidential.

### **III. Deadline for Initial Manufacturer Reports**

Under § 3.6(2) of SB 539, the Department must compile a list of prescription drugs essential for treating diabetes in Nevada whose WAC has increased by more than "[t]he percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year" or "[t]wice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years." If a manufacturer's drug is included on the § 3.6(2) list, this triggers additional reporting obligations under § 4 of SB 539.

Section 26.9 provides that the Department must publish the initial § 3.6(2) list "[o]n or before November 1, 2017," and manufacturers would then have eight months—until July 1, 2018—to prepare and submit their reports pursuant to § 4. The Department has not yet, however, published the § 3.6(2) list. In its February 14, 2018 comment letter to the initial draft regulations, PhRMA explained that the eight-month period that the Legislature required between the initial § 3.6(2) list and the § 4 report is essential to providing manufacturers adequate lead time to prepare their initial § 4 reports. PhRMA therefore requested that the Department confirm that no § 4 reporting would be due until at the earliest April 1, 2019 (the date on which § 4 reporting is due in 2019 and later years). The proposed regulations, however, do not address this issue.

The July 1 reporting deadline is now six weeks away, and the Department has not yet published the list contemplated by § 3.6(2). PhRMA reiterates its request that the Department confirm that no § 4 reporting will be due until at the earliest April 1, 2019.

#### **IV. Implementation Concerns**

As explained in PhRMA's prior comment letter, the proposed regulations offer no clarity to manufacturers as to what precise information they must disclose. The statute requires manufacturers to disclose information regarding "costs," "profits," and "administrative expenditures," but all of these terms are reasonably susceptible to multiple interpretations. PhRMA remains concerned that without further guidance, manufacturers will each inevitably report different "costs," resulting in an apples-to-oranges comparison that will be unhelpful to the Department. PhRMA would therefore urge the Department to define more precisely the information that manufacturers are required to provide.

\* \* \*

Once again, PhRMA thanks the Department and Legislative Counsel for their efforts thus far in crafting these important regulations to ensure that manufacturers trade secrets are not disclosed to third parties. We look forward to discussing these issues at the upcoming hearing before the Legislative Commission on May 16 and before the Department on May 31.

Respectfully submitted,



Joanne Chan  
Assistant General Counsel  
Law



May 31, 2018

Nevada Department of Health and Human Services  
4150 Technology Way, Suite 300  
Carson City NV 89703

*Via email: [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov)*

**Re: LCB File No. R042-18. Revises provisions related to drug transparency.**

To Whom it May Concern:

The Pharmaceutical Care Management Association (PCMA) submits the following comment letter in response to the Department's proposed rules in LCB File No. R042-18, implementing sections of SB 539 (2017) relating to drug price transparency. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through large and small employers, state governments, health insurance plans, labor unions, Medicaid managed care, Medicare Part D, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide feedback on the proposed rules. First, PCMA appreciates the Department's acknowledgment that certain proprietary price information is protected by the federal Defend Trade Secrets Act and appreciates that the Department has outlined a process to address those protections as the issues arise. PCMA remains concerned about the sensitive nature of the data required to be reported to the state, but believes that the Department intends to protect the data to the extent allowed under federal and state law. We have some concerns about the implementation of the language in the context of the Defend Trade Secrets Act and suggest amendments and provide rationale below that address these concerns.

1. In several sections<sup>1</sup> of the proposed rule, the language allows a PBM to submit a request to the Department to keep certain information confidential and not subject to public disclosure. PCMA strongly supports the Department's goal to provide a pathway to utilize the federal protections in the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836 (DTSA), and we appreciate the Department acknowledging this in the draft rule. We are concerned, however, that the standard for seeking relief outlined in the proposal is inconsistent with the DTSA. The DTSA's pathway for seeking relief is designed to protect against the disclosure of information that qualifies as a trade secret. Although we understand that the federal law uses "misappropriation" as the trigger to determine when a remedy is in order, using the term "misappropriation" in the state rule implies that the *Department* would need to act inappropriately or commit some sort of malfeasance for the ability of a PBM to initiate the procedure to protect the information from disclosure. Because the Department would be releasing information in accordance with its state statute, we believe the standard of

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<sup>1</sup> Sections 3(1), 3(2), 3(3), and 3(4).





“misappropriation” is not the appropriate standard for seeking relief under the DTSA. Instead, we suggest that the standard for seeking relief for PBMs to meet under the DTSA that would allow for the protection against disclosure should be any information that could cause competitive harm or information that qualifies as disclosure of a trade secret under the DTSA.

**PCMA suggests the following amendments:**

**Sections 3(1), 3(2)(b), 3(3)(b), and 3(4):** Delete ~~“would constitute misappropriation”~~ from all of these sections and replace with “could cause competitive harm or qualifies as a disclosure”

**Section 3(5):** Delete ~~“constitute misappropriation”~~ and replace with “cause competitive harm or does not qualify as a disclosure”

**Section 3(6)(a) & (b):** Delete from both (a) and (b) ~~“the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended”~~ and replace with “this regulation”

2. Section 3(3)(b) provides for the Department to perform an initial review of the potential public disclosure, and consider the interpretation and application given to the term “trade secrets” in Exemption 4 of the federal Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4), as amended. We are concerned that this section would have no effect because neither Exemption 4 of FOIA, nor the DTSA define the term “trade secret.” In addition, this section references “misappropriation of a trade secret,” which we believe, as described above, is not an appropriate standard for seeking relief.

**PCMA suggests deleting Section 3(3)(b).**

3. Section 3(5)(b) provides for the Department to provide notice to the PBM that sensitive information may be disclosed “as soon as reasonably practicable after” notifying the requester of information. PCMA is concerned that the 30-day clock begins running as soon as the notice has been provided to the requester, so the PBM would always be at a time disadvantage and may not have sufficient time to defend against disclosure when it is appropriate. We believe that the notice to the requester and the PBM should be concurrent.

**PCMA suggests the following amendment:**

**Section 3(5)(b):** Delete ~~“As soon as reasonably practicable after”~~ and replace with “Concurrent with”

4. Section 4(1) calls for any data that is released to be aggregated so that the identity of a drug, manufacturer, or PBM is not disclosed. PCMA is concerned that under this language, the Department may disclose the data separately by PBM. Even if those individual PBMs are not identified, it would not be difficult for a person with knowledge of the PBM market share, volume of sales, and formularies to figure out the names of the PBMs and separate total numbers. If drug manufacturers were to learn the rebate amounts and be able to identify the specific PBMs that were associated with those amounts, there is a significant

risk that competition in the marketplace among drug manufacturers would be impeded, which has the potential to lead to increased costs for Nevada consumers. On this point, the Federal Trade Commission has stated that, “[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors...then tacit collusion among manufacturers is more feasible...Whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely. The FTC has also warned several states that legislation requiring PBM disclosure of negotiated terms could increase costs and “undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford. Because we share these concerns, we are requesting that the report compiled by the Department only include combined data from all reporting PBMs.

**PCMA suggests the following amendment:**

Section 4(1): Only aggregated data of all manufacturers combined or all pharmacy benefit managers combined, as applicable, and that does not disclose or allow for the determination of the identity of any drug, manufacturer, plan or pharmacy benefit manager; and”

5. PCMA is concerned that there is no clear statement in the proposed rule that requires the Department to hold information in confidence and release data only as required by statute and this regulation.

**PCMA suggests the inclusion of a following new subsection (c):**

**Section 2(c) The Department shall hold all data in confidence and will release such data only as provided pursuant to these regulations.”**

We appreciate the opportunity to provide comments on this proposed rule and we welcome the opportunity to speak with you about our concerns. Please do not hesitate to contact me at 202-756-5743 if you have any questions.

Sincerely,



April C. Alexander  
Assistant Vice President, State Affairs

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<sup>2</sup> U.S. Federal Trade Commission and the U.S. Department of Justice, Improving Health Care: A Dose of Competition (July 2004).

<sup>3</sup> Letter from FTC to Rep. Patrick T. McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).



cc: Margot Chappel, MS, Manager, Primary Care and Health Workforce Development Office,  
Department of Health and Human Services