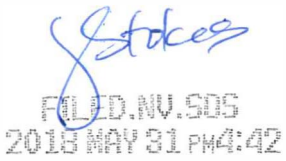
SECRETARY OF STATE
FILING DATA



Form For Filing
Administrative Regulations

Agency:
Department of Health and Human Services

FOR EMERGENCY
REGULATIONS ONLY

Effective date _____

Expiration date _____

_____
Governor's signature

Classification: **PROPOSED X ADOPTED BY AGENCY** **EMERGENCY**

Brief description of action:

The adopted regulation outlines how the Department of Health and Human Services will support submission of certain reports by manufacturers of prescription drugs, pharmacy benefit managers and pharmaceutical sales representatives by providing forms online. It describes the process by which a manufacturer or pharmacy benefit manager can submit a request for confidentiality covering certain information. Lastly, it describes procedures the Department will follow when public information requests for information are filed and for which a confidentiality request has been submitted.

Authority citation other than 233B:

Notice date: January 30, 2018; April 30, 2018 **Date of Adoption by Agency:** May 31, 2018

Hearing date: February 15, 2018; May 31, 2018

APPROVED REGULATION OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

LCB File No. R042-18

Effective May 31, 2018

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: §§1-4, NRS 439.930.

A REGULATION relating to prescription drugs; providing that the Department of Health and Human Services will make available on an Internet website maintained by the Department certain forms that must be used by manufacturers of prescription drugs, pharmacy benefit managers and pharmaceutical sales representatives to submit certain reports to the Department; authorizing a manufacturer or pharmacy benefit manager that submits such a report to request that the Department keep certain information confidential as a trade secret under federal law; establishing procedures for the Department to follow when it receives a request for public records seeking disclosure of information for which a manufacturer or pharmacy benefit manager has submitted a request for confidentiality; prescribing certain requirements for reports compiled by the Department concerning the prices of certain prescription drugs; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the Department of Health and Human Services to compile each year: (1) a list of prescription drugs essential for treating diabetes in this State; and (2) a list of such prescription drugs which have been subject to an increase in wholesale acquisition cost that exceeds a prescribed amount. (Section 3.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4297 (NRS 439B.630)) Existing law also requires the manufacturers of drugs that appear on those lists and pharmacy benefit managers to submit to the Department annual reports containing certain information about the prices of those drugs. (Sections 3.8, 4 and 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 and 439B.645)) Existing law further requires a pharmaceutical sales representative who markets prescription drugs on behalf of a manufacturer in this State to submit to the Department an annual report concerning the provision of compensation and free samples to certain persons. (Section 4.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.660)) **Section 2** of this regulation provides that the Department will make

available on an Internet website maintained by the Department the forms that must be used by the manufacturers, pharmacy benefit managers and pharmaceutical sales representatives to submit such annual reports.

Under existing law, commonly known as the Nevada Public Records Act, when a state or local governmental entity receives a request to disclose information contained in public records within its legal custody or control, the governmental entity must disclose the information, unless the information is confidential under state or federal law. (NRS 239.010; *City of Reno v. Reno Gazette-Journal*, 119 Nev. 55, 58-61 (2003)) Upon receiving such a request for public records, the governmental entity must respond to the requester within five business days by doing one of the following: (1) if the requested information is confidential under state or federal law, the governmental entity must provide the requester with written notice of the denial of the request and a citation to the specific statute or other legal authority that makes the information confidential; (2) if the requested information is not confidential under state or federal law and the governmental entity is able to make the information available within those five business days, the governmental entity must provide the requester with the information; or (3) if the governmental entity is unable to make the information available within those five business days, the governmental entity must provide the requester with written notice of that fact and a date and time after which the information will be made available. (NRS 239.0107)

Under existing federal law, when a state or local governmental entity is exercising its powers and duties under state or local law, the governmental entity must also comply with federal law, which supersedes any conflicting state or local law, because federal law is the supreme law of the land under the Supremacy Clause of the United States Constitution. (U.S. Const. Art. VI, cl. 2; *Alden v. Maine*, 527 U.S. 706, 755 (1999)) For example, if information is provided to state governmental entities and maintained in their databases as part of state regulatory programs and the information has potential commercial value in interstate commerce, Congress may exercise its power under the Commerce Clause of the United States Constitution to prohibit the state governmental entities from disclosing the information, even if such disclosure is authorized by state law. (U.S. Const. Art. I, § 8, cl. 3; *Reno v. Condon*, 528 U.S. 141, 143-51 (2000))

In the context of trade secrets related to products or services used in interstate commerce, Congress has exercised its power under the Commerce Clause to enact the federal Defend Trade Secrets Act of 2016 (DTSA), which authorizes the owner of a trade secret to bring a civil action to prevent the improper disclosure of information that would constitute misappropriation of a trade secret under federal law and, if such information is improperly disclosed, to provide remedies for violations of the federal law. (18 U.S.C. § 1836) In such a civil action brought under the federal DTSA, a court of competent jurisdiction may award legal and equitable relief, including protective orders, injunctive relief, compensatory damages, punitive damages and attorney's fees, to the owner of a trade secret to prevent or remedy violations of the federal law. (18 U.S.C. §§ 1833-1839) In addition to the remedies established by the federal DTSA, federal

law also prohibits certain conduct that constitutes theft of a trade secret and prescribes criminal penalties for such violations. (18 U.S.C. § 1832)

Because information that constitutes a trade secret may be submitted to federal agencies, the federal Trade Secrets Act prohibits federal officers and employees from disclosing such information, unless the disclosure is specifically authorized by federal law. (18 U.S.C. § 1905; *Chrysler Corp. v. Brown*, 441 U.S. 281, 294-319 (1979)) As a result of this federal prohibition, when federal agencies receive requests for public records under the federal Freedom of Information Act (FOIA), the federal agencies cannot disclose information that constitutes a trade secret under the federal Trade Secrets Act, and such information is also exempt from disclosure under the "trade secrets" exemption in FOIA, which is commonly referred to as "Exemption 4." (5 U.S.C. § 552(b)(4); 18 U.S.C. § 1905; *Canadian Commercial Corp. v. Dep't of Air Force*, 514 F.3d 37, 39 (D.C. Cir. 2008); *Pac. Architects & Eng'rs v. Dep't of State*, 906 F.2d 1345, 1346-47 (9th Cir. 1990); *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1286-90 (D.C. Cir. 1983))

To ensure that trade secrets are not improperly disclosed under the federal Trade Secrets Act and FOIA, federal agencies have a duty to adopt regulations establishing specific procedures that the federal agencies must follow when they receive requests for public records under FOIA seeking disclosure of information that may constitute a trade secret or other confidential commercial information. The purpose of such procedures is to ensure that persons who have submitted trade secrets or other confidential commercial information to federal agencies are provided with notice of the potential disclosure of the information under FOIA and an opportunity to respond and protect their interests in the confidentiality of the information before the federal agencies may disclose the information to the public. (*Predisclosure Notification Procedures for Confidential Commercial Information*, Exec. Order No. 12,600, 52 Fed. Reg. 23,781 (June 23, 1987); *OSHA Data/CIH v. Dep't of Labor*, 220 F.3d 153, 163-64 (3d Cir. 2000); *Venetian Casino Resort v. EEOC*, 530 F.3d 925, 934-35 (D.C. Cir. 2008))

Section 3 of this regulation establishes specific procedures that the Department will follow when it receives a request for public records under the Nevada Public Records Act seeking disclosure of information which: (1) may constitute a trade secret under the federal DTSA; and (2) is included by a manufacturer or pharmacy benefit manager in an annual report concerning the prices of prescription drugs submitted to the Department under sections 3.8, 4 or 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 or 439B.645). **Section 3** provides that a manufacturer or pharmacy benefit manager which is required to submit such a report may submit to the Department a request to keep information included in the report confidential if the manufacturer or pharmacy benefit manager reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA. If a manufacturer or pharmacy benefit manager submits a request for confidentiality, **section 3** requires the request to: (1) describe, with particularity, the information sought to be protected from public disclosure;

and (2) include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA.

If the Department receives a request for public records under the Nevada Public Records Act seeking disclosure of information for which the manufacturer or pharmacy benefit manager has submitted a request for confidentiality, **section 3** requires the Department, as soon as reasonably practicable after receiving the request, to provide the manufacturer or pharmacy benefit manager with: (1) written notice of the request for public records and the procedures set forth in **section 3**; and (2) a copy of the request for public records and the date on which the Department received the request. **Section 3** also requires the Department to undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA. When the Department undertakes its initial review, **section 3** states that the Department will consider, as persuasive authority, the interpretation and application given to the term "trade secrets" under Exemption 4 of FOIA.

If, after undertaking its initial review, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA, **section 3** provides that the Department will: (1) within the time required by the Nevada Public Records Act, provide the requester of public records with written notice that the Department must deny the request on the basis that the information is confidential under the federal DTSA; and (2) as soon as reasonably practicable after notifying the requester, provide the manufacturer or pharmacy benefit manager with written notice that the Department denied the request and a copy of the written notice provided to the requester and the date on which it was sent to the requester. Under the Nevada Public Records Act, the requester would have the right to bring an action against the Department to challenge the denial of the request for public records. (NRS 239.011; *City of Sparks v. Reno Newspapers*, 133 Nev. Adv. Op. 56, 399 P.3d 352, 354 (2017); *DR Partners v. Bd. of County Comm'rs*, 116 Nev. 616, 620-21 (2000)) If the requester were to bring such an action against the Department, the manufacturer or pharmacy benefit manager could assert a right to intervene in the action to protect its interests in the confidentiality of the information. (*Appleton v. FDA*, 310 F. Supp. 2d 194, 196-97 (D.D.C. 2004); *Yorkshire v. IRS*, 26 F.3d 942, 944-45 (9th Cir. 1994))

If, after undertaking its initial review, the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret under the federal DTSA, **section 3** requires the Department, within the time required by the Nevada Public Records Act, to provide the requester of public records with written notice that the Department intends to disclose the information. However, **section 3** also requires the Department to inform the requester that: (1) the Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and (2) if the manufacturer or pharmacy benefit manager timely commences an action within that 30-day period to enjoin disclosure of the information under the federal DTSA, the Department will not be able to disclose the information, unless the disclosure is permitted after final resolution of the

action, including any appeals. **Section 3** additionally requires the Department, as soon as reasonably practicable after notifying the requester, to provide the manufacturer or pharmacy benefit manager with: (1) written notice that the Department intends to disclose the information; and (2) a copy of the written notice sent to the requester and the date on which it was sent to the requester.

If, within the 30-day period following the date on which the Department sent the written notice to the requester, the manufacturer or pharmacy benefit manager does not commence an action to enjoin the Department from disclosing the information under the federal DTSA, **section 3** requires the Department to disclose the information. However, if such an action is timely commenced within the 30-day period, **section 3** provides that the Department will not disclose the information until final resolution of the action, including any appeals. Following commencement of the action, the requester of the public records could assert a right to intervene in the action to protect its interests in the disclosure of the information. (*Entergy Gulf States La. v. EPA*, 817 F.3d 198, 203-06 (5th Cir. 2016); *LaRouche v. FBI*, 677 F.2d 256, 257-58 (2d Cir. 1982))

After final resolution of the action, including any appeals, if the court enjoins the Department from disclosing the information as a trade secret, **section 3** provides that the Department will not disclose the information so long as the information retains its status as a trade secret. However, if the court does not enjoin the Department from disclosing the information as a trade secret, **section 3** provides that the Department will disclose the information as soon as reasonably practicable after final resolution of the action.

Finally, existing law requires the Department to: (1) analyze the information submitted by manufacturers and pharmacy benefit managers in their annual reports; and (2) compile a report on the prices of the prescription drugs that appear on the most current lists of essential diabetes drugs compiled by the Department. (Section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650)) **Section 4** of this regulation provides that the report compiled by the Department will include only aggregated data that does not disclose the identity of any drug, manufacturer or pharmacy benefit manager. **Section 4** also provides that the Department will include in the report: (1) a description of trends concerning the prices of the prescription drugs that appear on the most current lists of essential diabetes drugs compiled by the Department; and (2) an explanation of how those prices and trends may affect the prevalence and severity of diabetes in this State and the system of health care in this State.

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2, 3 and 4 of this regulation.

Sec. 2. *The Department will make available on an Internet website maintained by the Department the forms on which:*

1. A manufacturer is required to submit the reports required by sections 3.8 and 4 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635 and 439B.640).

2. A pharmacy benefit manager is required to submit the report required by section 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4298 (NRS 439B.645).

3. A person included on a list of pharmaceutical sales representatives provided by a manufacturer to the Department pursuant to subsection 1 of section 4.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.660), is required to submit the report required by subsection 4 of that section.

Sec. 3. *1. In complying with section 3.8, 4 or 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 or 439B.645), if a manufacturer or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department 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 manufacturer or pharmacy benefit manager may submit to the Department a request to keep the information confidential.*

2. A request for confidentiality submitted pursuant to subsection 1 must be divided into the following parts, which must be severable from each other:

(a) The first part of the request for confidentiality must describe, with particularity, the information sought to be protected from public disclosure. Upon a request for public records

pursuant to NRS 239.010, the Department will not disclose the description set forth in the request for confidentiality or the information sought to be protected from public disclosure, unless the description and information are disclosed pursuant to subsections 5 and 6.

(b) The second part of the request for confidentiality must include an explanation of the reasons why 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. Upon a request for public records pursuant to NRS 239.010, the Department will disclose the explanation set forth in the request for confidentiality.

3. If the Department receives a request for public records pursuant to NRS 239.010 seeking disclosure of any information for which a manufacturer or pharmacy benefit manager has submitted a request for confidentiality pursuant to subsection 1, the Department will:

(a) As soon as reasonably practicable after receiving the request for public records, provide the manufacturer or pharmacy benefit manager with:

(1) Written notice of the request for public records and the procedures set forth in this section; and

(2) A copy of the request for public records and the date on which the Department received the request.

(b) Undertake an initial review to determine whether the Department 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. In undertaking its initial 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, 5 U.S.C. § 552(b)(4), as amended.

4. If, after undertaking its initial review pursuant to subsection 3, the Department 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 Department will:

(a) Within the time prescribed by NRS 239.0107, provide the requester of the public records with written notice pursuant to paragraph (d) of subsection 1 of NRS 239.0107 that the Department must deny the request for public records on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended.

(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:

(1) Written notice that the Department denied the request for public records; and

(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.

5. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would not 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 Department will:

(a) Within the time prescribed by NRS 239.0107, provide the requester of the public records with written notice pursuant to paragraph (c) of subsection 1 of NRS 239.0107 that the Department intends to disclose the information, except that:

(1) The Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and

(2) If the manufacturer or pharmacy benefit manager timely commences an action within the 30-day period as provided in subsection 6, the Department will not be able to disclose the information, unless the disclosure is permitted by that subsection.

(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:

(1) Written notice that the Department intends to disclose the information; and

(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.

6. If, within the 30-day period following the date on which the Department sent the written notice to the requester of public records pursuant to subsection 5, the manufacturer or pharmacy benefit manager:

(a) Does not commence an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will disclose the information.

(b) Commences an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18

U.S.C. § 1836, as amended, the Department will not disclose the information until final resolution of the action, including any appeals. After final resolution of the action, if the court:

(1) Enjoins the Department from disclosing the information as a trade secret, the Department will not disclose the information so long as the information retains its status as a trade secret.

(2) Does not enjoin the Department from disclosing the information as a trade secret, the Department will disclose the information as soon as reasonably practicable after final resolution of the action.

Sec. 4. *In the report compiled by the Department pursuant to section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650), the Department will include:*

1. Only aggregated data that does not disclose the identity of any drug, manufacturer or pharmacy benefit manager; and

2. In addition to the information required by section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650), a description of trends concerning the prices of prescription drugs that appear on the most current lists compiled by the Department pursuant to section 3.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4297(NRS 439B.630), and an explanation of how those prices and trends may affect:

(a) The prevalence and severity of diabetes in this State; and

(b) The system of health care in this State.

NV Department of Health and Human Services
Legislative Review of Adopted Regulations – NRS 233B.066
LCB File No. R042-18

1. **A clear and concise explanation of the need for the adopted regulation:**
The adopted regulation outlines how the Department of Health and Human Services will support submission of certain reports by manufacturers of prescription drugs, pharmacy benefit managers and pharmaceutical sales representatives by providing forms online. It describes the process by which a manufacturer or pharmacy benefit manager can submit a request for confidentiality covering certain information. Lastly, it describes procedures the Department will follow when public information requests for information are filed and for which a confidentiality request has been submitted.

2. **Description of how public comment was solicited, a summary of public response, and an explanation of how other interested persons may obtain a copy of the summary.**
The Notice of Intent to Act Upon a Regulation for public hearing and adoption of Proposed Amendments was filed at the following locations on April 30, 2018.
1. Office of the Attorney General, 100 N. Carson Street, Carson City, NV
2. Office of the Attorney General, Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas, NV
3. Health Care Quality and Compliance, 4220 S. Maryland Pkwy, Las Vegas, NV
4. Department of Health and Human Services, 4126 Technology Way, First Floor Lobby, Carson City
5. Department of Health and Human Services, 4150 Technology Way, First Floor Lobby, Carson City
6. Legislative Building, 401 S. Carson Street, Carson City
7. Early Intervention Services, 1020 Ruby Drive, Suite 102, Elko, NV 89801
8. Division of Child and Family Services, 2655 Enterprise Road, Reno, NV 89512
9. Nevada State Library and Archives, 100 Stewart Street, Carson City, NV
10. The State of Nevada Website (www.notice.nv.gov)
11. The Nevada State Legislature Website (www.leg.state.nv.us)
12. The Nevada Department of Health and Human Services Website (www.dhhs.nv.gov)

A summary may be obtained by contacting Heather Mitchell, Management Analyst, Nevada Department of Health and Human Services, 775-684-4255 or by writing to the Nevada Department of Health and Human Services, 4150 Technology Way, Suite 300, Carson City, Nevada 89706.

3. **The number of persons who:**

	February 15, 2018	May 31, 2018
a) Attended each hearing	10	15
b) Testified at each hearing	1	2
c) Submitted written comments	17	3

4. **For each person identified in paragraphs (b) and (c) of number 3 above, the following information if provided to the agency conducting the Hearing:**

b) Testified at each hearing:

February 15, 2018	
Name	Paul Young
Telephone Number	775-323-1611
Business Address	n/a
Business Telephone Number	n/a

Electronic mail address	paul.young@rrpartners.com
Name of entity of organization represented	R&R Partners
Comment: Paul Young with R & R Partners, representing Pharmaceutical Care Management Associates, made the following public comment at the workshop on February 15, 2018 Section 3; Subsection 2, Subsection B of proposed rule there is a "typo" for lack of a better word, removing "manufacturer" and putting "Policy Benefit Manager" of Section 1. Subsection 2 of our proposal or submittal the Medicare law, it's PCMA's position that the requesting of Medicare Part D information violates federal law. They have read on a couple different cases and statues. That is their (PCMA)'s position that requesting Medicare information be sent to the State is not something that PCMA is able to do at this time, since the same information is already being provided to the Secretary of State and the Feds. PCMA would like to know what the State is requesting regarding the regulation. PCMA is objecting to the proposed law, with regards to transparency and the rebate information.	

May 31, 2018	
Name	Paul Young
Telephone Number	775-323-1611
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	paul.young@rrpartners.com
Name of entity of organization represented	R&R Partners
Comment: Paul Young with R & R Partners, representing Pharmaceutical Care Management Associates, made the following public comment at the hearing on May 31, 2018 that the public comment had been submitted in advance.	

May 31, 2018	
Name	Barry Smith
Telephone Number	775-885-0866
Business Address	102 Curry St., Carson City, NV 89703
Business Telephone Number	n/a
Electronic mail address	nevadapress@att.net
Name of entity of organization represented	Nevada Press Association
Comment: Barry Smith from Nevada Press Association made the following public comment at the hearing on May 31, 2018 that he wanted to know how the regulation related to the Nevada Public Records act in defining certain drug information as confidential.	

c) Submitted written comments:

February 15, 2018	
Name	Jack Geisser via electronic delivery
Telephone Number	202-962-9200
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	n/a

Name of entity of organization represented	Biotechnology Innovation Organization (BIO)

Summary: Dated February 15, 2018;

- Biotechnology Innovation Organization submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations would not provide for trade secret protections and that there was a concern that the reporting would be burdensome for small emerging biotechnology companies.
- Section 1 – Drug Transparency does not focus on patients, is not holistic, and does not enhance the innovative healthcare ecosystem
- Section 2 – Prescription Drug Manufacturers – Trade Secret Protections are Not Consistent with Federal Law

February 15, 2018	
Name	Bobbette Bond
Telephone Number	n/a
Business Address	1901 Las Vegas Blvd. South, Suite 101, Las Vegas, NV 89104
Business Telephone Number	n/a
Electronic mail address	n/a
Name of entity of organization represented	Culinary Health Fund

Summary: Dated February 15, 2018

- Culinary Health Fund submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations allowed drug manufacturers to mark reports as confidential and therefore would be exempt from public records requests.
- Request that the State return to regulation setting and create new regulation that implement SB 539 as it was adopted and signed by the Governor at the conclusion of PhRMA's lawsuit. The Culinary Health Fund disagrees with DHHSs' interpretation of the law. These comments and the Culinary Health Fund's participation in the adoption of temporary regulations should not be construed to prejudice the Fund's positions in PhRMA's pending lawsuit in any way.

February 15, 2018	
Name	Joanne Chan via e-mail
Telephone Number	202-835-3400
Business Address	950 F Street, NW, Suite 300, Washington, DC 20004
Business Telephone Number	n/a
Electronic mail address	n/a
Name of entity of organization represented	PhRMA

Summary: Dated February 14, 2018

- PhRMA submitted written public comment for the February 15, 2018 workshop stating that they were concerned stating that the request by manufacturers to contain information as confidential and to challenge any public records requests would be financially burdensome, that the descriptions for costs to be reported was

not specific enough and that the regulations did not provide for trade secret protections.

February 15, 2018	
Name	April C. Alexander
Telephone Number	n/a
Business Address	325 7th Street, NW, 9th Floor, Washington, DC 2004
Business Telephone Number	n/a
Electronic mail address	n/a
Name of entity of organization represented	Pharmaceutical Care Management Association (PCMA)

Summary: Dated February 13, 2018

- Pharmaceutical Care Management Association submitted written public comment for the February 15, 2018 workshop stating that they were concerned there was a typing error in section 3 (2)(b) of the proposed regulation, that the regulation appeared to require reporting that is already required to be reported under Medicare Part D.

February 15, 2018	
Name	Laura Chenoweth
Telephone Number	n/a
Business Address	235 East 42nd Street, New York, NY 10017-5755
Business Telephone Number	n/a
Electronic mail address	n/a
Name of entity of organization represented	Pfizer

Summary: Date February 15, 2018

- Pfizer submitted written public comment for the February 15, 2018 workshop stating that they were concerned with the implementation prior to July 1, 2018, and that there was not strong enough trade secret protections.

February 15, 2018	
Name	Clair E. Irwin via e-mail
Telephone Number	256-520-1130
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	clair.irwin1@gmail.com
Name of entity of organization represented	Self

Summary: Date February 6, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Mike Lawson via e-mail
Telephone Number	623-252-1981
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	mikelawson@gmail.com
Name of entity of organization represented	Self

Summary: Date February 6, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Brandon Porath via e-mail
Telephone Number	n/a
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	bporath908@gmail.com
Name of entity of organization represented	Self

Summary: Date February 7, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Melinda Wedding
Telephone Number	972-979-6836
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	melinda.wedding@me.com
Name of entity of organization represented	Parent of Minor

Summary: Date February 15, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Sara Stock
Telephone Number	n/a
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	sara77theeler@gmail.com
Name of entity of organization represented	Self

Summary: Date February 6, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Robert Frisk via e-mail
Telephone Number	906-360-3205
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	n/a
Name of entity of organization represented	Self; REPID Scholar (NIH-NHLBI) BS Biochemistry and Molecular Biology/Biotechnology Department of Biochemistry and Molecular Biology Michigan State University

Summary: Date February 22, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Paul Clements
Telephone Number	n/a
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	pcleme3@gmail.com
Name of entity of organization represented	Self

Summary: Date February 22, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Christopher Luckett MA
Telephone Number	502-417-0868
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	celuckett@gmail.com
Name of entity of organization represented	Self

Summary: Date February 22, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Angela Lautner via e-mail
Telephone Number	n/a
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	angelalautner@yahoo.com
Name of entity of organization represented	Self

Summary: Date February 7, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	Donna Robinson via e-mail
Telephone Number	n/a
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	angelalautner@yahoo.com
Name of entity of organization represented	Family (child/sister/brother)

Summary: Date February 6, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

February 15, 2018	
Name	C. Scott Strumello via e-mail
Telephone Number	347-829-9321
Business Address	n/a
Business Telephone Number	n/a
Electronic mail address	sstrumello@gmail.com
Name of entity of organization represented	Self

Summary: Date February 12, 2018

- Submitted written public comment for the February 15, 2018 workshop stating that they were concerned that the regulations worked to prevent transparency for patients.

May 31, 2018	
Name	Joanne Chan via e-mail
Telephone Number	202-835-3400
Business Address	950 F Street, NW, Suite 300, Washington, DC 20004
Business Telephone Number	n/a
Electronic mail address	n/a

Name of entity of organization represented	PhRMA
Summary: Dated May 15, 2018; Technical comments to SB539 Reg: • PhRMA submitted written public comment for the May 31, 2018 hearing stating that they were concerned with Section 3 (1) of the regulations requiring the manufacturer to explain why public disclosure of trade secrets would constitute misappropriation and that the explanation would be shared with the public and that the deadline to submit reports should not be until 2019.	

May 31, 2018	
Name	McCracken, Stemerman & Holsberry, LLP via electronic & U.S. Mail via Paul L. More
Telephone Number	702-386-5107
Business Address	1630 S. Commerce St., Suite A-1, Las Vegas, NV 89102 and 595 Market St., Suite 800, San Francisco, CA 94105
Business Telephone Number	415-597-7200
Electronic mail address	n/a
Name of entity of organization represented	Culinary Health Fund
Summary: Dated May 15, 2018; Conclusion • Culinary Health Fund submitted written public comment for the May 31, 2018 hearing stating that they were concerned that the regulations exceeded the Department's authority, that the regulations adopt federal Freedom of Information Act and that the regulations would amend the Nevada Public Records Act. • The proposed regulations exceed NDHH'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 object to them and requests that they be withdrawn.	

May 31, 2018	
Name	Paul Young
Telephone Number	775-323-1611
Business Address	6160 Plumas Street, Suite 200, Reno, NV 89519
Business Telephone Number	n/a
Electronic mail address	paul.young@rrpartners.com
Name of entity of organization represented	Pharmaceutical Care Management Association (PCMA)
Summary: Dated May 14, 2018; Conclusion • Pharmaceutical Care Management Association submitted written public comment for the May 31, 2018 hearing stating that they were concerned that the Defend Trade Secrets Act was an incorrect standard to use, that the information request per section 3(5)(b) should be concurrent with the notification to the requestor and that the information reported under section 4(1) should be aggregated.	

- There is 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 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.

5. **A description of how comment was solicited from affected businesses, a summary of their response and an explanation of how other interested persons may obtain a copy of the summary.**
The Notice of Intent to Act Upon a Regulation for public hearing and adoption of Proposed Amendments was filed at the following locations on April 30, 2018.
1. Office of the Attorney General, 100 N. Carson Street, Carson City, NV
2. Office of the Attorney General, Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas, NV
3. Health Care Quality and Compliance, 4220 S. Maryland Pkwy, Las Vegas, NV
4. Department of Health and Human Services, 4126 Technology Way, First Floor Lobby, Carson City
5. Department of Health and Human Services, 4150 Technology Way, First Floor Lobby, Carson City
6. Legislative Building, 401 S. Carson Street, Carson City
7. Early Intervention Services, 1020 Ruby Drive, Suite 102, Elko, NV 89801
8. Division of Child and Family Services, 2655 Enterprise Road, Reno, NV 89512
9. Nevada State Library and Archives, 100 Stewart Street, Carson City, NV
10. The State of Nevada Website (www.notice.nv.gov)
11. The Nevada State Legislature Website (www.leg.state.nv.us)
12. The Nevada Department of Health and Human Services Website (www.dhhs.nv.gov)

A summary may be obtained by contacting Heather Mitchell, Management Analyst, Nevada Department of Health and Human Services, 775-684-4255 or by writing to the Nevada Department of Health and Human Services, 4150 Technology Way, Suite 300, Carson City, Nevada 89706.

6. **If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change.**
The concerns from public comment were received in advance in writing and considered.

7. **The estimated economic effect of the regulation on the business which it is to regulate and on the public:**
   (a) Estimated economic effect on the businesses which they are to regulate
   None.

(b) **Estimated economic effect on the public which they are to regulate**
None.

8. **The estimated cost to the agency for enforcement of the proposed regulation:** None.

9. **A description of any regulations of other State of governmental agencies which the regulation overlaps or duplicates and a statement explaining why the duplication or overlap is necessary. If the regulation overlaps or duplicates a federal regulation, the name of the regulating federal agency.** None.

10. **If the regulation includes provisions that are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.** None.

11. **Of the regulation provides a new fee or increases an existing fee, the total annual amount of the agency expects to collect and the manner in which the money will be used.** None.