

APPROVED REGULATION OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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Name of entity of organization represented	R&R Partners
<p>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.</p>	

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
<p>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.</p>	

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
<p>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.</p>	

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)
<p>Summary: Dated February 15, 2018;</p> <ul style="list-style-type: none"> • Biotechnology Innovation Organization submitted written public comment for the 	

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<p>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.</p> <ul style="list-style-type: none"> • 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
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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
<p>Summary: Dated February 15, 2018</p> <ul style="list-style-type: none"> • 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 DHHS’ 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
<p>Summary: Dated February 14, 2018</p> <ul style="list-style-type: none"> • 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

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Telephone Number	n/a
Business Address	325 7 th Street, NW, 9 th 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)
<p>Summary: Dated February 13, 2018</p> <ul style="list-style-type: none"> 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 42 nd Street, New York, NY 10017- 5755
Business Telephone Number	n/a
Electronic mail address	n/a
Name of entity of organization represented	Pfizer
<p>Summary: Date February 15, 2018</p> <ul style="list-style-type: none"> 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
<p>Summary: Date February 6, 2018</p> <ul style="list-style-type: none"> 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

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Name of entity of organization represented	Self
Summary: Date February 6, 2018 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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

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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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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	

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- 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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, Stemberman & Holsberry, LLP via electronic & U.S. Mail via Paul L. More

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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
<p>Summary: Dated May 15, 2018; Conclusion</p> <ul style="list-style-type: none"> • 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)
<p>Summary: Dated May 14, 2018; Conclusion</p> <ul style="list-style-type: none"> • 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 	

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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
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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.

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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.