

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the adoption of Regulations of the Department of Health and Human Services

HEARING AGENDA

State of Nevada, Department of Health and Human Services

May 31, 2018 • 11:00 a.m.

Location of Hearing:

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

Available via Videoconference at:

Legislative Counsel Bureau
Grant Sawyer State Office Building
Room 4412
555 E. Washington Ave.
Las Vegas, NV 89101

A live broadcast of the hearing may be viewed at www.leg.state.nv.us

1. Open Hearing with presentation:

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

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.

2. Public Comment on LCB File No. R042-18
3. Adoption of regulations contained in LCB File No. 42-18 (for possible action)
4. Close Hearing.

Members of the public are encouraged to submit written comments for the record.

Members of the public who are disabled and require special accommodations or assistance at the hearing are requested to notify Veronica Sheldon, in writing, no later than five (5) working

days before the hearing: 4150 Technology Way, Suite 300, Carson City, Nevada 89706, or drugtransparency@health.nv.gov.

Supporting public material for this hearing may be requested from Veronica Sheldon, Nevada Department of Health and Human Services, 4150 Technology Way, Suite 300, Carson City, Nevada 89706, (775) 684-4255, or drugtransparency@dhhs.nv.gov.

The following information is provided pursuant to the requirements of NRS 233B.0603:

1) The need for and the purpose of the proposed regulation or amendment.

LCB File No. R042-18: 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.

2) If the proposed regulation is a temporary regulation, either the terms or the substance of the regulations to be adopted, amended, or repealed, or a description of the subjects and issues involved. If the proposed regulation is a permanent regulation, a statement explaining how to obtain the approved or revised text of the proposed regulation prepared by the Legislative Counsel pursuant to NRS 233B.063.

A copy of the proposed regulation can be obtained at the Department website at www.dhhs.nv.gov and selecting "Drug Transparency" in the right hand column, or by contacting Veronica Sheldon at (775) 684-4255, drugtransparency@dhhs.nv.gov. A reasonable fee for copying may be charged.

3) A statement identifying the methods used by the agency in determining the impact on a small business prepared pursuant to subsection 3 of NRS 233B.0608.

The request for input regarding impact was sent to the following websites and listservs:

- Nevada Department of Health and Human Services webpage
- Nevada Board of Pharmacy website
- Bureau of Health Care Quality and Compliance Nevada health facilities listserv
- Nevada Medical Association website
- Indian Health Services, Nevada Services Units
- Nevada Department of Health and Human Services Facebook page
- Nevada Division of Public and Behavioral Health Facebook page

- Nevada Primary Care Association newsletter
- Nevada Department of Health and Human Services Twitter page

A workshop to hear input was held February 15, 2018. Comments and recommendations were considered by the Department and incorporated into draft regulations submitted to Nevada Legislative Counsel Bureau on March 9, 2018.

- 4) **The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately and, in each case, must include:**
 - a) **Both adverse and beneficial effects; and**
The regulation does not economically affect business owners.
 - b) **Both immediate and long-term effects.**
Benefits stated above appear to be immediate and long term.

- 5) **The estimated cost to the agency for enforcement of the proposed regulation.**
The Nevada Department of Health and Human Services believes that the cost of enforcement of the proposed regulations will be minimal.

- 6) **A description of the citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.**
The Department is not aware of any overlapping or duplicating of federal or state regulations.

- 7) **If the regulation is required pursuant to federal law, a citation and description of the federal law.**
The Department is not aware of any requirement to federal law.

- 8) **If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.**
No duplication of a federal regulation.

- 9) **Whether the proposed regulation establishes a new fee or increases an existing fee.**
The regulation does not establish any new fees.

Persons wishing to comment upon the proposed action by the Nevada Department of Health and Human Services may appear at the scheduled public hearing or may address their comments, data, views, or arguments, in written form, to Nevada Department of Health and Human Services, 4150 Technology Way, Suite 300, Carson City, NV 89703 or by e-mail to drugtransparency@dhhs.nv.gov. Written submissions must be received by the Nevada Department of Health and Human Services on or before May 31, 2018 at 5:00 P.M. If no person who is directly affected by the proposed action appears to request time to make an oral

presentation, the Nevada Department of Health and Human Services may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation to be adopted will be on file at the Nevada State Library and Archives, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted will be available at Department of Health and Human Services, for inspection and copying by members of the public during business hours. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations, which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at <http://www.leg.state.nv.us>. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, if requested to do so by an interested person either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption and incorporate therein its reason for overruling the consideration urged against its adoption.

NOTICES FOR THIS HEARING HAVE BEEN POSTED IN ACCORDANCE WITH NRS 241 AT THE FOLLOWING LOCATIONS:

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)
13. Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library

Douglas County Library

833 Las Vegas Boulevard North
Las Vegas, NV 89101

1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
210 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Water Street
Henderson, NV 89105

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

White Pine County Library
950 Campton Street
Ely, NV 89301-1965