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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 137
DEPARTMENT OF JUSTICE

FILED
09/30/2019 11:27 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Representations Regarding Health Benefits of Goods

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/14/2019 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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503-934-4400
cheryl.hiemstra@doj.state.or.us

Department of Justice
1162 Court St. NE
Salem,OR 97301

Filed By:
Angie Emmert
Rules Coordinator

HEARING(S)

Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/14/2019
TIME: 10:00 AM - 12:00 PM
OFFICER: Cheryl Hiemstra
ADDRESS: Department of Justice
1162 Court St. NE
Salem, OR 97301-4096
SPECIAL INSTRUCTIONS:
Kulongoski Conference Room

NEED FOR THE RULE(S):

The rule is necessary to protect consumers and provide a level playing field for advertisers and sellers. Many goods claim to have health benefits. However, some claims are not substantiated by competent and reliable scientific evidence, and thus may be deceiving consumers and inducing consumer to purchase goods that will not provide the health benefits as described. This deception not only leads consumers to lose money on fruitless goods, but could also lead to adverse health consequences: if a consumer is using an unsubstantiated good, the consumer might be missing out on the health benefits of a different, substantiated good. Advertisers and sellers of goods with substantiated claims could be harmed by losing business to deceitful advertisers and sellers.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Documents relied upon include news articles, (See examples submitted, including: https://www.thelundreport.org/content/dollars-docs-database-shows-oregon-doctors-have-accepted-428-million-gifts-payments-industry; https://www.newyorker.com/news/news-desk/the-birth-tissue-profiteers), the current text of the Oregon Revised Statutes 646.608(4) and ORS 646.608(1)(u), and information regarding the Federal Trade Commission's advertising substantiation requirements (in place since at least 1983, some discussion available at: https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation).

FISCAL AND ECONOMIC IMPACT:

The fiscal impact to state agencies is minimal to none.
The estimated economic impact to sellers and advertisers of health goods is mixed.
There is positive economic impact to some sellers and advertisers, of national breadth, who expressed appreciation that this rule would put Oregon on par with the Federal Trade Commission and most other states that require claimed health benefits to be supported by competent and reliable scientific evidence, allowing for a more even playing field for businesses. The rule would also reward advertisers and sellers, regardless of size, who substantiated health benefits and thereby saved money for the consumers. These cost savings to consumers will be for consumers who could spend their funds on substantiated health goods, instead of having to purchase an unsubstantiated good and keep searching for relief elsewhere if the unsubstantiated good fails to deliver on its claims.
The negative economic impact to some sellers and advertisers would be to spend more time to substantiate health benefits. However, the impact is mitigated because the Federal Trade Commission, who has national enforcement, uses the same standard as in the proposed rule, and thus would not create a unique burden.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

1. Units of state or local government that receive complaints from the public regarding unsubstantiated health goods would send complaints to the Department of Justice for consideration of enforcement. Members of the public who buy goods for health benefits are likely to be economically affected positively, as the public would be buying more goods with substantiated health benefit claims.
2a. The identified types of small businesses subject to the rule include: pharmacy, vitamin shops, retail establishments, manufacturers of tinctures, CBD sellers, and the like. Certain professions might also be included: naturopaths, chiropractors, ophthalmologists, and massage therapists (when selling goods, but the rule does not cover the services of these practitioners). The number of businesses was unable to be estimated by business groups and others in a Rulemaking Advisory Committee. The stakeholders in the Rules Advisory Committee, including those representing small business, were asked to estimate the number of small businesses that would be subject to the rule, but they were unable to provide an estimate of the number.
2b. There would be a cost associated with this recordkeeping and administrative activities, but not regular reporting. There would be a cost to business for having to review advertisements with claims of health benefits before they are published, perhaps and added cost for some small businesses that currently subcontract advertising tasks and do not already review advertisements before publication. However, as this is currently the requirement nationally, most businesses probably do review their advertisements. Small businesses need to have substantiation for their health benefit claims, however, the small businesses would not need to conduct the research and studies themselves. For example, small businesses could keep on file some websites and research conducted by others and that are publicly available. Also, some of the cost would be perhaps mitigated: if businesses can provide more evidence that the advertised good is beneficial, this could eventually establish claims and good reputation. The amount of net cost for the businesses was difficult to quantify or measure, due to the fact that it will depend on the type of business, the product for sale, and these factors could vary greatly from business to business.
2c. There would perhaps be a cost associated with establishing marketing guidelines, and perhaps discussions with an attorney if enforcement actions were pursued. No fiscal impact due to the need for extra equipment, supplies, or labor was identified.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were consulted in 2015-2016 with an earlier version of the text of the rule that applied to both goods and services. After substantial concerns about the inclusion of services raised by many small health practitioners (chiropractors, naturopaths, etc), the decision was made to remove services from the text of the rule. In 2019, a Rulemaking Advisory Committee was consulted regarding the impact of the advertisers and sellers of goods only, as the text stands now. The discussion included a representative from Main Street Alliance, a group of small business owners, Oregon Business and Industry, an association for businesses both large and small, Oregon Health and Science University, the Consumer Healthcare Products Association, who represents manufacturers and sellers of many goods with health benefit claims, the Oregon Trial Lawyers Association, and the Oregon State Public Interest Research Group. Members of the Pharmaceutical Research and Manufacturers of America were also in attendance at the Rulemaking Advisory Committee meeting. It was discussed that pharmaceuticals are required to meet a more rigorous standard than the proposed rule; thus there was little to no impact for pharmaceuticals.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

ADOPT: 137-020-0900

RULE SUMMARY: Makes it an unfair and deceptive practice to represent, without competent and reliable scientific evidence, that a good has a health benefit.

CHANGES TO RULE:

137-020-0900
Representations Regarding Health Benefits of Goods
It is unfair and deceptive for an advertiser or seller to make a representation of fact about a health benefit of a good without first having competent and reliable scientific evidence upon which to base a reasonable belief in the truth of the representation.
Statutory/Other Authority: ORS 646.608(4), ORS 646.608(1)(u)
Statutes/Other Implemented:

AMENDED FISCAL AND ECONOMIC IMPACT:

The fiscal impact to state agencies is minimal to none.
The estimated economic impact to sellers and advertisers of health goods is mixed.
There is positive economic impact to some sellers and advertisers, of national breadth, who expressed appreciation that this rule would put Oregon on par with the Federal Trade Commission and most other states that require claimed health benefits to be supported by competent and reliable scientific evidence, allowing for a more even playing field for businesses. The rule would also reward advertisers and sellers, regardless of size, who substantiated health benefits and thereby saved money for the consumers. These cost savings to consumers will be for consumers who could spend their funds on substantiated health goods, instead of having to purchase an unsubstantiated good and keep searching for relief elsewhere if the unsubstantiated good fails to deliver on its claims.
The negative economic impact to some sellers and advertisers would be to spend more time to substantiate health benefits. However, the impact is mitigated because the Federal Trade Commission, who has national enforcement, uses the same standard as in the proposed rule, and thus would not create a unique burden. Another possible fiscal impact, identified in the comments to the rulemaking, was the possibility of people filing private causes of action against advertisers and sellers making health claims about a good, as the rule is necessarily promulgated under ORS 646.608(1)(u), containing a private right of action via ORS 646.638.