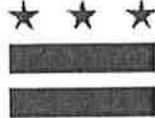


GOVERNMENT OF THE DISTRICT OF COLUMBIA
OFFICE OF THE ATTORNEY GENERAL



ATTORNEY GENERAL
KARL A. RACINE

Legal Counsel Division

MEMORANDUM



TO: Phillip Husband
General Counsel
Department of Health

FROM: Janet M. Robins
Deputy Attorney General
Legal Counsel Division

A handwritten signature in cursive script, appearing to read "Janet M. Robins".

DATE: October 3, 2016

SUBJECT: Effect of Licensing Exemption for Pharmaceutical Detailers Established in the "Pharmaceutical Detailing Licensure Exemption Amendment Act of 2015"
(AL-16-493)

This responds to your August 16, 2016 request that this Office advise you regarding the scope of an exemption in the Pharmaceutical Detailing Licensure Exemption Amendment Act of 2015¹ from the requirement that individuals engaging in pharmaceutical detailing must be licensed. "Pharmaceutical detailing" is the practice in which a representative of a pharmaceutical company communicates with a licensed health professional (or his or her employee) to sell or promote a pharmaceutical product.² For the reasons set out below, we agree with the Board of Pharmacy that the exemption may be claimed only by those who engage in pharmaceutical detailing for a single period of up to 29 consecutive days during a calendar year.

Background

¹ Included as part of the Fiscal Year 2016 Budget Support Act of 2015, effective October 22, 2015 (D.C. Law 21-36; D.C. Official Code § 3-1205.02) (2016 Supp.)) ("2015 Amendment").

² "See the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99), as amended by the SafeRx Amendment Act of 2008, effective March 26, 2008 (D.C. Law 17-131; D.C. Official Code § 3-1201.01 (10A) (2012 Repl.)) ("SafeRx Law").

In 2008 the Council enacted the SafeRx Law, which requires pharmaceutical detailers to be licensed.³ The Committee Report for this law stated that one purpose of the legislation was

to ensure that those individuals who conduct direct-to-physician marketing are not engaging in behaviors that run counter to the medical needs of patients [and] to monitor and address detailing practices that result in overdependence on costly new generation pharmaceuticals when generic options are equally effective for a fraction of the cost.

After the SafeRx Law took effect, some stakeholders were concerned that people who come to the District to attend medical conferences once or twice a year to provide information about drug products (often doctors talking to other doctors) would stop attending the conferences rather than go to the trouble of becoming licensed, and that this could prompt conference organizers to move their events to other jurisdictions.⁴ In response to this concern, in 2009 the Board of Pharmacy issued rules that refined the definition of pharmaceutical detailing in the SafeRx Act to provide that this phrase refers to communications occurring in “a non-conference setting.”⁵ In 2010 the Board issued another rule defining the word “conference” to include meetings, expositions, and similar gatherings organized for the purpose of discussing health-related issues, and scientific and educational meetings or symposia.⁶

In 2015, the Council enacted an exemption from the licensing requirement generally applicable to pharmaceutical detailers, providing that the requirement does not apply “[t]o an individual engaged in the practice of pharmaceutical detailing for less than 30 consecutive days per calendar year.”⁷ The Department of Health interpreted this exemption language to apply to an individual who comes into the District one time during the year and engages in pharmaceutical detailing for a period of less than 30 consecutive days.⁸ Representatives for the pharmaceutical industry argue that this new language creates an exception for anyone who engages in pharmaceutical detailing for periods of less than 30 consecutive days, even if that person engages in this practice repeatedly during a single calendar year.⁹ Put another way, the *only* people who would be subject to the rule would be those who do some detailing for seven days straight a week for 30 or more days – a set that is, admittedly, likely null.

Analysis

Industry representatives argue that the plain meaning of the statute is unambiguous and necessitates their interpretation. However, the plain meaning of the language is not nearly so clear. First, “engaged in the practice of pharmaceutical dealing” does not necessarily mean actively detailing each and every day. A person employed as a detailer might be said to be

³ SafeRx Law, § 102(e); D.C. Official Code § 3-1205.01(a)(1).

⁴ Memorandum from you to Mark H. Tuohey, p. 3 (August 16, 2016) (“DOH Memorandum”).

⁵ 17 DCMR § 8300.5 (56 DCR 2951, April 17, 2009).

⁶ 17 DCMR § 8399.1 (57 DCMR 5739, July 2, 2010).

⁷ 2015 Amendment, § 5031(a), D.C. Official Code § 3-1205.02(2A) (2016 Supp.) (emphasis added).

⁸ Department of Health “Frequently Asked Questions” document (included as an attachment to the DOH Memorandum).

⁹ DOH Memorandum, p. 3.

“engaged in [that] practice” even though he or she takes off weekends. At the same time, the language may be interpreted consistently with DOH’s view: The exemption allowing unlicensed individuals to engage in pharmaceutical detailing for less than 30 days “per calendar year” suggests that the exemption refers to one single period in a calendar year. Because the exemption language does not, however, unambiguously support DOH’s view (by stating, for example, that a person is exempt if he or she engages in pharmaceutical detailing for a single period of no more than 30 consecutive days per calendar year”), we applied traditional tools of statutory interpretation to analyze the exemption language. The context, legislative history, and cannon against absurd results all favor DOH’s interpretation of the language.

“It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.”¹⁰ Here, the overall statutory scheme set out in D.C. Official Code, Title 3, Chapter 12, requires identified health care professionals to be licensed by the District, unless they are covered by a specific exemption. Several of these exemptions apply generally to those in health care occupations, *e.g.*, those providing emergency treatment.¹¹ The provision at issue here is the only exemption specifically applicable to pharmaceutical detailers. If we adopt the interpretation urged by the pharmaceutical industry, someone who engages in pharmaceutical detailing for 29 days, then takes a day off, and then repeats this process, for a total of 12 times during a calendar year (thus working as a pharmaceutical detailer in the District for 348 days during a calendar year), would be exempt from the District’s licensing requirement. A full-time pharmaceutical detailer who worked Monday-Friday throughout the year in the District, but who did not work over weekends, would also, under the industry-supported interpretation, be exempt from the licensing requirement. This would have the effect of exempting virtually all pharmaceutical detailers from the District’s overall statutory scheme, which requires those working in the District in health occupations, including pharmaceutical detailing, to be licensed.

We also considered the legislative history of the 2015 amendment.¹² It supports our conclusion that the amendment did not establish an exemption from the licensing requirement for anyone who avoids engaging in pharmaceutical detailing for more than 30 consecutive days in the District. The Committee Report for the amendment states that

[t]he SafeRx Act Amendment Act of 2008 was [enacted] to regulate the act of pharmaceutical detailing in the District. However, the broadly written law requires scientists and medical doctors, employed by pharmaceutical companies, to register with the District before interacting with registered physicians, even if they are giving a speech at a medical conference or convention in the

¹⁰ *Roberts v. Sea-Land Services, Inc.*, 132 S. Ct. 1350, 1357 (2012). See also *In re M.M.D.*, 662 A.2d 837, 845 (D.C. 1995) (“*M.M.D.*”) (legislative purpose determined by examining statute as a whole).

¹¹ D.C. Official Code § 3-1205.02(a)(1).

¹² See *Samantar v. Yousuf*, 560 U.S. 305, 325 (2010) (considering legislative history to determine legislative intent and meaning of federal statute); *FOP/Metropolitan Police Dep’t Labor Comm. v. District of Columbia*, 2016 D.C. App. LEXIS 262 (D.C. 2016) (court “must consider the objectives . . . [and] legislative history” when interpreting a statute) (internal citations and quotation marks omitted); *M.M.D.*, 662 A.2d 845 (legislative history may provide evidence of legislature’s intent and may be used in statutory interpretation).

District.¹³

As originally considered by the Committee on Health and Human Services, the 2015 amendment would have exempted those who engaged in pharmaceutical detailing for “less than 3 consecutive months per calendar year.”¹⁴ One Councilmember was concerned that although the requirement enacted in 2008 may have been overly broad, this exemption would create a loophole allowing pharmaceutical companies to hire employees for just under three months, thus exempting them from the licensing requirements.¹⁵ Councilmember Cheh

echoed Councilmember Grosso’s concerns regarding the potential creation of a loophole that could exempt a broad group of people from licensure requirements for engaging in the practice of pharmaceutical detailing. However, she also noted . . . her concern that the SafeRx Act of 2008 was overly broad and that has prevented physicians from attending medical conferences in the District.”¹⁶

Later, apparently in response to these concerns that the exemption that had been proposed initially was too broad and would create a loophole, the Council amended the bill to limit the exemption to those engaged in pharmaceutical detailing for less than 30 consecutive days per calendar year. This reflects the Council’s desire to *limit* the exemption, rather than create the extraordinarily broad exemption that the industry representatives suggest was intended.

The Committee Report’s summary language, noting that the problem with the original law was that it required people to become licensed pharmaceutical detailers in order to engage in the limited activity of giving a speech at a convention or conference, is consistent with our interpretation of the 2015 amendment – that it created a limited exemption from the licensing requirement for pharmaceutical detailers to come to the District to work for a limited period of time (less than 30 days) to participate in, for example, a conference or short-term professional course. Nothing in the legislative history supports the proposition that the Council intended to create a loophole that would envelope the rule, as the industry position would.

In addition, “[w]hen interpreting a statute, ‘absurd results are to be avoided.’”¹⁷ As detailed above, under the interpretation urged by industry representatives a pharmaceutical detailer who worked under a conventional full-time schedule, *i.e.*, Monday-Friday, for every week during a year, or a person who worked a series of 29-day periods with a day off in between each period, thus working for 348 days during a year, would be exempt from the District’s licensing requirement. Only people who worked almost every day, including week-ends and holidays,

¹³ Report and Recommendations of the Committee on Health and Human Services on the Fiscal Year 2016 Budget for Agencies Under Its Purview (“Committee Report”), at 153 (May 14, 2015), available at <http://hims.dccouncil.us/Download/33645/B21-0158-CommitteeReport5.pdf> (last visited, August 26, 2016).

¹⁴ *Id.* at 154.

¹⁵ *Id.* at 156.

¹⁶ Committee Report at 166.

¹⁷ *U.S. House of Representatives v. Burwell*, 2016 U.S. Dist. LEXIS 62646 at *40 (D.D.C. 2016) (quoting *McNeill v. United States*, 563 U.S. 816, 822 (2011)).

would be subject to the licensing requirement. This would create an exception that swallows the rule -- in our view, an absurd result.¹⁸

Accordingly, we agree with your interpretation of the 2015 exemption and conclude that it provides an exemption for those who engage in pharmaceutical detailing during a single period of up to 29 consecutive days during a calendar year.

If you have any questions with regard to these comments, please contact Katherine Kelley, Assistant Attorney General, at 724-5533, or me at 724-5524.

JMR/kvk

¹⁸ Cf. *NLRB v. Little River Band of Ottawa Indians Tribal Gov't*, 788 F.3d 537, 546 (6th Cir. 2015) (citing *Plains Commerce Bank v. Long Family Land & Cattle Co.*, 554 U.S. 316, 330 (2008) (court will not construe limited exceptions in a manner that would “swallow” the underlying rule); *ICM Registry, LLC v. U.S. Dep't of Commerce*, 538 F. Supp. 2d 130, 133 (D.D.C. 2008) (avoiding applying a statutory exception in a way that swallows the underlying rule); *Dick v. Holder*, 67 F. Supp. 3d 167, 178 (D.D.C. 2014) (same).