



February 18, 2016

The Honorable Bradley H. Jones, Jr.
Massachusetts House of Representatives
Room 124, State House
Boston, MA 02133-1054

Dear Representative Jones:

The Antitrust Division of the U.S. Department of Justice (the “Division”) and the staff of the Federal Trade Commission¹ (the “FTC”) welcome the opportunity to share our views on Massachusetts House Bill 1973 (the “Bill”), which would allow optometrists to treat glaucoma patients, with certain restrictions.² Glaucoma is a group of chronic, progressive diseases of the optic nerve that can lead to irreversible vision loss and blindness.³ Currently, the treatment of glaucoma in Massachusetts is limited to ophthalmologists.

We recognize the critical importance of patient health and safety and the role of state legislators and regulators in determining the optimal balance of policy priorities and defining the appropriate scope of practice for medical professionals, including ophthalmologists and optometrists. At the same time, however, we note that unnecessarily broad scope of practice restrictions can

¹ This letter expresses the views of the FTC’s Office of Policy Planning, Bureau of Competition, and Bureau of Economics. The letter does not necessarily represent the views of the FTC or of any individual Commissioner. The Commission, however, has voted to authorize staff to submit these comments.

² Letter from Massachusetts State Representative Bradley H. Jones, Jr. to Marina Lao, Director, Office of Policy Planning, Fed. Trade Comm’n (Dec. 3, 2015).

³ See *Facts About Glaucoma*, NAT’L EYE INST., NAT’L INST. OF HEALTH, https://nei.nih.gov/health/glaucoma/glaucoma_facts (last visited Jan. 21, 2016).

impose significant competitive costs on health care consumers and other payors.⁴ For this reason, we generally have encouraged legislatures to avoid restrictions that are not necessary to address well-founded patient safety concerns.⁵ Similarly, we write now to highlight the potential competitive costs of a continued prohibition on Massachusetts optometrists' ability to treat glaucoma and to encourage the legislature to consider the competitive implications of such a restriction in its evaluation of the Bill.⁶

⁴ For example, the FTC staff's 2014 policy paper on the regulation of advanced practice nurses details the competition concerns with unnecessarily broad scope of practice regulations. See FED. TRADE COMM'N STAFF, POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES (2014), <http://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf> [hereinafter FTC STAFF POLICY PERSPECTIVES].

⁵ See, e.g., Letter from FTC Staff to Hon. Kay Khan, Massachusetts House of Representatives (Jan. 14, 2014) (regarding removal of supervision requirements for nurse practitioners and nurse anesthetists), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettsnursesletter.pdf; Letter from FTC Staff to Hon. Heather A. Steans, Illinois State Senate (Apr. 19, 2013), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-heather.steans-illinois-state-senate-concerning-illinois-senate-bill-1662-and-regulation-certified/130424illinois-sb1662.pdf; FTC Staff Letter to Hon. Jeanne Kirkton, Missouri House of Representatives (Mar. 27, 2012), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-representative-jeanne-kirkton-missouri-house-representatives-concerning/120327kirktonmissouriletter.pdf; FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Ch. 2, 25-33 (July 2004), http://www.usdoj.gov/atr/public/health_care/204694.htm (considering the competitive impact of licensing restrictions). See also Letter from Scott D. Hammond, Acting Assistant Att'y Gen., U.S. Dep't of Just., & Jon Leibowitz, Chairman, Fed. Trade Comm'n, to the Hawai'i State Bar Association (Apr. 20, 2009), <http://www.justice.gov/atr/comments-revised-proposed-rule-concerning-unauthorized-practice-law> (addressing the competitive effects of a rule that unduly restricts unauthorized practice of law); Letter from J. Robert Kramer, II, Director of Operations, U.S. Dep't of Just., to Hon. Mark Boitano, New Mexico Senate (Feb. 13, 2009) (addressing the competitive impact of "minimum service laws" in real estate).

⁶ We recognize that the Bill's scope extends beyond the treatment of glaucoma. Our comments, however, are limited to the Bill's effect on glaucoma care.

I. The Agencies' Interest and Experience in Health Care Competition

Competition is the core organizing principle of America's economy,⁷ and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality goods and services, increased access to goods and services, and greater innovation.⁸ The FTC and the Division (the "Agencies") work to promote competition through enforcement of the antitrust laws, which prohibit certain transactions and business practices that harm competition and consumers, and through competition advocacy, whereby the Agencies advance outcomes that benefit competition and consumers via comments on legislation, discussions with regulators, and court filings, among other means.

Because of the importance of health care competition to the economy and consumer welfare, this sector has long been a priority for the Agencies.⁹ The Agencies have extensive experience investigating the competitive effects of mergers and business practices by hospitals, insurers, pharmaceutical companies, physicians, and other providers of health care goods and services. The Agencies also have provided guidance to the health care community on the antitrust laws, and have devoted significant resources to examining the health care industry by sponsoring various workshops and studies. Finally, through their competition advocacy program, the Agencies have encouraged states to consider the competitive impact of various health care-related legislative and regulatory proposals, including scope of practice restrictions.¹⁰

⁷ See, e.g., *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101, 1109 (2015) ("Federal antitrust law is a central safeguard for the Nation's free market structures."); *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.").

⁸ See, e.g., *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695 (1978) (noting that the antitrust laws reflect "a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services. . . . The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.").

⁹ A description of, and links to, the FTC's various health care-related activities can be found at <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care>. An overview of the Division's health care-related activities is available at <http://www.justice.gov/atr/health-care>.

¹⁰ See *supra* note 5.

II. Glaucoma Care in the United States

Glaucoma is the second leading cause of blindness worldwide, and glaucoma is increasingly prevalent among Americans.¹¹ Past estimates have suggested that 50 percent of Americans with glaucoma are undiagnosed, including many who present with severe disease when seeking care.¹² Early diagnosis, when the disease is generally asymptomatic, and managed treatment can protect against serious vision loss and blindness from glaucoma. Early diagnosis and treatment may also be cost-effective, as costs escalate with disease severity.¹³

Because there is no single test for glaucoma, a diagnosis involves a probabilistic assessment based on symptoms and clinical results.¹⁴ Managing a patient's glaucoma may include monitoring his or her progress with regular visits and treatment with eye drops, laser procedures, or intraocular surgery.¹⁵ All aspects of glaucoma care, including surgery, can be provided by an ophthalmologist, a medical doctor, or doctor of osteopathy specializing in eye and vision care.

Massachusetts law currently does not permit optometrists to treat glaucoma patients.¹⁶ Our understanding is that in all other states, some aspects of glaucoma care, such as pharmaceutical treatment, can also be provided by an

¹¹ Harry A. Quigley et al., *The Cost of Glaucoma Care Provided to Medicare Beneficiaries from 2002 to 2009*, 120 OPTHALMOLOGY 2249, 2249 (2013); *Glaucoma, Open-angle*, NAT'L EYE INST., NAT'L INST. OF HEALTH, <https://nei.nih.gov/eyedata/glaucoma> (last visited Jan. 21, 2016) (approximately 2.7 million Americans have been estimated to have primary open angle glaucoma).

¹² Hussein Hollands et al., *Do Findings on Routine Examination Identify Patients at Risk for Primary Open-Angle Glaucoma? The Rational Clinical Examination Systematic Review*, 309 JAMA 2035, 2035 (2013) (citing research from 1978 to 2001).

¹³ Harry A. Quigley et al., *supra* note 11 at 2256 (citing studies that cost escalates with disease severity); J. Scheetz et al., *Validity and Reliability of Eye Healthcare Professionals in the Assessment of Glaucoma – A Systematic Review*, 69 INT'L J. OF CLINICAL PRAC. 689, 690 (2015) (reporting an estimate that costs for U.S. patients average \$623 per patient in early stages of the disease and \$2511 in late stages of the disease).

¹⁴ J. Scheetz et al., *supra* note 13 at 690; Anna C. Momont & Richard P. Mills, *Glaucoma Screening: Current Perspectives and Future Directions*, 28 SEMINARS IN OPTHALMOLOGY 185, 185-88 (2013).

¹⁵ Hussein Hollands et al., *supra* note 12 at 2035.

¹⁶ MASS. GEN. LAWS ch. 112, §§ 66-66B (2015).

optometrist, sometimes with certain additional requirements and restrictions. For instance, states neighboring Massachusetts impose requirements that optometrists who wish to treat glaucoma patients complete a certain number of training hours and pass an examination.¹⁷ Specifically, Rhode Island,¹⁸ Connecticut,¹⁹ and New York²⁰ require optometrists to complete a certain number of clinical hours. Other common requirements are that optometrists consult with ophthalmologists for a period of time after completing their glaucoma training²¹ or refer glaucoma patients to ophthalmologists under certain circumstances.

III. House Bill 1973

With respect to glaucoma, the Bill under consideration would allow “registered optometrists” in Massachusetts to “utilize and prescribe topical and oral therapeutic pharmaceutical agents” to diagnose, prevent, correct, manage or treat the disease.²² Optometrists would continue to be prohibited from treating patients in need of invasive surgical treatment or with newly diagnosed congenital glaucoma, and the Bill includes a requirement that optometrists refer those patients to qualified physicians.²³ Patients who, during the course of optometric examination, are found to be exhibiting “signs of previously unevaluated disease” requiring treatment outside of the scope of optometric practice also would be referred to physicians or other qualified health care practitioners.²⁴

¹⁷ Conn. Gen. Stat. Ann. § 20-127 (West 2015); N.H. Rev. Stat. Ann. § 327:6-c (2015); N.Y. Educ. Law § 7101-a (McKinney 2015); R.I. Gen. Laws Ann. § 5-35.1-12 (West 2015); Vt. Stat. Ann. Tit. 26 § 1728d, 1729a (West 2015).

¹⁸ R.I. Gen. Laws Ann. § 5-35.1-12 (West 2015).

¹⁹ Conn. Gen. Stat. Ann. § 20-127(d) (West 2015).

²⁰ N.Y. Educ. Law § 7101-a(4)(b) (McKinney 2015).

²¹ N.H. Rev. Stat. Ann. § 327:6-c(IV) (2015) (two years); N.Y. Educ. Law § 7101-a (McKinney 2015) (three years or seventy-five patients); Vt. Stat. Ann. Tit. 26 § 1729a (West 2015) (six months and at least five patients).

²² H.1973, §§ 66C(a).

²³ H.1973, § 66C(d).

²⁴ H.1973, § 66C(c).

Additionally, the Bill imposes certain educational and reporting requirements on optometrists. First, it would require that optometrists take an examination designed to test the qualifications necessary to safely utilize and prescribe pharmaceutical agents, including those used in the treatment of glaucoma. To utilize and prescribe certain pharmaceuticals, optometrists would be required to provide “evidence of the satisfactory completion of 40 hours of didactic education and 20 hours of supervised clinical education.”²⁵ Second, “[a]s a condition of license renewal,” the Bill would require optometrists to complete three hours of continuing education specific to glaucoma.²⁶ Third, it would require both optometrists and insurers or risk management organizations providing coverage to optometrists to participate in federal and state reporting and data collection efforts on patient safety and error reduction. The reported data will be used to develop “evidence-based best practices to reduce errors and enhance patient safety.”²⁷

IV. Competitive Considerations Regarding House Bill 1973

We recognize that certain professional scope of practice regulations can be important to ensure quality and patient safety, and regulation of glaucoma care is no exception. Competition consistent with patient safety, however, can bring important benefits to health care consumers. Generally, competition in health care markets benefits consumers by containing costs, expanding access and choice, and promoting innovation. Unnecessarily strict scope of practice restrictions can suppress these important benefits by limiting the supply of qualified care providers. Additionally, they can inhibit the development of new, collaborative models of care. For this reason, we recommend that the legislature consider the potential benefits of enhanced competition among glaucoma care providers that could be facilitated by the Bill and maintain only those scope of practice limitations necessary to ensure patient health and safety.

In this case, additional competition among providers of glaucoma care could help to alleviate, in particular, two important barriers to glaucoma care: access and cost. First, optometrists tend to be more convenient to see than ophthalmologists. Across the United States, optometrists outnumber ophthalmologists, and U.S. counties in rural areas and other underserved

²⁵ H.1973, § 68C(b).

²⁶ H.1973, § 68C(e).

²⁷ H.1973, §66C(e).

communities tend to have fewer ophthalmologists.²⁸ Optometrists see patients for routine eye exams and optical care, positioning them to serve as a first line of defense, which may facilitate earlier diagnosis and less costly treatment of glaucoma. Second, certain patients may forego or delay needed care if it is too costly. Excluding optometrists from providing non-surgical glaucoma care may limit price competition to serve these patients.²⁹ By contrast, allowing optometrists to deliver glaucoma care at a level commensurate with their training could help to ensure that more patients have access to affordable providers.

Thus, insofar as optometrists can adequately serve as substitute providers for aspects of glaucoma care, they may enable more patients to obtain and maintain treatment. Further, to the extent that optometrists can serve as complementary providers, ophthalmologists and patients may benefit from collaboration between the two types of providers. These consumer benefits may produce overall public health benefits for Massachusetts' glaucoma patients, many of whom may be undiagnosed or face an extended course of treatment to preserve their vision.

Under current law, however, Massachusetts prohibits optometrists from treating glaucoma. Unwarranted restrictions may be reducing patient access, raising costs, and foreclosing opportunities for early treatment. For these reasons, we encourage the legislature to consider whether patient welfare can be appropriately served by loosening this restriction. Though the existing published health services research is limited,³⁰ we note that the experience of other states may be informative as the legislature considers the Bill. Aside from

²⁸ Diane M. Gibson, *The Geographic Distribution of Eye Care Providers in the United States: Implications for a National Strategy to Improve Vision Health*, 73 PREVENTIVE MED. 30, 32 (2015) (finding 17,793 ophthalmologists and 44,402 optometrists in the U.S. in 2011 and finding that U.S. counties with fewer ophthalmologists per capita had significantly lower population densities, larger proportions of rural residents, and higher proportions of residents aged 65 years and older).

²⁹ See, e.g., NEW HAMPSHIRE INS. DEP'T, PAYMENT DIFFERENCES IN REIMBURSEMENT TO OPHTHALMOLOGISTS AND OPTOMETRISTS (2013), https://www.nh.gov/insurance/reports/documents/diff_reimb_optha_optom.pdf (comparing the charges and payments for procedures performed by optometrists and ophthalmologists); Mordachai Soroka, *Comparison of Examination Fees and Availability of Routine Vision Care by Optometrists and Ophthalmologists*, 106 PUB. HEALTH REP. 455, 457-459 (1991) (comparing examination fees and appointment availability between optometrists and ophthalmologists).

³⁰ See J. Scheetz et al., *supra* note 13 at 701 (systematically characterizing existing studies comparing the performance of providers, such as optometrists, in assessing glaucoma, and finding that the quality of existing evidence makes robust inferences "difficult").

Massachusetts, we understand that the other 49 states and the District of Columbia currently allow optometrists to have a role in treating glaucoma patients. Some states do require additional glaucoma-specific training or certifications and impose requirements for when a case must be referred to an ophthalmologist. Similarly, relaxing Massachusetts' prohibition on optometrists' ability to treat glaucoma patients, with conditions the legislature finds appropriate to ensure patient safety, would be broadly consistent with the approaches taken in other states.³¹

V. Conclusion

As we detail above, competition among health care professionals has the potential to benefit consumers by improving access to care, containing costs, and encouraging more ways to deliver needed care. By allowing optometrists to participate in glaucoma care at a level commensurate with their training, patients in Massachusetts may experience increased access to care, more choice in how their care is delivered, and more cost-effective treatment. Because these benefits of competition could be significant to Massachusetts glaucoma patients, we encourage the legislature to carefully consider whether a continued prohibition on optometric treatment of glaucoma is warranted. Relaxing the prohibition consistent with patient safety has the potential to bring the benefits of additional competition to Massachusetts health care consumers.

We appreciate this opportunity to present our views.

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³¹ See Section II, *supra*.