UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

January 28, 2010

Kentucky Cabinet for Health and Family Services
Attention: Jill Brown, Office of Legal Services
275 East Main Street 5 W-B
Frankfort, KY 40601

Dear Ms. Brown,

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition[1] are pleased to respond to the invitation for comments on the proposed regulation of limited service clinics (LSCs) in Kentucky.[2] LSCs are health care clinics located in retail settings, such as pharmacies and supermarkets, that offer consumers a convenient way to obtain basic medical care at competitive prices.[3] The types of care offered at LSCs are similar to those offered in urgent care centers and other limited care, outpatient settings.[4] A typical LSC provides basic screening services (such as cholesterol screening, pregnancy testing, diabetes screening, and strep throat infection testing), administers certain common vaccines (such as flu vaccine), and treats certain basic complaints (such as cold sores, flu, and minor burns and rashes).[5] The American Medical

[1] This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission ("Commission") or any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

[2] *See* Kentucky Cabinet for Health and Family Services, Office of Inspector General, Division of Health Care, New Administrative Regulation, 902 KAR 20:400. Limited services clinics (filed Dec. 15, 2009), *available at* http://www.lrc.ky.gov/kar/902/020/400reg.htm [hereinafter Proposed Rule] (public hearing and pubic comment period announced at draft p. 17).

[3] *See* Massachusetts Dept. Pub. Health, Commonwealth to Propose Regulations for Limited Service Clinics: Rules May Promote Convenience, Greater Access to Care (Jul. 17, 2007), *available at* http://www.mass.gov/?pageID=pressreleases&agId=Eeohhs2&prModName=dphpressrelease&prFile=070717_clinics.xml.

[4] LSCs offer a subset of primary care services – an overlapping, but narrower range of basic health care services than that offered at primary care centers, ambulatory care clinics, and urgent care centers. *See, e.g.*, Ateev Mehrotra et al., et al., *Retail Clinics, Primary Care Physicians, and Emergency Departments: A Comparison of Patients Visits*, 27 HEALTH AFFAIRS 1272, 1279 (September/October, 2008) ("ten complaints account for more than 90 percent of all retail clinic visits. . . . [but] 13 percent of adult PCP [primary care practice] visits, 30 percent of pediatric PCP visits, and 12 percent of ED [Emergency Department] visits.").

[5] *See id.*

Association has reported that consumers perceive advantages to LSCs, including factors such as convenient locations, shorter wait times, longer operating hours, and lower prices.[6]

The New Administrative Regulation for LSCs (Proposed Rule) would regulate the operation of LSCs. Numerous provisions of the Proposed Rule – such as the requirement that licensed health care professionals at LSCs operate within the scope of their licensure – mirror basic consumer protection standards that are imposed on competing providers of basic health care services.[7] As such, they do not raise competition concerns. However, several provisions impose costs and restrictions on both LSCs and the health care professionals who practice there, such as physicians and advanced registered nurse practitioners (ANPs),[8] that do not apply in other limited care settings, such as urgent care centers.

Imposing disparate regulations on competitors can reduce competition among them and thereby harm consumers. By reducing competition among providers of basic health care services, the Proposed Rule is likely to raise prices and decrease the availability of health care services for Kentucky consumers. Consumers may conceivably benefit from this disparate regulation only if is necessary to protect consumers' interests. Studies indicate, however, that the quality of LSC care is just as good as that in other clinic settings.[9] LSCs are operating successfully in more than thirty states, including Kentucky.[10] Thus, the available evidence does not appear to suggest a need for additional costs and limits on LSCs that do not apply in analogous limited care settings.[11] Moreover, the Proposed Rule does not articulate a justification for treating LSCs and other limited care settings differently.

In the absence of a justification, the Proposed Rule appears likely unnecessarily to limit competition from LSCs to provide basic health care services. Therefore, FTC staff

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[6] *See* American Medical Association, Report 7 of the Council on Medical Service (A-06), Store-Based Health Clinics 1 (June 2006).

[7] For the purposes of this comment, FTC staff have not analyzed, and do not address, Kentucky's basic requirements for the licensure of health care professionals or the state's basic standards of care for health care clinics. This comment addresses only the competitive implications of those requirements that (a) discriminate between licensed providers of basic health care based on clinic ownership or setting *without* (b) any evident health or safety rationale for that discrimination.

[8] FTC staff understands that the nurse practitioners, or advanced practice nurses, who would help staff LSCs in Kentucky are advanced registered nurse practitioners (ANPs), whose scope of practice generally is established pursuant to KRS Chapter 314.

[9] *See, e.g.*, Ateev Mehrotra et al., *Comparing Costs and Quality of Care at Retail Clinics with that of Other Medical Settings for 3 Common Illnesses*, 151 ANNALS INTERNAL MED. 321, 326 (2009) (analysis of 14 quality metrics for commonly treated ailments otitis media [ear infection], streptococcal pharyngitis [strep], and urinary tract infections); *infra* text accompanying notes 22-25.

[10] *See* Rena Rudavsky, Craig Evan Pollack, & Ateev Mehrotra, *The Geographic Distribution, Ownership, Prices, and Scope of Practice at Retail Clinics*, 151 ANNALS INTERNAL MED. 315, 315 (2009) (LSCs in 33 states in August 2008).

[11] FTC staff do not mean to suggest that the published evidence regarding LSCs health care is definitive. Rather, published data tend to support the contention that LSCs offer high quality and low prices for certain basic health care services, provided by licensed health care professionals, and we are unaware of countervailing empirical findings.

recommend that The Kentucky Cabinet for Health and Family Services (Cabinet) eliminate the provisions of the Proposed Rule that would impose greater costs and limits on LSCs (and the professionals who practice there) than on other limited care settings.

The Cabinet also might wish to consider whether a separate rule for LSCs is necessary or whether existing standards for licensing comparable facilities, such as primary care centers, might be adapted to regulate Kentucky LSCs as well. We understand that LSCs in Kentucky already operate successfully under such regulations,[12] and that primary care centers, hospitals, and other providers can offer the same basic services and staffing at satellite or extension facilities.[13] The Proposed Rule does not clearly distinguish when such services, staff, and facilities would be regulated under LSC regulations or otherwise. To the extent that the Cabinet does not identify distinct health and safety concerns associated with doctor and ANP provision of basic health care services in these settings, this ambiguity might be resolved better by modifying existing clinic regulations to accommodate LSCs.

Interest and Experience of the Federal Trade Commission

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[14] Competition is at the core of America's economy,[15] and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, more choices, and greater innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key target of FTC law enforcement[16] and research.[17] The FTC and its staff also encourage health care competition through advocacy, and have urged several states to reject or narrow restrictions that limit health care access and raise prices to consumers by limiting competition among health care providers and professionals.[18]

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[12] FTC staff have been told that LSCs presently operate in Kentucky under primary care center licensure, ambulatory care clinic licensure, and otherwise. *Cf.* Kentucky Cabinet for Health and Family Services, Office of Inspector General, Directory of Licensed Health Care Facilities: Miscellaneous Directory (OIG directories *available at* http://chfs.ky.gov/os/oig/directories.htm) (listing, among others, Walgreens-Option Care, Inc. clinics in the Louisville, Paducah, and Somerset, KY areas, most affiliated with Integrity Healthcare Services, Inc.).

[13] *See supra* notes 4, 12, 37 - 39, and accompanying text.

[14] Federal Trade Commission Act, 15 U.S.C. § 45.

[15] *See National Society of Professional Engineers v. United States*, 435 U.S. 679, 695 (1978) ("The heart of our national economy long has been faith in the value of competition.").

[16] *See generally, e.g.*, FEDERAL TRADE COMMISSION (FTC), FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (Mar. 2008), *available at* http://www.ftc.gov/bc/0608hcupdate.pdf ; *see also* Competition in the Health Care Marketplace: Formal Commission Actions, *available at* http://www.ftc.gov/bc/healthcare/ antitrust/commissionactions.htm.

[17] *See, e.g.*, FTC AND U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 7 (2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[18] *See, e.g.*, Letter from FTC Staff to Hon. Timothy Burns, Louisiana Legislature, (May 1, 2009) (regarding proposed restrictions on mobile dentistry); *available at* http://www.ftc.gov/os/2009/05/V090009 louisianadentistry.pdf; Letter to Senator James L. Seward, New York Senate re Pharmacy Benefit Manager

A Brief Background on Limited Service Clinics

LSCs – sometimes called "retail clinics" or "store-based clinics" – are one way to deliver a limited range of basic health care services in a clinic setting. LSCs are staffed by licensed health care professionals, typically nurse practitioners or ANPs who are overseen by physicians, and sometimes physicians or physician assistants.[19] LSCs tend to be located in non-traditional provider settings, such as pharmacies and supermarkets, and tend to offer more extensive evening and weekend hours of operation than many primary care clinics.[20] LSCs generally provide only a pre-specified menu of basic health care services, with retail prices posted so that they are conspicuous to consumers prior to treatment.[21]

Evidence shows that the quality of care in LSCs is "similar to that provided in physician offices and urgent care centers and slightly superior to that of emergency departments."[22] Indeed, "[f]or most measures, quality scores of retail clinics were equal to or higher than those of other care settings."[23] Patients at LSCs and other primary care clinics appear equally likely to receive preventive care, including follow-up visits to doctors' offices where such care is typically delivered.[24] In addition, prescription rates are similar at LSCs,

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Provisions of Senate Bill 58, Matter No. V090006, *available at* http://www.ftc.gov/os/2009/04/V090006newyorkpbm.pdf; Letter from FTC Staff to Elain Nekritz, Illinois Legislature (May 29, 2008) (regarding proposed LSC regulations); *available at* http://www.ftc.gov/os/2008/06/V080013letter.pdf; Letter from FTC Staff to Massachusetts Dep't of Health (September 27, 2007) (regarding proposed LSC regulations); *available at* http://www.ftc.gov/os/2007/10/v070015massclinic.pdf. Many of these advocacy efforts have been successful in preserving competition. For example, following the above referenced advocacy letters, the Louisiana and Illinois legislatures rejected the proposed restrictions on competition, and Massachusetts followed FTC Staff recommendations in adopting its final LSC regulations.

[19] *See generally* William M. Sage, *Might the Fact that 90% of Americans Live Within 15 Miles of a Wal-Mart Help Achieve Universal Health Care?*, 55 U. KAN. L. REV. 1233, 1238 (2007) (describing the size and scope of limited service clinics); Mary Kay Scott, Scott & Company, *Health Care in the Express Lane: Retail Clinics Go Mainstream*, Sept. 2007, at 22 (Report prepared for the California HealthCare Foundation), *available at* http://www.chcf.org/publications.

[20] *See supra* note 19; Rudavsky et al., *supra* note 10 at 317 ("In a random sample of 98 clinics, all had weekday and weekend hours and 95 (97%) had evening hours (after 6 p.m.) on weekdays.").

[21] *See supra* note 19. According to a recent RAND study, more than 90% of LSC patients present with one of ten common conditions, including upper respiratory issues, pharyngitis, sinusitis, and conjunctivitis. Mehrotra et al., et al., *Retail Clinics*, *supra* note 4, at 1278.

[22] Mehrotra et al., *Comparing Costs*, *supra* note 9, at 326 (analysis of 14 quality metrics for commonly treated ailments otitis media [ear infection], streptococcal pharyngitis [strep], and urinary tract infections).

[23] *Id.* at 325; *see also* Mary Kay Scott, *supra* note 19, at 21 (comparing Minute Clinic compliance with evidence based guidelines for sore throat and strep throat – over 99% – with New England Journal of Medicine study indicating that "Americans receive evidence-based care only 55% of the time at other kinds of health care providers," citing Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2641 (2003)).

[24] Comparing LSCs, physician offices, and urgent care centers, Mehrotra et al. found that "rates of preventive care received at the initial visit through the subsequent 3 months were similar for retail clinics and physician offices. For patients who visit a retail clinic, preventive care was typically delivered in a physician's office,

physician offices, and urgent care centers (perhaps slightly lower on average at LSCs),[25] assuaging earlier concerns that LSCs connected with retail pharmacies might over-prescribe antibiotics.

Furthermore, "[o]verall costs of care for episodes initiated at retail clinics were substantially lower than those of matched episodes initiated at physician offices, urgent care centers, and emergency departments."[26] This is likely to be especially important for the uninsured and underinsured patients who often visit LSCs.[27] Such patients may face stark health care choices. When they lack regular health care providers, they may need to choose between costly emergency room care and no care at all.[28] When LSCs function as a safety-net provider for patients who do have regular health care providers, LSCs can relieve some of the stress placed on emergency rooms by patients who require care, but not emergency care.[29]

Discussion

Several provisions of the Proposed Rule appear to impose costs and limits on LSCs and LSC-employed health care professionals that do not apply in comparable health care

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which suggests that the clinics are not disrupting opportunities for preventive services." *See* Mehrotra et al., *Comparing Costs*, *supra* note 9, at 326.

[25] *Id.*

[26] *Id.* at 324; *see also* Marcus Thygeson et al., *Use and Costs of Care in Retail Clinics Versus Traditional Care Sites*, 27 HEALTH AFFAIRS 1283, 1287-88 (2008) ("average total cost for a MinuteClinic episode was $51 less than in the urgent care setting, $55 less than in the physician office setting, and $279 less than in the ED setting.") These studies provide some evidence not just that LSC retail prices are lower for individual services, but that prices per episode-of-care are lower when treatment is begun at an LSC instead of a physician office, urgent care center, or emergency department. That observation has been made by researchers taking reasonable steps to control for systematic differences in case-mix across these different types of facilities. FTC staff also note that differences in case-mix may themselves represent an efficiency: LSCs provide consumers an opportunity to sort themselves across types of facilities, seeking care for lower-severity complaints disproportionately at LSCs, where labor and other costs generally are lower.

[27] A recent study indicates that one third of LSC visits were not paid for with health insurance, Ateev Mehrotra et al., RAND Health, Research Highlights, *Health Care on Aisle 7: The Growing Phenomenon of Retail Clinics* 3 (2009), *available at* http://www.rand.org/pubs/research_briefs/RB9491/. Additional RAND research indicates that "almost all (97%) [LSCs] accepted private insurance and Medicare fee-for-service (93%)," and most accepted some form of Medicaid. Rudavsky et al., *supra* note 10, at 317.

[28] Data indicate that LSC patients are much "less likely to have a personal doctor" than patients generally. Mehrotra et al., *Health Care on Aisle 7*, *supra* note 27, at 3 (39% of LSC patients reported having personal doctor versus 80% of patients nationally). The evening and weekend hours typically offered by LSCs may be of special benefit to working people who are uninsured or underinsured, and may reinforce the stark choice between LSCs (when available) and costly emergency room care for non-emergent conditions. *Cf.* Rudavsky et al., *supra* note 10, at 317 ("In a random sample of 98 clinics, all had weekday and weekend hours and 95 (97%) had evening hours (after 6 p.m.) on weekdays.")

[29] "If retail clinics were not available, it is unclear whether these patients would have gone to a PCP office, urgent care clinic, or ED or if they would have sought medical care at all. It is possible that retail clinics could serve as a safety-net provider for some patients who now seek care in EDs." Mehrotra et al., *Comparing Costs* , *supra* note 9, at 1279 (regarding younger population of LSC patients who pay out-of-pocket).

settings. In turn, these additional restrictions are likely to increase prices and decrease choices for Kentucky patients, without providing any countervailing benefits.

A. The Proposed Rule

The Proposed Rule contains three categories of regulatory provisions that are likely to raise competitive concerns. The first involves limits on the scope of professional services that may be provided at an LSC – limits that do not apply to the same credentialed professionals in comparable limited care settings. The second involves certain physical or operational restrictions that do not apply to comparable limited care clinics. The third involves mandatory licensing fees in excess of those required of any other health care facility.

(1) Scope of Service. The Proposed Rule, while listing thirty-nine services that LCSs may provide,[30] appears to prevent credentialed health care professionals from providing basic health care services in LSCs that they can provide in comparable limited care settings, such as urgent care clinics. If this list were to exhaust the types of care that physicians and ANPs may provide at LSCs, it would restrict the basic care that credentialed professionals may provide based solely on the setting in which that care is offered. For example, under the Proposed Rule, a physician or ANP at an LSC may provide a physical examination for sports or camp, but not for school.[31] The same physician or nurse could provide a school physical at a comparable clinic, however. The Proposed Rule also would restrict physicians and ANPs – only at an LSC – from providing a vaccination unless the patient were 16 or older.[32] Similar questions are presented by, e.g., the provision that LSCs may treat "[f]ever, excluding patients who have had a fever longer than seventy-two (72) hours;" and may treat "[u]rinary infection for females only, age twelve (12) to sixty-five (65)."[33]

More generally, the Proposed Rule prohibits licensed health care professionals at LSCs from treating people with chronic or recurring ailments that the same professionals could treat in similar limited care settings, such as urgent care clinics.[34] For example, the Proposed Rule appears to prohibit licensed professionals from treating in an LSC intermittent, mild, and moderate asthma, which are chronic ailments that the same professionals would be permitted to treat elsewhere.[35] There do not appear to be comparable

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[30] Proposed Rule at § 3(4)(b).

[31] Proposed Rule at § 3(4)(b)(32).

[32] *Id.* at § 3(4)(b)(34).

[33] *Id.* at §§ 3(4)(b)(14) and (31).

[34] "A clinic shall not: (a) Treat a person with a recurring or chronic illness; or (b) Refill a prescription for a patient who requires continuity of care." Proposed Rule at § 3(3) (a) and (b).

[35] *See generally* National Institutes of Health, Asthma, *available at* http://health.nih.gov/topic/Asthma (describing asthma as chronic condition and providing links to detailed information provided by the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, and other NIH sources). In addition, health care professionals may be concerned about liability issues if they do – or do not – provide, e.g., emergency treatment of an immediate asthma flare-up that could be life-threatening: such

restrictions on the scope of practice in primary care centers, special health clinics, or ambulatory care clinics.[36]

We are unaware of any justification for restricting the types of services physicians and ANCs may provide based solely on the type of basic care settings in which they provide it.

(2) Unnecessary Costs. The Proposed Rule imposes conditions regarding LSC operations, equipment, and environment that are not imposed on outpatient clinics offering even broader types of basic health care services, such as ambulatory care clinics,[37] primary care centers,[38] or special health clinics.[39] For example, the off-hours coverage provisions in the Proposed Rule would require that an LSC offer some form of answering and referral service around the clock.[40] There are no such requirements for primary care centers or special health clinics, which are more likely than LSCs to be treating conditions that require follow-up care.[41] Under the Proposed Rule, LSCs – but not primary care centers, special health clinics, or ambulatory care clinics – would be required to have an automated external defibrillator on-site, to provide a separate "waiting room or waiting area," and to meet other equipment, plumbing, and construction requirements.[42]

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treatment may be well within their scope of practice generally, but prohibited by LSC licensure restrictions on the treatment of chronic illness. Following the general point at note 7, *supra*, FTC staff do not rely on any analysis regarding asthma treatment guidelines or professional qualifications requisite to asthma treatment. Rather, staff are concerned about the competitive impact of restrictions that discriminate against one type of provider without an apparent health and safety justification for the discrimination.

[36] *See generally*, 902 KAR 20: 058 (Operation and services; primary care center); 902 KAR 20: 260 (Special health clinics); and 902 KAR 20: 073 (Clinics: Ambulatory care).

[37] *See generally* 902 KAR 20: 073 (Clinics: Ambulatory care).

[38] *See generally*, 902 KAR 20: 058 (Operation and services; primary care center.) FTC staff also notes that a primary care center may provide services "on a temporary or regular basis in locations separate from its permanent facility," 902 KAR 20:058, with special provisions possible for operating extensions at schools. *Id.* and KRS 216B.176. The extent to which primary care center regulations restrict facilities, staffing, and scope of practice at physician satellite or temporary extensions is unclear.

[39] *See generally*, 902 KAR 20: 260 (Special health clinics.)

[40] An LSC must "make arrangements for the delivery of the services it provides during the hours when it is not open, which may include an answering service referring patients to another provider of the same services that is open at those hours." Proposed Rule at § 5(4). The range of off-hours services that might satisfy this requirement is not clear.

[41] There do not appear to be comparable requirements for primary care centers under 902 KAR 20:058 or special health clinics under 902 KAR 20:260. Ambulatory care clinics providing much broader services are required to "provide telephone screening and referral services for prospective patients after regularly scheduled hours of operation." 902 KAR 20:073 § 4(3). Comparing service offerings, see *supra* note 4 ("ten complaints account for more than 90 percent of all retail clinic visits. . . . [but] 13 percent of adult PCP [primary care practice] visits, 30 percent of pediatric PCP visits, and 12 percent of ED visits.").

[42] Proposed Rule at § 5(5) (equipment). Proposed § 7, regarding physical and sanitary environment, requires, among other things, that an LSC have "a waiting room or waiting area," and that each exam room is a minimum square footage and includes "a handwashing facility with hot and cold water and blade type operating handles or knee or foot controls." Also, although an LSC "located on the premises of another entity may share toilet facilities with that entity," [i]f a clinic provides services in which a urine sample is needed, the clinic's toilet

(3) Fees. Both initial and annual licensure fees for LSCs are set at $800 under the Proposed Rule.[43] No other type of clinic must pay as much.[44] For example, annual licensing fees are $270 for primary care centers[45] and ambulatory surgical centers,[46] $140 for rural health clinics, and $10 per bed – with a minimum total fee of $155 – for accredited hospitals.[47] In addition, the Proposed Rule appears to impose the $800 annual fee on each individual LSC. By contrast, Kentucky regulations impose only a $25 fee on each satellite primary care center.[48]

B. Likely Effects on Kentucky Consumers

At least some of the costs of the Proposed Rule are likely to be passed on to Kentucky consumers through higher prices or fewer health care options. First, the costs and restrictions discussed above can be significant for small clinics seeking to provide very basic care at a low price, likely causing some LSCs to curtail services or hours or to raise prices. Further, faced with higher costs of operations, some LSCs that would otherwise open may fail to do so, and some existing LSCs may close their doors. Finally, because the Proposed Rule disadvantages LSCs, it will reduce the competitive pressure that LSCs place on other providers of basic health care services. This reduction in competition may lead those providers that compete with LSCs also to raise their prices or reduce the quality or convenience of the services that they offer.

The impact of the Proposed Rule is likely to be felt most by the uninsured, underinsured, and other vulnerable citizens of Kentucky. To justify the increased prices for, and decreased access to, basic health care services that the Proposed Rule likely would impose, there should be a showing that the disparate regulatory treatment of LSCs is necessary to protect patients seeking care in limited service settings. We are unaware of any such justifications. To the contrary, the available evidence does not point to any need to

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facilities shall be located within the clinic." There appear to be neither automated external defibrillator (AED) nor other medical device requirements imposed upon primary care centers under 902 KAR 20:058 or ambulatory care clinics under 902 KAR 20:073, and although limited "physical environment" requirements are imposed upon special health clinics under 902 KAR 20:260 § 5, these have chiefly to do with basic housekeeping and maintenance standards and basic waste disposal requirements that are among the general procedural requirements for all health care clinics – they do not include AEDs.

[43] Proposed Rule at § 2(2).

[44] See generally 902 KAR 20:008 (License procedures and fee schedule). New fees for health care "personal services agencies" under emergency administrative regulation 906 KAR 1:180E also are lower than proposed LSC fees.

[45] *Id.* at § 3(2)(l).

[46] *Id.* at § 3(2)(c).

[47] *Id.* at § 3(2)(l)(1).

[48] *See supra* note 44. Hence licensing fee disparities may be magnified if, e.g., a primary care clinic with four satellite centers need pay only $370 in annual fees, while a competing cluster of five LSCs under common ownership and management, with roughly the same categories of health care providers offering very similar services, must pay $4,000 in annual fees.

impose distinct regulatory burdens on LSCs and the professionals who practice at LSCs. As noted above, studies suggest that LSCs provide care that is equal to or better than that found in other settings.[49] Further, we are unaware of any health-related justification for the scope of service restrictions, such as prohibiting professionals from vaccinating younger children or providing physical examinations for schools in an LSC, just as they could in another limited care setting. Finally, we are also unaware of any administrative rationale for imposing disproportionately high licensing fees on LSCs.

Conclusion

Consumers are paying more for health care every year, and rising prices continue to leave many people without reliable or meaningful access to health care services. LSCs have the potential to expand access to health care by making very basic medical care more convenient and less costly. Many who visit LSCs may need to chose between the LSC, an emergency room, and no care at all; not all consumers can afford or have easy access to a regular treating physician in a consistent primary care clinic setting. We urge the Cabinet not to adopt regulatory provisions that have the unnecessary and unintended consequences of making care less affordable and less convenient for Kentucky health care consumers.

Two alternative approaches should be considered. First, to avoid unnecessary costs and restrictions on LSCs, the Cabinet can strike needlessly disparate requirements from the final Rule. Alternatively, the Cabinet may wish to consider whether LSC scope of service, physical plant, and operations requirements could be better specified through amendments to Kentucky's existing licensing rules for health care clinics. If distinct health and safety problems are not associated with doctor and ANP provision of basic health care services in LSCs, adaptation of existing clinic rules may help preserve a competitive playing field, with greater benefits and lower costs to Kentucky health care consumers.

We appreciate your consideration of these issues.

[49] *See* notes 22-25, *supra*, and accompanying text.

Respectfully submitted,

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Richard A. Feinstein, Director
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