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Erratum

This is the article as amended in 2014.

Retail Medical Clinics: Increasing Access to Low Cost Medical Care Amongst a Developing Legal Environment

*Kristin E. Schleiter, J.D., LL.M.**

This article reflects the personal views and opinions of Kristin Schleiter in her individual capacity only. It does not necessarily represent the views of the American Medical Association.

INTRODUCTION

Retail medical clinics are an innovation in health care with the potential to increase access to low-cost basic health care services. In 1995, Newt Gingrich predicted that in the future, patients would either “go to Canada or Wal-Mart.”¹ Today, this prediction has been realized. The trend toward patient-centered care has produced a new category of health care facility: the retail medical clinic (RMC). If successful, retail medical clinics “could change the way many people receive routine, non-urgent medical care,” with significant implications for insurers and health care providers” alike.² The legal environment surrounding retail medical clinics is developing as states begin to consider the most appropriate and mutually beneficial way in which to fit the clinics into each state’s existing health care system.

Part I of this paper will begin by discussing the theory and history behind retail medical clinics, as well as the interests at stake for the primary players in the health care industry. Part II will discuss the various legal considerations that surround RMCs, including state legislative activity, licensing and scope of practice considerations, regulation of the mid-level providers who staff retail medical clinics, fraud and abuse issues such as the Stark law and the federal Anti-Kickback Statute, the corporate practice of medicine doctrine, and exposure of RMCs to medical malpractice liability.

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1. Newt Gingrich, *Newt’s Brave World*, FORBES ASAP, Feb. 27, 1995, at 94 [hereinafter, Sage 2008].

2. MARY KATE SCOTT, CAL. HEALTHCARE FOUND., HEALTH CARE IN THE EXPRESS LANE: THE EMERGENCE OF RETAIL CLINICS 18 (2006), www.chcf.org/documents/policy/HealthCareInTheExpressLaneRetailClinics.pdf [hereinafter CHCF 2006].

The bottom line is that retail medical clinics provide quality medical care at a reasonable cost with the potential to increase access to basic health services in underserved populations. As the number of Americans without health care coverage continues to increase, and the underlying cost of medical services even for those with health insurance escalates, consumers cannot afford to have such a convenient alternative for health care delivery absent from the marketplace. The patient-centered model of health care demands it. However, the success of RMCs depends on a unique and constrained place in the medical market. RMC operators must recognize that, legally and clinically, the clinics are not meant to be a substitute for primary care providers. Scope of practice considerations have and continue to be a primary point of debate as states tackle the issue of RMC regulation and licensure. Though there is not yet a national consensus on how best to deal with retail medical clinics, several states have made an effort to fit retail medical clinics within new and existing regulations that govern their state health credentialing systems.

BACKGROUND

“A couple of years ago, medical centers thought if they ignored [the trend of retail medical clinics], it would go away. But patients tell us this is what they want.”

– Tricia Dahl, Mayo Clinic’s Albert Lea Medical Center.³

Retail medical clinics are health care clinics located in retail settings such as supermarkets and pharmacies, which treat simple medical conditions and provide basic preventive care. They are sometimes referred to as “convenient care clinics,” “store-based health clinics,” or “limited service clinics.” Clinics are open extended hours and weekends.⁴ The average cost of services offered by RMCs ranges from \$30 to \$110.⁵ RMCs offer health care almost exclusively through nurse practitioners (NPs) or physician assistants (PAs) who offer a limited scope of care under physician supervision.⁶

Retail medical clinics’ growing popularity can be attributed to a variety of factors. Patients are facing shrinking selection of primary care providers,

3. SCOTT & CO., FED. TRADE COMM’N, *RETAIL CLINICS – THE CARE AND BUSINESS MODEL, PLAYERS, AND THE FUTURE*, 10 (2008), http://www.ftc.gov/bc/health_care/hcd/docs/Scott.pdf.

4. JOSEPH P. ANNIS, COUNCIL ON MED. SERV., *REPORT 7 OF THE COUNCIL ON MED. SERV. (A-06), STORE-BASED HEALTH CLINICS 7* (2006), <http://www.ama-assn.org/ama1/pub/upload/mm/372/a-06cmsreport7.pdf> [hereinafter CMS Report 7-A-06].

5. *Id.* at 1.

6. Ateev Mehrotra et al., *Retail Clinics, Primary Care Physicians, and Emergency Departments: A Comparison of Patients’ Visits*, 27 *HEALTH AFFAIRS* 1272, 1272 (2008) [hereinafter Mehrotra 2008].

while deductibles and copays continue to rise.⁷ RMCs encourage consumer use through convenience, easy access, quick service, lower cost, and transparent pricing.⁸ Low-cost labor and small spaces allow RMCs to optimize cost of care, while quality is maintained by technology, physician oversight, and practitioner adherence to a strict set of protocols.⁹ Today's RMCs focus on customer service, in contrast to hospitals that for decades regarded the physician as the customer rather than the patient as the customer.¹⁰

Transparent, low pricing is a primary feature of retail medical clinics. While RMCs offer a more narrow range of services than are offered by traditional primary care providers or emergency rooms, the full range of services provided and corresponding prices are unambiguously posted in a way that some have likened to a McDonalds menu.¹¹ The conditions treated and therapies offered require no physician evaluation and either no or minimal follow-up.¹² Diagnoses can be made by using a simple test or by applying a rigid, protocol-based decision rule.¹³ Most importantly, conditions can be diagnosed and treated quickly.¹⁴ Most RMC visits last between fifteen and twenty-five minutes.¹⁵

Retail medical clinics do not treat medical emergencies and are not intended for people with recurring illnesses.¹⁶ A typical RMC treats about thirty minor illnesses, performs health screenings, and administers vaccines.¹⁷ Ten acute conditions and preventive care account for the vast majority (90.3%) of RMC visits: upper respiratory infections, sinusitis, bronchitis, pharyngitis, immunizations, otitis media (middle ear infection), otitis externa (outer ear infection, also known as "swimmer's ear"), conjunctivitis, urinary tract infections, and screening lab test or blood

7. Annie Hsu, *Legal Issues Concerning Retail Clinics*, 20 HEALTH LAW. 13, 13 (2008).

8. Marcus Thygeson et al., *Use and Costs of Care in Retail Clinics Versus Traditional Care Sites*, 27 HEALTH AFFAIRS 1283, 1283 (2008).

9. MARY KATE SCOTT, CAL. HEALTHCARE FOUND., HEALTH CARE IN THE EXPRESS LANE: RETAIL CLINICS GO MAINSTREAM 6 (2007), <http://www.chcf.org/documents/policy/HealthCareInTheExpressLaneRetailClinics2007.pdf> [hereinafter CHCF 2007].

10. Sage 2008, *supra* note 1, at 1241.

11. Richard Bohmer, *The Rise of In-Store Clinics – Threat or Opportunity?*, 356 NEW ENG. J. MED. 765, 766 (2007); George Flynn, *One Stop Health Care Shopping? The Rise of "McClinics" and Their Impact on Emergency Care*, 48 ANNALS EMERGENCY MED. 566, 566 (2006).

12. Bohmer, *supra* note 11, at 767.

13. *Id.* at 766-67.

14. *Id.* at 767.

15. Tine Hansen-Turton et al., *Convenient Care Clinics: The Future of Accessible Health Care*, 10 DISEASE MGMT. 61, 63 (2007).

16. CMS Report 7-A-06, *supra* note 4, at 1.

17. *Id.*

pressure check.¹⁸ The most frequently provided service is strep throat testing.¹⁹

While almost all retail medical clinics offer basic exams, vaccines and preventive care, some clinics are adding risk assessment and management services.²⁰ These added services create more opportunities to serve patients, generate revenue, and can add volume through lab testing and other screening.²¹ It is expected that RMCs will eventually expand the range of offered preventive and proactive services that are aimed at helping patients to better manage their health, rather than just providing treatment for illnesses.²² However, a recent study found that RMCS had not expanded its scope of care into chronic disease management as of August 2008.²³ Most retail medical clinics have developed medical protocols to assist the mid-level practitioner with the operation of the clinics.²⁴ For example, MinuteClinic has developed medical protocols that are based upon practice guidelines established by the American Academy of Family Physicians, American Academy of Pediatrics and Institute for Clinical Systems Improvement.²⁵ Some RMC operators emphasize that physician consultants are always available to support the clinics' mid-level providers.²⁶ Indeed, most health care practitioners at RMCs are in close contact with local area physicians.²⁷ To ensure continuity of care, patients are given a copy of their health record at the end of a visit to a retail medical clinic, which they are able to share with their primary health care provider.²⁸ Most RMCs also offer to fax, mail, or e-mail the patient's medical record to the patient's physician of choice.²⁹

A key aspect of retail medical clinics is referral of patients to physicians' offices or an emergency department for treatment of conditions outside the RMC's narrow scope of practice.³⁰ Any condition which the RMC is not

18. Mehrotra 2008, *supra* note 6, at 1276.

19. Sage 2008, *supra* note 1, at 1238.

20. Hsu, *supra* note 7, at 15.

21. *Id.*

22. *Id.*

23. Rena Rudavsky et al., *The Geographic Distribution, Ownership, Prices, and Scope of Practice at Retail Clinics*, 151 ANNALS INTERNAL MED. 315, 319 (2009).

24. CMS Report 7-A-06, *supra* note 4, at 2.

25. MinuteClinic: National Clinical Practice Guidelines, <http://www.minuteclinic.com/en/USA/About/Quality/National-Clinical-Practice-Guidelines.aspx> (last visited Feb. 12, 2010).

26. CMS Report 7-A-06, *supra* note 4, at 2.

27. *Id.*

28. Hansen-Turton, *supra* note 15, at 63.

29. Howard J. Anderson, *Retail Clinics Rely on Automation*, HEALTH DATA MGMT. MAGAZINE, Apr. 1, 2008, http://www.healthdatamanagement.com/issues/2008_49/26009-1.html.

30. CHCF 2006, *supra* note 2, at 24.

technically or professionally equipped to treat will be referred to the appropriate care provider.³¹ RMCs generally maintain relationships with local physicians or hospitals for these referrals.³² Patients are also advised to seek medical attention from a physician, rather than continuing to visit the RMC, after the patient has visited the RMC a certain number of times.³³ Clinics estimate that patients are triaged to an emergency department or physician's office during 2.3% of visits.³⁴

Three types of retail stores typically host retail medical clinics: (1) pharmacies who see RMCs as a way to increase prescription spending (65%); (2) discounters or mass merchandisers who see RMCs as a venue for consumer services (20%); and (3) grocers who see RMCs as a way to increase store visits and "basket" size (15%).³⁵ RMCs are commonly structured as one of three models. In the "retailer leasing" model, the retailer leases space to an independent retail medical clinic operator that employs clinicians.³⁶ Both profits and losses flow to the RMC operator.³⁷ Under the "retailer ownership model," the retailer owns the RMC and employs clinicians.³⁸ Profits and losses flow to the retailer in this model.³⁹ In the "retailer practice management" model, the retailer leases space and non-clinical items (equipment, furniture, HIT, administrative staff) to the independent clinic operator, who employs physicians and/or mid-level practitioners.⁴⁰ Profits and losses flow to the RMC operator, but the retailer shares risk in the form of a practice management fee.⁴¹

Payment for medical services at retail medical clinics varies. While historically RMC visits were paid for out of pocket, today health insurers including Medicare and Medicaid often pay for these visits.⁴² From 2000 to 2007, the percentage of RMC visits paid for out of pocket fell from one hundred percent to sixteen percent.⁴³ Currently almost all retail clinic

31. Deloitte, Center for Health Solutions, *RETAIL CLINICS: FACTS, TRENDS, AND IMPLICATIONS* 6 [hereinafter, Deloitte].

32. CHCF 2006, *supra* note 2, at 9.

33. CMS Report 7-A-06, *supra* note 4, at 2.

34. Mehrotra 2008, *supra* note 6, at 1276.

35. CHCF 2007, *supra* note 9, at 14.

36. Robert Belfort, Partner, Manatt, Phelps & Phillips, LLP, Address at the American Health Lawyers Association Fraud and Compliance Forum: Compliance Issues for Retail Medical Clinics (Oct. 6, 2008) (transcript available with the American Health Lawyers Association).

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.*

42. Mehrotra 2008, *supra* note 6, at 1272.

43. *Id.* at 1276.

operators (97%) accept private insurance, and only slightly less (93%) accept Medicare.⁴⁴ To make insurance coverage feasible, RMCs keep their administrative systems simple and compatible with most insurers' systems.⁴⁵ A typical retail medical clinic measures between two hundred and five hundred feet.⁴⁶ RMCs operate with "a simple setup of a reception desk and one or two exam rooms," with limited space for private rooms, toilets or sinks.⁴⁷ As a result, clinics focus on noninvasive procedures that do not require fluid samples or disrobing.⁴⁸ The California HealthCare Foundation has labeled this restriction the "plumbing and privacy" paradigm.⁴⁹ RMCs usually keep electronic medical records (EMR), and need very little medical equipment.⁵⁰

Take the example of Walgreens' Take Care Clinic. Take Care is the country's second-largest RMC, second only to CVS' MinuteClinic. The clinic is part of Take Care Health Systems, a wholly-owned subsidiary of Walgreens.⁵¹ Take Care's premise of "It's quality family healthcare built around you" is structured to position Take Care's expertise as a provider of high-quality, accessible healthcare that puts patients first.⁵² Since 2005, Take Care has treated over 750,000 patients.⁵³

Similar to the model described above, a typical Take Care clinic has two patient exam rooms with exam tables and sinks, touch-screen check-in kiosks, and electronic health records that are accessible at any Take Care Clinic location.⁵⁴ Every visit is followed up with a phone call.⁵⁵ The clinics are staffed by board-certified, licensed family nurse practitioners and physician assistants, and collaborate with local physicians who are available for consultations at all times patients are being treated.⁵⁶

44. Rudavsky, *supra* note 23, at 317.

45. Sage 2008, *supra* note 1, at 1239.

46. CHCF 2006, *supra* note 2, at 9; Hansen-Turton, *supra* note 15, at 63.

47. CHCF 2006, *supra* note 2, at 9.

48. *Id.*

49. *Id.*

50. *Id.* at 11.

51. Take Care Clinic at Select Walgreens, About Us, <http://www.takecarehealth.com/about> (last visited Mar. 17, 2010).

52. Take Care Clinic at Select Walgreens, About Us: Our Commitment, <http://www.takecarehealth.com/about/our-commitment.aspx> (last visited Mar. 17, 2010).

53. Take Care Clinic at Select Walgreens, Take Care Health Systems Launches National Brand and Advertising Campaign, http://www.takecarehealth.com/about/press-releases/press_101608_01.aspx (last visited Mar. 17, 2010).

54. Take Care Clinic at Select Walgreens, About Your Visit, <http://www.takecarehealth.com/about-your-visit/> (last visited Mar. 17, 2010).

55. Take Care Clinic at Select Walgreens, About Us: Our Commitment, <http://www.takecarehealth.com/about/our-commitment.aspx> (last visited Mar. 17, 2010).

56. Take Care Clinic at Select Walgreens, About Us: Our Care Providers, <http://www.takecarehealth.com/about/our-care-providers.aspx> (last visited Mar. 17, 2010);

Take Care Clinics accept most forms of insurance, including Medicare and Medicaid.⁵⁷ Insured patients can pay their regular co-pay, while prices for the uninsured or with insurance that does not cover retail clinic visits start at \$65 for common illnesses.⁵⁸ If a patient doesn't have a primary care physician, the RMC can help the patient find one.⁵⁹ If the patient's condition falls outside the scope of practice at the RMC, the patient is referred back to his or her primary care physician for follow-up care.⁶⁰ Take Care is a model retail medical clinic system that embraces patient-centered, quality, and technologically adept medical care, while at the same time accepting its limited place in the health care delivery system.

A. *History of Retail Medical Clinics*

The first retail medical clinic was established in St. Paul, Minnesota in 2000 after founder Rick Krieger waited over two hours in an urgent care center for his son to get a strep throat test.⁶¹ According to Krieger,

We started talking about why there was not a way to just get a simple question answered or a simple test, like strep throat, done. Why was there not some way to just slip in and be seen quickly? Wasn't there some way to get care in a timely manner for a relatively simple illness? A quick convenient way to diagnose without waiting in the ER or clinic for two hours? We are not talking about diabetes, cancer, or heart disease! We are talking about colds and throat and ear infections.⁶²

Krieger soon created QuickMedx and partnered with Cub Foods to offer medical services in a retail setting.⁶³ QuickMedx was re-named MinuteClinic in 2002.⁶⁴ In 2006, CVS purchased MinuteClinic for an

Take Care Clinic at Select Walgreens, Walgreen Co. to Acquire Convenient Care Clinic Operator Take Care Health Systems, http://www.takecarehealth.com/about/press-releases/press_051607_01.aspx (last visited Mar. 17, 2010).

57. Take Care Clinic at Select Walgreens, Insurance Partners, <http://www.takecarehealth.com/insurance-providers.aspx> (last visited Mar. 17, 2010) (most regions accept Medicare and/or Medicaid).

58. Take Care Clinic at Select Walgreens, About Your Visit: Paying for Your Visit, <http://www.takecarehealth.com/about-your-visit/paying-for-your-visit.aspx> (last visited Mar. 17, 2010).

59. Take Care Clinic at Select Walgreens, About Your Visit: Working with Your PCP, <http://www.takecarehealth.com/about-your-visit/working-with-your-pcp.aspx> (last visited Mar. 17, 2010).

60. *Id.*

61. MinuteClinic, Our History, <http://www.minuteclinic.com/en/USA/About/History.aspx> (last visited Mar. 17, 2010).

62. CHCF 2006, *supra* note 2, at 8, (citing Richard M.J. Bohmer & Jonathan P Groberg, *QuickMedx Inc.*, HARV. BUS. SCH. CASES, 1-30 (2002)).

63. CHCF 2006, *supra* note 2, at 8.

64. CVS Caremark, History, <http://www.info.cvscaremark.com/our-company/history> (last visited Mar. 17, 2010).

estimated \$170 million.⁶⁵ As of June 2008, MinuteClinic had approximately 520 clinics, and the company's long-term forecast calls for 2,500.⁶⁶

The first retail medical clinics charged a \$35 flat fee for rapid testing, diagnosis, and prescriptions for eleven common medical conditions, including strep throat, influenza, ear infection, pink eye, and seasonal allergies.⁶⁷ They did not accept insurance, which Krieger explains was a strategic choice "to compete on a purely retail level and be able to profit on a copayment-type basis."⁶⁸ While early RMC models focused on diagnostic "get well" care, newer models are placing greater emphasis on "stay well" care.⁶⁹

In 2006, the phenomenon of retail medical clinics took off. There were 220 new clinics opened, and 130 more opened before April 2007.⁷⁰ Also in 2006 RMCs created their own trade organization, the Convenient Care Association (CCA).⁷¹ The CCA enables RMCs to share best practices, establish national standards of operation, and develop professional relationships with the medical community and health care providers.⁷²

In contrast to the rapid growth of 2006, the trend seen in 2008 was one of consolidation and closing. Nearly 150 RMCs closed in 2008, largely a result of privately backed operators going out of business.⁷³ Meanwhile, major players such as Walgreens and CVS have continued to dominate the market. CVS' MinuteClinic (550 clinics) and Walgreens' Take Care Clinic (318 clinics) currently account for nearly seventy-five percent of the clinics open in the United States.⁷⁴ However, even these large retailers are adapting to the current economic climate. CVS closed one hundred MinuteClinic locations during spring 2009, not to open until the fall 2009 flu season or

65. Rick Stouffer, *One-Stop Clinics Gain in Popularity*, PITT. TRIB. REV., Feb. 25, 2007, at A1; WILLIAM A. DOLAN, COUNCIL ON MED. SERV. REPORT 5 (A-07), UPDATE ON STORE-BASED HEALTH CLINICS 1 (2007), <http://www.ama-assn.org/ama1/pub/upload/mm/372/a07cms5.pdf> [hereinafter CMS Report 5-A-07].

66. Deloitte, *supra* note 31 at 3.

67. CHCF 2006, *supra* note 2, at 8.

68. *Id.*

69. *Id.* at 11.

70. CHCF 2007, *supra* note 9, at 6.

71. CMS Report 5-A-07, *supra* note 65, at 2.

72. *Id.*

73. HSA UPDATE (Am. Bankers Ass'n, Washington, DC), Mar. 31, 2009, <http://www.aba.com/ABA/hsacouncil.htm> (follow "Newsletter" hyperlink; then follow "2009 Editions" hyperlink; then follow "March 31, 2009" hyperlink).

74. Take Care Clinic at Select Walgreens, About Us, <http://www.takecarehealth.com/about/> (last visited Mar. 18, 2010); CVS Caremark, Our Businesses, MinuteClinic, <http://www.info.cvscaremark.com/our-company/our-businesses/minuteclinic> (last visited Mar. 18, 2010); BUREAU OF NAT'L AFFAIRS, HEALTHCARE POLICY REPORT 4 (2009), http://www.healthlawg.typepad.com/files/BNA_Health_Care_Policy_Report_-_Retail_Health_Clinics_042009.pdf.

when other seasonal demands necessitate their services.⁷⁵ Walgreens chose not to temporarily shutter its clinics, but rather to focus on year-round services such as vaccinations, blood-pressure tests, and wound care and to get customers into the habit of using retail medical clinics, no matter the cost.⁷⁶ The chain announced that it would offer free care until the end of 2009 to people who are unemployed and uninsured.⁷⁷

Analysis says that the current drop in retail medical clinic behavior does not mean that RMCs are a failing business model.⁷⁸ Rather, the trend indicates that it is time to change strategy.⁷⁹ Key to sustainability may be RMCs ability to partner with hospitals that can better shoulder losses and utilize hospital name recognition and existing hospital staff.⁸⁰ According to Bruce Shepard, Director of Health Business Relationship Development for Wal-Mart, the company decided that hospital partnerships would lead to a more sustainable business model.⁸¹ This would be the result of hospitals that are “willing to take on the initial financial loss as part of an overall marketing strategy focused on access to care” and enhanced points of entry for patients in need of a primary care physician.⁸² However, building relationships with hospitals has proven to be a slow and deliberative process, as both parties determine the most effective business strategy and how best to coordinate delivery of care between hospital and clinic operators.⁸³

Retail medical clinics have been labeled a “disruptive innovation,” a pattern of business innovation defined as a product (or service) that enters a market as a simpler, lower cost alternative to an existing product that is overbuilt for the needs of the market.⁸⁴ RMCs are a disruptive innovation in healthcare delivery because they provide simple, low cost services outside the traditional setting of a medical practice and employ a sustainable value proposition (price, quality, service).⁸⁵ According to the CCA, RMCs have

75. Sarah Rubenstein, *CVS Shuttters 90 Retail Clinics for the Season*, WALL ST. J., Mar. 10, 2009, <http://www.blogs.wsj.com/health/2009/03/10/cvs-shuttters-90-retail-clinics-for-the-season>.

76. *Id.*

77. Parija B. Kavilanz, *Wal-Mart Wants Your Rash & Strep Throat*, CNNMONEY.COM, Apr. 14, 2009, http://www.money.cnn.com/2009/04/13/news/economy/healthcare_retail_clinics/index.htm.

78. Pamela Lewis Dolan, *Number of Retail Clinics Shrinking*, AM. MED. NEWS, July 27, 2009, <http://www.ama-assn.org/amednews/2009/07/27/bil20727.htm>.

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. Thygeson, *supra* note 8, at 1291.

85. Deloitte, *supra* note 31, at 4-5, 7.

been labeled a disruptive innovation because they are a consumer-driven response to those individuals who are frustrated with today's conventional health care delivery system that provides little access to basic health care services.⁸⁶ Regardless of market trends, it is clear that retail medical clinics are not a fad.

B. Health Information Technology

Retail medical clinics rely on sophisticated health information technology (HIT) systems to ensure consistent decision-making protocols, quality, and limited scope of care at the clinics. Since commercially available electronic record systems are often too broad to meet the needs of retail clinics, many clinics have created their own software that mimics physician decision-making by leading the clinic's providers through evidence-based treatment protocols.⁸⁷ All data is entered into the patient's electronic medical record (EMR), where it is matched to a knowledge base.⁸⁸ The software then calculates care algorithms to direct the practitioner in providing care.⁸⁹

The software used by retail medical clinics helps to restrict the range of medical conditions that can be treated at the clinic by ensuring that any conditions outside of a narrow scope of treatment or potentially emergent or unusual conditions are referred elsewhere.⁹⁰ In addition, after a certain number of visits, the software alerts the healthcare practitioner to advise the patient to visit a physician.⁹¹

Retail clinics are also using HIT to enhance customer service. Examples of customer service innovations used by clinics include "online check-in; online search for locations with the shortest wait time; in-store touch screen kiosks for registration; and a magnetic card system to streamline check-in, access to personal health records, and payment."⁹² Many of the EMR systems, while not interoperable, can be accessed at any clinic site across the country through the host store's data network.⁹³

Innovations in HIT will certainly enhance the future capabilities of retail medical clinics. For instance, while RMCs are not currently structured to manage chronic conditions, many have the foundations of the technology infrastructure needed to support the delivery of disease management

86. Hansen-Turton, *supra* note 15, at 62.

87. CMS Report 7-A-06, *supra* note 4, at 2; CHCF 2006, *supra* note 2, at 24.

88. See CHCF 2006, *supra* note 2, at 17, 24.

89. Deloitte, *supra* note 31, at 5.

90. CHCF 2006, *supra* note 2, at 9.

91. CMS Report 7-A-06, *supra* note 4, at 2.

92. CHCF 2007, *supra* note 9, at 11.

93. Anderson, *supra* note 29.

programs.⁹⁴ Consider that effective chronic disease management depends on frequent patient visits.⁹⁵ RMCs are best positioned to facilitate easy and convenient access to disease management services during patients' frequent visits to grocery stores, pharmacies, and discount stores.⁹⁶ More than ninety million Americans live with one or more chronic diseases, such as diabetes or cardiovascular disease.⁹⁷ Moreover, the number of children with chronic illness is rising rapidly.⁹⁸

The prospect of enhancing the ability of this vast number of patients to conveniently manage their disease or that of their children with each trip to the grocery store is an appealing prospect for retail medical clinics. Indeed, eighty-eight percent of consumers say they would be interested in using a self-monitoring device at home if they were to develop a health condition that required regular monitoring because of elimination of the need for trips to the doctor's office (75%) and the convenience of reporting results to the doctor electronically (69%).⁹⁹ Consumers clearly want greater convenience and freedom in the management of their chronic illness.

Innovations in HIT will also enable retail medical clinics to perform more sophisticated procedures. For example, new devices have the potential to deliver faster, less invasive blood pressure and glucose testing with data feeds directly to EMRs.¹⁰⁰ Other testing devices that capture and transmit electronic data have similar potential.¹⁰¹ Imaging devices may one day be small, quick, cost effective and simple enough for use in RMCs.¹⁰² Finally, the nationwide network of technologically integrated retail clinics may serve as a data repository for epidemiological surveillance.¹⁰³ MinuteClinic has approached the Center for Disease Control (CDC) to determine how they can best utilize the data.¹⁰⁴ As health information technology advances, so too will the capabilities of retail clinics and their role in the healthcare delivery system.

94. Deloitte, *supra* note 31, at 9.

95. *Id.*

96. *Id.*

97. Weinberg, et al., *Tracking the Care of Patients with Severe Chronic Illness*, DARTMOUTH ATLAS HEALTH CARE, 1 (2008), http://www.dartmouthatlas.org/atlas/2008_Chronic_Care_Atlas.pdf.

98. James M. Perrin et al., *The Increase of Childhood Chronic Conditions in the United States*, 297 J. AM. MED. ASS'N 2755, 2755 (2007).

99. DELOITTE CTR. FOR HEALTH SOLUTIONS, DELOITTE LLP, 2008 SURVEY OF HEALTH CARE CONSUMERS 14 (2008), http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_ConsumerSurveyExecutiveSummary_200208.pdf.

100. CHCF 2007, *supra* note 9, at 29.

101. *Id.*

102. *Id.*

103. Deloitte, *supra* note 31, at 10.

104. *Id.*

C. Economics

The cost of opening and operating a retail medical clinic includes the cost of design and construction of clinic space, including meeting building code requirements, infrastructure for electronic medical records systems, technology for practitioners to provide evidence-based care, marketing for the brand, and the cost of recruiting and training personnel.¹⁰⁵ Human resources, lease payments, and corporate overhead are responsible for over eighty-five percent of expenses generated.¹⁰⁶ RMC operators often pay for physical retrofitting of the clinic space, which ranges from \$25,000 for a basic clinic with one basic room to \$145,000 for a multi-room clinic offering broader services.¹⁰⁷ The average cost is between \$50,000 and \$75,000.¹⁰⁸ The clinic space is allocated to extract the most profit possible per square foot.¹⁰⁹ Once established, an average clinic has fixed annual costs of approximately \$600,000.¹¹⁰ Since each clinic generates an average of \$52 per visit, a clinic needs to see about 11,500 patients a year—220 a week or more than 30 per day—to break even.¹¹¹ It typically takes between 18 and 24 months for clinics to reach the break-even point.¹¹²

D. Acceptance of Retail Clinics

Many players within the United States healthcare system have a vested interest in retail medical clinics. While most groups have been welcoming to retail medical clinics, some groups—namely physicians—have been slower in their welcome of these clinics. However, consumers are quickly accepting RMCs as providers of basic health care services.

1. Patients/Consumers: A desire for consumer-driven health care

An interesting thing happens when discussing retail medical clinics: individuals cease to be referred to as “patients,” and begin to be referred to as “consumers.” Retail clinics have placed patients in a role of medical consumer within the era of consumer-driven health care. Indeed, a study by Deloitte Center for Health Solutions commented that while health care providers might be inclined to think of individuals as “patients”—passive, inactive, and dependent on doctors to make decisions for them—this

105. CHCF 2007, *supra* note 9, at 11.

106. *Id.*

107. CHCF 2006, *supra* note 2, at 9; CHCF 2007, *supra* note 9, at 4.

108. CHCF 2007, *supra* note 9, at 4.

109. Deloitte, *supra* note 31, at 12.

110. *Id.*

111. CHCF 2006, *supra* note 2, at 21; Deloitte, *supra* note 31, at 12.

112. CHCF 2007, *supra* note 9, at 11.

perspective is shortsighted.¹¹³ Health care is a consumer market. Many patients are already active consumers in decisions about their healthcare (e.g. use substitutes for traditional health services, search for price and quality comparisons), and many more are eager to become active.¹¹⁴ Patients are seeking alternatives out of sheer frustration with the current health care delivery system.¹¹⁵ RMC operators seize upon this frustration by continually probing what patients want and evaluating whether the clinic's marketing approach works – an approach not utilized or even considered by most health care providers.¹¹⁶

The business community has recognized the RMC's innovative strategy. *Forbes Magazine* featured MinuteClinic in the list of top ten innovators of the past decade, along with Google, Blackberry, Netflix, iPod, and Nintendo's Wii.¹¹⁷

Retail medical clinics have come on the scene during an era of consumer-centric healthcare. Consumers are paying more of their own health care costs in the form of higher premiums and deductibles, and are increasingly making decisions about how, when and where they receive medical services.¹¹⁸ Copayments are expected to rise for all insurance plans.¹¹⁹ The purchase of health insurance that requires subscribers to pay for much or most out-of-pocket medical costs has been prompted by a new tax shelter for Health Savings Accounts (HSA).¹²⁰ These HSAs are designed to induce patients to shop like consumers for quality medical care at a low cost.¹²¹

As a result, patients, rather than physicians, insurers or the government, are often in the driver's seat for medical spending decisions.¹²² Physician-informed or based on their own research, and driven by their own financial interest, insured patients are increasingly expected to decide which health care services and goods are worth the cost at each point of purchase in the

113. DELOITTE CTR. FOR HEALTH SOLUTIONS, *supra* note 99, at 20.

114. *Id.*

115. CHCF 2007, *supra* note 9, at 10.

116. CHCF 2006, *supra* note 2, at 22.

117. Sarah Ratner, Senior Legal Counsel, MinuteClinic, Address at an FTC One-Day Public Workshop Innovations in Health Care Delivery: Delivering Greater Access to Affordable Healthcare 5 (Apr. 24, 2008), available at <http://www.ftc.gov/bc/healthcare/hcd/docs/Ratner.pdf>.

118. CHCF 2007, *supra* note 9, at 19-20.

119. *Id.*

120. Mark A. Hall, *The Legal and Historical Foundations of Patients as Medical Consumers*, 96 GEO L.J. 583, 587 (2008).

121. Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 645 (2008).

122. Hall, *supra* note 120, at 587.

health care system.¹²³ However, few can negotiate the healthcare market wisely, and missteps can destroy patients economically.¹²⁴ Doctors or contracts rarely specify upfront fees for services provided. Though this is understandable—physicians deal with a number of insurers, each with fees negotiated in a market that regards prices as trade secrets—patients are left not knowing and unable to discover upfront what such things will cost.¹²⁵ It is even harder to anticipate hospital charges.¹²⁶

This consumer-driven model of health care may have its drawbacks. The model calls for a fundamental reordering of the patient-physician relationship wherein the physician is no longer the ultimate decision-maker. Increased reliance is placed on commercial ethics, and professional ethics is diminished as the guiding force for patient-physician interactions.¹²⁷ As Berenson noted in the *Journal of the American Medical Association*, medical “[p]rofessionalism has economic and social value as a mediating force in the health care system—and the move to a more market-oriented, consumer-directed model threatens to erode this important influence.”¹²⁸ As patients continue to take medical decision-making into their own hands, the market must adapt to offer consumer protection and guidance for these important decisions.

Retail medical clinics are appealing to patients because they offer health care that is quick, convenient and affordable. Seventy-eight percent of consumers who were aware of RMCs agreed that such clinics provide busy people with a fast and easy way to get basic medical services.¹²⁹ In contrast to physician offices, RMCs are typically open seven days a week and require no appointment. Only 10.6% of the U.S. population (29.9 million persons) live within a five-minute driving distance from a retail medical clinic, and 28.7% (80.7 million persons) live within a 10-minute driving distance.¹³⁰ Visits take an average of fifteen minutes, waiting time is minimal, and patients often receive a pager so they can shop at the host store without risk of missing their appointment.¹³¹

123. *Id.*

124. Hall & Schneider, *supra* note 12121, at 645.

125. *Id.* at 657.

126. *See id.* at 657-58.

127. Robert A. Berenson & Christine K. Cassel, *Consumer-Driven Health Care May Not Be What Patients Need—Caveat Emptor*, 301 J. AM. MED. ASS’N. 321, 321 (2009).

128. *Id.*

129. Harris Interactive, *Many Agree on Potential Benefits of Onsite Clinics in Major Retail Stores that Can Provide Basic Medical Services, Yet Large Numbers Are Also Skeptical*, WALL ST. J. ONLINE, Oct. 26, 2005, at 1, available at http://www.harrisinteractive.com/news/newsletters/wshealthnews/wsjonline_hi_health-carepoll2005vol4_iss21.pdf.

130. Rudavsky, *supra* note 23, at 317.

131. CMS Report 7-A-06, *supra* note 4, at 2.

Further, the cost of services provided at RMCs is often less than the cost of services provided at physician offices or emergency rooms, particularly for those individuals who lack health insurance.¹³² For simple diagnoses such as strep throat, for example, a visit to a retail clinic offers a savings of \$240 or more over an emergency room visit.¹³³ A study published in the *Annals of Internal Medicine* found that the overall costs of care for episodes initiated at retail medical clinics were significantly lower than the equivalent episodes at physician offices, urgent care centers, and emergency departments (\$110 vs. \$166, \$156, and \$570, respectively).¹³⁴

The majority of population has become aware of the existence of retail medical clinics only recently. Consumer awareness of RMCs has jumped to fifty-six percent, up from thirty-eight percent in 2007.¹³⁵ A 2007 survey indicated that only three percent of respondents had used a retail clinic.¹³⁶ While RMCs are most popular among young, lower-income individuals, Medicare enrollees are also receptive to the clinics. Thirty-six percent of Medicare patients have indicated that they are open to using a retail medical clinic, and eleven percent have done so already.¹³⁷

Those who have used such clinics are satisfied with the care provided. Fifty-five percent of those who had visited a RMC reported that they were very likely to use a clinic again in the future.¹³⁸ Of the five percent of respondents to a Harris poll survey who visited a RMC, the vast majority were very or somewhat satisfied with the quality of care they received (90%), with having qualified staff to provide care (85%), and with the convenience that the RMC offered (83%).¹³⁹ Indeed, a recent study that compared the care received at Minnesota RMCs for three acute conditions (otitis media, pharyngitis, and urinary tract infection) with that received at other care settings found no adverse effect on quality of care.¹⁴⁰ Rather, for most measures, quality scores for RMCs “were equal to or higher than those of other care settings.”¹⁴¹ Satisfaction with the care offered by retail medical clinics is growing as mid-level providers become more mainstream. In comparison to the 2005 Harris survey, a 2007 companion survey found fewer respondents reporting concern about the qualifications

132. *Id.*

133. CHCF 2007, *supra* note 9, at 20.

134. 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, 324 (2009) [hereinafter Mehrotra 2009].

135. Kavalanz, *supra* note 777.

136. CMS Report 5-A-07, *supra* note 655, at 2.

137. Deloitte, *supra* note 31, at 4.

138. CMS Report 5-A-07, *supra* note 655, at 2.

139. CHCF 2007, *supra* note 9, at 19.

140. Mehrotra 2009, *supra* note 1344, at 325.

141. *Id.*

of retail medical clinic staff (71% in 2005 vs. 64% in 2007) or their ability to accurately diagnose medical problems (75% in 2005 vs. 68% in 2007).¹⁴² Forty-four percent of consumers said they were comfortable with the safety, accuracy and quality of care offered in a RMC staffed by a NP, and only slightly more respondents said they would be comfortable if the NP was affiliated with a local doctor's office.¹⁴³ Though consumers are quickly warming to the idea of retail medical clinics, the physician community is much more slowly accepting the clinics as an acceptable model for health care delivery.

2. Physicians and Organized Medical Groups:

Concern for quality, continuity and the physician-patient relationship

Physicians, a group likely to experience the most significant disruption from the emergence of retail clinics, have expressed concern with the quality of care provided by retail clinics, the potential lack of continuity of care resulting from fragmentation of care, and the potential for these clinics to disrupt existing patient-physician relationships. When care is fragmented, physicians argue, trends suggestive of serious underlying conditions may be missed.¹⁴⁴ Even visits for such minor ailments as the common cold provide a physician an opportunity to evaluate a patient's overall health and wellness and to take advantage of the "patient encounter with recommendations for preventive care and health improvement."¹⁴⁵

Some medical practices have used the retail medical clinic trend to evaluate their own practices and better serve their patients' preferences for convenience and accessibility by adding same-day scheduling, extended hours, electronic prescribing and other features common to RMCs.¹⁴⁶ Though many physician groups have voiced the concerns discussed in the paragraph above, and while "in an ideal world all patients would go to their personal physician regularly and for every health issue," most physician groups have recognized the staying power of RMCs.¹⁴⁷ With an eye toward damage control, physician groups have enacted guidelines on how best to

142. Harris Interactive, *Most Adults Satisfied with Care at Retail-Based Clinics*, WALL ST. J. ONLINE, Apr. 11, 2007, at 2, available at http://www.harrisi.org/news/newsletters/wsjhealthnews/HI_WSJ_HealthCarePoll_2007_v06_i06.pdf.

143. DELOITTE CTR. FOR HEALTH SOLUTIONS, *supra* note 99, at 12; Deloitte, *supra* note 31, at 5.

144. Bohmer, *supra* note 11, at 767.

145. See Thygeson, et al., *supra* note 8, at 1283-84.

146. William M. Sage, *The Wal-Martization of Health Care*, 28 J. LEGAL MED. 503, 512-13 (2007) [hereinafter Sage 2007].

147. American Osteopathic Association, *Retail Clinics Are Here – Are You Ready?*, http://www.osteopathic.org/index.cfm?PageID=aoa_nwsretailclinics (last visited Feb. 15, 2010).

work with and enhance the care provided by RMCs. The American Osteopathic Association, for example, encourages its members to get on a clinic referral list or become a clinic supervisor and to evaluate and adjust their own practices, such as by offering the patient-friendly options described above.¹⁴⁸

The American Medical Association (AMA), while concerned with the operation of such clinics in relation to patient awareness, physician oversight, and continuity of care, has shifted its position on retail medical clinics as the clinics have expanded. At the 2006 Annual Meeting of the AMA House of Delegates, AMA members testified that RMCs should not be a substitute for the traditional physician-patient relationship.¹⁴⁹ AMA members also expressed concern about the standards of care, safety and hygiene of retail clinics, and expressed support for rigorous federal and state regulation of these clinics.¹⁵⁰ Some members called for the AMA to support an outright ban on RMCs.¹⁵¹

However, the AMA has recognized that the “concept of retail clinics appears to be consistent with market-based, pluralistic health care delivery systems supported by long-standing AMA policy.”¹⁵² The AMA has noted that some physicians have begun to compete with RMCs by owning and operating them, and in some cases, staffing the clinics with physicians.¹⁵³ For example, Solantic, a Florida-based RMC, is staffed and owned by physicians, who are on-site at the clinic at all times.¹⁵⁴ Perhaps with the intent of supporting those physicians who have invested in retail medical clinics, the AMA adopted guidelines for those who own and operate retail medical clinics.¹⁵⁵

Figure 1. AMA Policy H-160.921, *Store-Based Health Clinics*

It is AMA policy that any individual, company, or other entity that establishes and/or operates store-based health clinics should adhere to the following principles:

- Store-based health clinics must have a well-defined and limited scope of clinical services, consistent with state scope of practice laws;
- Store-based health clinics must use standardized medical protocols derived

148. *Id.*

149. Kaiser Family Foundation, *AMA Examines Retail Health Clinics, Other Issues at Annual Meeting*, KAISER DAILY HEALTH POL’Y REP., June 12, 2006, http://www.kaiser-network.org/daily_reports/rep_index.cfm?DR_ID=37849.

150. Hsu, *supra* note 7, at 16.

151. *Id.* at 17.

152. CMS Report 7-A-06, *supra* note 4, at 5.

153. CMS Report 5-A-07, *supra* note 65, at 3.

154. *Id.*

155. AM. MED. ASS’N, POLICY H-160.921 STORE-BASED HEALTH CLINICS (2006).

from evidence-based practice guidelines to insure patient safety and quality of care;

- Store-based health clinics must establish arrangements by which their health care practitioners have direct access to and supervision by MD/DOs, as consistent with state laws;
- Store-based health clinics must establish protocols for ensuring continuity of care with practicing physicians within the local community;
- Store-based health clinics must establish a referral system with physician practices or other facilities for appropriate treatment if the patient's conditions or symptoms are beyond the scope of services provided by the clinic;
- Store-based health clinics must clearly inform patients in advance of the qualifications of the health care practitioners who are providing care, as well as the limitation in the types of illnesses that can be diagnosed and treated;
- Store-based health clinics must establish appropriate sanitation and hygienic guidelines and facilities to insure the safety of patients;
- Store-based health clinics should be encouraged to use electronic health records as a means of communicating patient information and facilitating continuity of care;
- Store-based health clinics should encourage patients to establish care with a primary care physician to ensure quality of care[. . .]

AMA policy also forbids retail medical clinics from waiving insurance co-pays.¹⁵⁶

The American Academy of Family Physicians (AAFP), which opposes RMCs because it believes that such health care delivery could interfere with the medical home model, enacted guidelines that recognize certain “desired attributes” of retail clinics.¹⁵⁷ These guidelines recognize that RMCs must have a well-defined and limited scope of medical services, and that clinical services and treatment must be evidence-based and oriented toward quality improvement.¹⁵⁸ The AAFP supports a team-based approach in which RMCs have formal connections and a referral system with physician practices in the local community (preferably with family physicians) to provide continuity of care.¹⁵⁹

Interestingly, though initially a signatory, Walgreens' Take Care Clinic

156. *Id.*

157. American Academy of Family Physicians, *Desired Attributes of Retail Health Clinics*, <http://www.aafp.org/online/en/home/policy/policies/r/retailhealthclinics.html> (last visited Feb. 15, 2010) [hereinafter AAFP]; *see also* American College of Emergency Physicians, *Retail Based Clinics*, <http://www.acep.org/practres.aspx?id=32334> (last visited Feb. 15, 2010).

158. AAFP, *supra* note 1577.

159. *Id.*

informed AAFP in 2008 that it would not renew its commitment to AAFP's "desired attributes," which limited the scope of services provided.¹⁶⁰ According to a Take Care Health Systems spokesperson, "after treating over 1 million patients, Take Care determined that there's a real demand for extended services," and intends to meet the demand. Refusing to renew its commitment to the "desired attributes" indicates Walgreens and Take Care's intent to expand the range of services offered by its clinics and further integrate itself into the health care market, even if it means going against organized medicine.

The American Academy of Pediatrics (AAP), a physician group with a unique perspective on retail clinics, opposes retail medical clinics as a source of medical care for infants, children and adolescents.¹⁶¹ The AAP recognizes that what is happening in the world of pediatric practice is disconnected from the world the AAP would like it to be.¹⁶² As such, the AAP believes that the emergence and expansion of RMCs requires a reappraisal of how pediatricians practice and how public health programs and private health plans pay for medical services.¹⁶³ The AAP has challenged pediatricians to clearly demonstrate to the public the value of quality and continuity of care in comparison to the care offered by RMCs.¹⁶⁴

Thus far, physicians' concerns have been largely theoretical. Retail medical clinics have worked to maintain good relationships with physicians, use software that searches for patterns of repeat presentations, and rely on strict evidence-based protocols to ensure quality of care.¹⁶⁵ Given the strong influence and lobbying power that physicians and physician groups wield, however, it would be wise for RMC operators to maintain a friendly working relationship with physicians to avoid or minimize risk of further physician pushback against retail medical clinics in the future.

3. Insurers: Embracing another way to cut health care costs

Initially, insurance providers were not part of the retail medical clinic

160. Sheri Porter, *Expect Retail Health Clinics to Expand Scope of Practice, Q&A with Health Care Consultant, Researcher Mary Kate Scott*, AAFP NEWS NOW, July 12, 2008, at 1, available at <http://www.aafp.org/online/en/home/publications/news/news-now/professional-issues/20080723retail-q-a.html>.

161. Stephen Berman, *Continuity, the Medical Home, and Retail-Based Clinics*, 120 PEDIATRICS 1123, 1124 (2007), available at <http://pediatrics.aappublications.org/cgi/content/full/120/5/1123>.

162. *Id.*

163. *Id.*

164. *Id.*

165. Bohmer, *supra* note 11, at 767.

equation, since the first RMCs asked consumers to pay for the full cost of their visits.¹⁶⁶ This soon changed. Insurers quickly became attracted to the RMC model, though nervous such clinics may act as a means for additional, rather than substitute, health care encounters.¹⁶⁷ Usage patterns indicated, however, that RMCs did not increase overall demand for medical services.¹⁶⁸ RMC operators report a strong relationship with most payors, including relatively prompt payments and limited claims denial.¹⁶⁹

Today, all major national private insurers, many smaller regional insurance companies, and Medicare and Medicaid provide coverage for visits to retail medical clinics.¹⁷⁰ According to a 2007 Harris Survey, insurance covered forty-two percent of all RMC visits, with co-payments ranging from \$15 to \$35.¹⁷¹ Some insurers have contracted with RMCs to reduce co-payments for patients who go to the clinics for selected primary care services.¹⁷² Other insurers have completely eliminated copayments for RMCs to encourage their insureds to use the clinics for lower-cost services and preventive care, a practice that the AMA opposes.¹⁷³ Since the average cost of a RMC visit is significantly less than a trip to a doctor's office, the insurance companies see copayment waiver as a matter of saving money for both consumers and insurers.¹⁷⁴

4. Hospitals & Health Systems:

An attempt to retain patients and patient dollars

Along with physicians, hospitals have recognized the emergence and importance of retail medical clinics. The Mayo Clinic, for instance, recently opened a RMC in Minnesota.¹⁷⁵ Through retail clinics, hospitals can provide a complete spectrum of options for their patients, retain these patients in their networks, and raise the visibility of their "brand" in the community.¹⁷⁶ Hospitals can also promote continuity of care through their affiliated RMCs, particularly when such clinics are connected to the

166. CHCF 2006, *supra* note 2, at 19; Mehrotra 2008, *supra* note 6, at 1272.

167. CHCF 2006, *supra* note 2, at 19-20.

168. *Id.* at 19.

169. CHCF 2007, *supra* note 9, at 17.

170. *Id.*

171. *Id.*

172. CMS Report 7-A-06, *supra* note 4, at 3.

173. AM. MED. ASS'N, *supra* note 155.

174. Hsu, *supra* note 7, at 14.

175. Chen May Yee, *Major Players Catch a Case of Quick-Clinic Fever - Medical Centers Once Scoffed at "Mall Medicine." but the Trend Has Cut into Business, And Now even the Mayo Clinic Is Getting in the Game*, STAR TRIB., Nov. 13, 2007, at A1.

176. CHCF 2007, *supra* note 9, at 12.

hospital's EMR system.¹⁷⁷ RMCs can also divert non-emergent cases from overcrowded emergency room or primary care waiting rooms without diverting the income from such bread-and-butter cases.¹⁷⁸ What is more, hospital-affiliated retail clinics can tap into their vast pool of resources to run clinics with their own healthcare professionals and administrative staff.¹⁷⁹ RMC operators report that, while their physicians were not in support of the clinics before they opened, once the clinics were open, physicians started to view them as a worthwhile addition to the hospital's care network.¹⁸⁰

5. Retailers: Seeking a greater stake in the health care market

Retail medical clinics pose an obvious incentive for retailers. Through RMCs, retailers can assert their position in the health and wellness market, which some predict will reach one trillion dollars in size in a few years.¹⁸¹ RMCs can attract new customers and increase foot traffic.¹⁸² A retailer's pharmacy, prescription, and over-the-counter medication business can also be strengthened by RMCs.¹⁸³ Approximately ninety-five percent of RMC visitors receiving a prescription at retail clinics have their prescription filled at the same store.¹⁸⁴ Seventy percent of retail medical clinic patients become new pharmacy customers.¹⁸⁵

Retail medical clinics also drive sales elsewhere in the store. Host stores hope that customers will shop while waiting to be seen at the clinic, thus, filling their shopping carts with prescriptions, over-the-counter medication, or non-health related products.¹⁸⁶ Target, for example, recently found that ninety percent of RMC customers came into the store for medical care, not necessarily to shop, but ended up buying something anyway.¹⁸⁷ Similarly, CVS found that eighty percent of MinuteClinic customers purchase general merchandise at their store during their visits.¹⁸⁸

177. *Id.*

178. Mary Kate Scott, *Retail Clinics – Friend or Foe of the Hospital? Part 1: The Opportunity for Hospitals to Win with a Retail Clinic Model*, HEALTH LEADERS MEDIA, Jan. 4, 2008, <http://www.healthleadersmedia.com/content/LED-203107/Retail-ClinicsFriend-or-Foe-of-the-Hospital-Part-I-The-opportunity-for-hospitals-to-win-with-a-retail-clinic-model.html>.

179. CHCF 2007, *supra* note 9, at 12.

180. *Id.*

181. Hsu, *supra* note 7, at 16; *see* CHCF 2007, *supra* note 9, at 15.

182. CHCF 2007, *supra* note 9, at 15.

183. *Id.*

184. CMS Report 7-A-06, *supra* note 4, at 3; CHCF 2006, *supra* note 2, at 19.

185. CHCF 2006, *supra* note 2, at 19.

186. *Id.*

187. *Id.*

188. *Id.*

Despite their growing presence, however, retail medical clinics are in only one to three percent of retailer's stores.¹⁸⁹ In operating RMCs, retailers risk fallout from failure to achieve expected results and to keep up with the rapid turnaround, constant reinvention, and intense competition of the retail industry.¹⁹⁰ In addition, RMCs have come under intense pressure from regulators and state legislators as the clinics have gained acceptance in the healthcare community.

LAW

Retail medical clinics invite a host of legal issues. Since RMCs are medical facilities, they are subject to state licensing laws, as well as to state and federal fraud and abuse. Both RMCs and the health care professionals they employ are subject to state licensing, certification, and scope of practice laws. Because retail medical clinics are housed in host stores, the corporate practice of medicine is implicated. Importantly, serious concerns have been raised about the potential anti-competitive nature of these clinics and their host stores. While most states do not currently have legislation specific to RMCs, some states are testing the waters with licensing restrictions and other legislation. One thing is certain: many legal questions relating to RMCs remain unanswered. As the clinics continue to develop, so too will the laws that guide them.

A. *State Legislative Activities*

Through licensing activities and medical practice acts, state legislatures act to support the public health and safety and ensure that basic structural requirements are in place in order for health care facilities to provide safe, quality care.¹⁹¹ State requirements for retail medical clinics and physician involvement with such clinics vary from state to state and are constantly changing, depending on the state's licensure requirements and other issues pertaining to specific clinic operations. Various regulators set licensing requirements, scope of practice restrictions, and degree of mid-level practitioner autonomy.¹⁹² In many states, RMCs are licensed as physician practices and are regulated by the state's medical board.¹⁹³

While only Massachusetts enacted legislation specific to retail medical clinics, Illinois and Oklahoma had several failed attempts to pass similar legislation. Many state policy makers are waiting until market forces

189. CHCF 2007, *supra* note 9, at 14.

190. CHCF 2006, *supra* note 2, at 10.

191. Paul Welk, *The Corporate Practice of Medicine Doctrine as a Tool for Regulating Physician-Owned Physical Therapy Services*, 23 J.L. & COM. 231, 236 (2004).

192. Hsu, *supra* note 7, at 18-19.

193. CHCF 2006, *supra* note 2, at 12.

“decide” whether RMCs have sufficient staying power to warrant similar legislation.¹⁹⁴ Until then, states have utilized their present regulatory roles to indirectly regulate clinics, such as through laws that effectively force host stores to choose between RMCs and the sale of alcohol or tobacco. States can also regulate the buildings that house RMCs or the people who work in the buildings.¹⁹⁵ Through these various forms of legislation, states have attempted to control and define retail medical clinics.

1. States with proposed or enacted legislation
specific to retail medical clinics

Each state has different requirements for credentialing and licensing of healthcare facilities, as well as physician and mid-level practitioner oversight. Three states—Massachusetts, Illinois, and Oklahoma—attempted to pass legislation specific to retail medical clinics, with only the former state being successful. With the support of Governor Schwarzenegger, California legislators attempted to work around strict corporate practice of medicine and nurse practitioner supervision laws to allow greater access to RMCs. Rather than draft new legislation, New Jersey state regulators have been allowed to organize RMCs under a “captive physician” model currently regulated under New Jersey state law. Texas has utilized an approach to RMCs similar to California, through which restrictions on supervision of midlevel practitioners are loosened with the hope that more RMCs will be established in the state. Florida enjoys strict control over RMC licensing through recent laws regulating a broader category of health care clinics. New Hampshire is just beginning to study RMCs through the establishment of a commission on the subject. Proposed or actual requirements for retail medical clinics vary considerably and are evolving as states begin to examine retail medical clinics’ place within their state health care system.

a. *Massachusetts:*

A separate licensure category for retail medical clinics

The Commonwealth of Massachusetts has successfully passed legislation specific to the establishment and operation of retail medical clinics in its state.¹⁹⁶ This legislation was the subject of fierce debate, which largely centered on the potential anticompetitive nature of the RMCs.

In 2006, when CVS’ Minute Clinic requested permission to open its

194. MARY TAKACH & KATHY WITGERT, NAT’L ACAD. FOR STATE HEALTH POL’Y, ANALYSIS OF STATE REGULATIONS AND POLICIES GOVERNING THE OPERATION AND LICENSURE OF RETAIL CLINICS 10 (2009).

195. *Id.*

196. 105 MASS. CODE REGS. 140.000 (2008).

retail medical clinics in Massachusetts, state lawmakers realized that existing clinic regulations did not fit within the RMC model.¹⁹⁷ For the state to issue a clinic license at that time, the state would have had to grant multiple waivers and would be unable to limit the scope of services offered once a license was granted.¹⁹⁸ Regulations were also needed to address issues regarding the physical space of RMCs and potential for fragmentation of care, as well as issues raised by the medical community.

To gain a perspective on the nature and concerns regarding retail medical clinics, the Massachusetts Department of Public Health (MDPH) held public hearings on what it labeled “limited service clinics.” During these hearings the MDPH heard testimony from the stakeholders including the Federal Trade Commission (FTC), Massachusetts Association of Family Physicians, and the Massachusetts Medical Society.¹⁹⁹ Areas of concern included corporate profits, fragmentation of care, tobacco sales, and the quality and safety issues that arise from allowing NPs to practice without supervision.²⁰⁰

Massachusetts ultimately passed legislation specific to retail medical clinics²⁰¹ and, as a result, in 2008 CVS’ Minute Clinic became the first RMC to open in Massachusetts. The approved regulations added to existing regulation on licensure of clinics conditions specific to RMCs. Notably, the law was the first in the country to address means by which to strengthen RMC’s cooperation with primary care.²⁰² The regulations also strengthened language on credentialing to ensure sufficient staffing in the clinics and stipulate things such as what age and medical conditions RMCs can treat, proper medical record keeping procedures, referral procedures, and treatment of repeat patients.²⁰³ The statute regulates the sale of tobacco products if the clinic is located in a retailer that sells such products, though it does not prohibit alcohol or tobacco sales outright.²⁰⁴

Figure 2. 105 Mass. Code Regs. 140.000(K)

RMCs must make referrals to primary care providers including physicians, nurse practitioners and community health centers

RMCs must maintain rosters of PCPs who are accepting new patients

197. *Id.* at 15.

198. *Id.*

199. *Id.*

200. *Id.*

201. 105 MASS. CODE REGS. 140.000.

202. TAKACH & WITGERT, *supra* note 1944, at 15.

203. NATIONAL CONFERENCE OF STATE LEGISLATORS, RETAIL HEALTH CLINICS: STATE LEGISLATION AND LAWS (2009), <http://www.ncsl.org/programs/health/RetailClinics.htm> [hereinafter “NCSL”].

204. *Id.*

RMCs must develop a process to identify and limit, if necessary, the number of repeat encounters with individual patients
RMCs must prominently post (a) a list of the services provided; (b) a statement that indicates that the patient should seek care from his primary care practitioner or emergency care provider for all other complaints or concerns; and (c) a statement that indicates that the patient may purchase prescription medication at any location.
With patient consent, RMCs will provide a copy of the visit encounter to the patient's primary care providers
If the RMC is located within a retail location that sells tobacco products, the clinic must post information regarding tobacco usage.
RMCs must provide a toll-free number that will enable the caller to speak w/a practitioner during off-hours
RMCs are not required to provide a reception area.
RMCs examination rooms must be at least 56 square feet.
Each RMC must provide hand sanitizer outside its examination rooms.

To address “safety net” concerns, Massachusetts’ Commissioner of Public Health encouraged community health centers to open RMCs, though none have done so due to Medicaid reimbursement issues.²⁰⁵ Massachusetts’ regulations represent the most comprehensive, tailored laws regarding retail clinics in the country. With this model legislation, many state legislators that have been waiting or have attempted to pass legislation specific to retail medical clinics are sure to follow suit with similar laws.

b. Illinois: Experiencing legal barriers to proposed legislation

The Illinois legislature has tried unsuccessfully several times to pass legislation specific to retail medical clinics. Illinois law currently classifies RMCs as physician offices, and, as a result, the clinics are not licensed or subject to oversight by the Illinois Department of Public Health (IDPH) and are not required to obtain certificate of need licensure.²⁰⁶ Illinois does have control over the licensure of NPs, however, and through this control the state indirectly regulates the scope of services offered by RMCs.²⁰⁷

In 2007, the Illinois General Assembly introduced the Retail Health Care Facility Permit Act (H.B. 1885).²⁰⁸ This proposed Act would have imposed on Illinois retail medical clinics a requirement to acquire a permit before such clinics could open. Backed by the Illinois State Medical Society (ISMS), the Act would set forth advertising and other requirements for

205. *Id.*

206. TAKACH & WITGERT, *supra* note 1944, at 12.

207. *Id.*

208. H.B. 1885, 95th Gen. Assem. (Ill. 2007).

obtaining such a permit. RMCs would be prohibited from advertising their fees in comparison to physicians' fees or from misleading insured patients about the out-of-pocket costs of RMC services, and the clinics would have to notify patients about RMC visits and outcomes.²⁰⁹ The clinic also would have to give patients the freedom to fill prescriptions at their pharmacy of choice.²¹⁰ The bill would limit the number of physician supervisors to one physician supervisor for every two NPs.²¹¹ Finally, RMC operators would have to pay \$2,500 to secure the permit from the Illinois Department of Healthcare Facilities.²¹² The bill was held in committee.²¹³

Figure 3. Illinois H.B. 1885 (94th General Assembly)

Health care services must be provided in accordance with a limited scope of services .

No health care services may be provided unless a physician, an APN, or a PA is on the premises at the time these services are provided.

Collaborative agreements may be strictly maintained and followed.

No physician may collaborate with more than 2 APNs.

No physician may be a medical director of more than 2 facilities.

A medical director who is a licensed physician must be available to admit patients to a local hospital.

The RMC must have a referral system to physician practices or other health care entities appropriate to the patient's symptoms outside the scope of service provided by the RMC.

Medical records must be maintained in accordance with existing law.

The RMC must provide notification of patient visits and outcomes to patient's primary care provider.

Patients must have the opportunity to purchase any medications, fill any prescriptions, or seek services from any provider not affiliated with the facility, store or pharmacy in which the RMC is located.

On February 19, 2008, Illinois tried again to directly regulate retail medical clinics with the introduction of another Retail Health Care Facility Permit Act (H.B. 5372).²¹⁴ The law was strongly advocated for by the ISMS but opposed by the IDPH due to fiscal considerations.²¹⁵ To help "ensure

209. *Id.*; NCSL, *supra* note 2033; Kevin B. O'Reilly, *Physicians Pushing Lawmakers to Regulate Burgeoning Retail Clinics*, AM. MED. NEWS, (June 4, 2007), available at <http://www.ama-assn.org/amednews/2007/06/04/pr110604.htm>.

210. H.B. 1885; NCSL, *supra* note 2033, at 1; O'Reilly, *supra* note 2099.

211. H.B. 1885; NCSL, *supra* note 2033, at 1; O'Reilly, *supra* note 209.

212. H.B. 1885; O'Reilly, *supra* note 2099.

213. H.B. 1885.

214. H.B. 5372, 95th Gen. Assem. (Ill. 2008).

215. *Id.*; TAKACH & WITGERT, *supra* note 1944, at 12.

patient safety and adequate follow up care” the bill would have authorized the IDPH to issue a separate application and permit for each RMC, with inspections of each facility to occur within 90 days of application.²¹⁶ Physician-or hospital-owned RMCs would be exempt from such requirements.²¹⁷ The bill also would ban the sale of alcohol and tobacco in facilities that served as host to retail medical clinics.²¹⁸

Figure 4. Illinois H.B. 5372 (95th General Assembly)

The health care services provided must be in accordance with a limited scope of services as determined by the facilities’ medical director and approved by the IDPH.

Health care services may only be provided if a physician, an APN, or a PA is on the premises at the time the services are provided.

The RMC must have a referral system to physician practices or other health care entities appropriate to the patient’s symptoms outside the limited scope of services provided by the facility.

The RMC must provide notification of any patient visits and outcomes to the patient’s primary care physician.

The RMC must establish appropriate sanitation and hygienic protocols.

The RMC must have a designated receptionist and waiting area.

Patients must be given a written notice that (a) stresses the importance of having a personal physician and (b) of their opportunity to purchase medications from any provider.

The RMC must have a medical director who is a physician licensed to practice medicine in all its branches with active medical staff privileges to admit patients to a local licensed hospital.

Medical records must be maintained in accordance with existing law.

All personnel must wear clearly visible identification indicating his professional licensure status.

The RMC must operate under written protocols approved by the medical director and the APNs or the PAs providing services at the retail clinic.

Payers shall not be allowed to waive or lower co-payments or offer financial incentives for visits to retail-based clinics in lieu of visits to primary care physicians’ offices.

“Host” will be prohibited from selling tobacco and alcohol products.

H.B. 5372 spurred vocal opposition by Illinois Representative Elaine Nekritz, who felt that bill’s purpose “was to slow the growth of clinics and regulate them to a point that made them no longer viable.”²¹⁹ With

216. H.B. 5372; TAKACH & WITGERT, *supra* note 1944, at 12.

217. H.B. 5372; TAKACH & WITGERT, *supra* note 1944, at 12.

218. H.B. 5372; TAKACH & WITGERT, *supra* note 1944, at 12.

219. H.B. 5372; TAKACH & WITGERT, *supra* note 1944, at 12-13.

encouragement from CVS, Nekritz wrote a letter to the FTC and voiced her concerns over what she perceived as anti-competitive provisions. The FTC's response, which included lengthy criticism of the bill, is discussed under Section C, below. The bill did not pass the Rules Committee.²²⁰ Given the ISMS' strong and persistent opposition to unregulated RMCs, it is very likely that Illinois has not seen the end of this debate.

*c. California: Exploring the development of retail clinics
in the current healthcare delivery system*

California retail medical clinic operators had difficulty navigating the state's longstanding corporate practice of medicine (CPOM) laws. Pending legislation would make the California regulatory environment more welcoming to such clinics. California RMCs currently operate under several different models and offer a varying range of services.²²¹ All are exempt from state licensure.²²²

State CPOM laws require health care facilities to be owned by local area physicians; out-of-state physicians or non-physicians cannot own clinics.²²³ Clinic operators recognize that these laws make it challenging to establish retail medical clinics in the state. One clinic executive noted, "It's very difficult to justify the investment in California when you can't own equity in the clinics or employ nurse practitioners directly, particularly when there are forty-seven other states that don't present these obstacles."²²⁴

In an attempt to remedy this situation, California lawmakers have introduced health reform proposals that are friendly to retail medical clinics. Pending legislation would allow physician-owned medical corporations to own clinics, so long as the medical corporation directly hires the medical staff.²²⁵ Another proposal introduced in the California Assembly noted that "eliminating barriers in state law that prohibit establishing additional walk-in, neighborhood health clinics will enable California families to access more convenient health clinics at pharmacies, grocery stores, and shopping malls in their communities."²²⁶

Those attempting to ease the restrictions on retail medical clinics in California are aided by California Governor Arnold Schwarzenegger's support of the RMC model. The Governor believes that RMCs might "help curb the rate of growth of health care costs by providing affordable primary

220. TAKACH & WITGERT, *supra* note 1944, at 12.

221. *Id.* at 16.

222. *Id.*

223. CHCF 2007, *supra* note 9, at 25.

224. *Id.*

225. CMS Report 5-A-07, *supra* note 655, at 6.

226. *Id.* at 26.

care in a more accessible setting, while also alleviating the burden in the state's over-crowded emergency rooms."²²⁷ A health care reform bill introduced by Governor Schwarzenegger purports to "remove statutory and regulatory barriers to expansion of lower-cost models of health care delivery such as retail-based medical clinics by making scope of practice changes for 'physician extenders'" such as NPs and PAs.²²⁸ The Governor's office has proposed allowing physicians to supervise up to six NPs (the current limit is four) and is currently studying the issue of NP supervision of unlicensed medical assistants,²²⁹ a proposition that California physicians are sure to take issue with. California will be an interesting state to watch as state lawmakers continue to debate how best to fit RMCs within the existing healthcare environment.

d. New Jersey:

Working retail medical clinics into the existing health system

In New Jersey, retail medical clinics must be organized as private physician offices to qualify for exemption from state regulation and licensure.²³⁰ If RMCs were organized as ambulatory care centers—the only other model that RMCs could fit into under New Jersey law—they would be subject to regulation by the New Jersey Department of Public Health.²³¹ As such, New Jersey RMCs have been organized under a "captive physician" model, in which each clinic is owned by a physician and staffed by NPs, but managed by a larger corporate entity.²³² The corporate entity provides management services such as hiring staff and billing patients and insurance companies.²³³

HealthRite provides an example of this model. HealthRite was originally organized as part of the not-for-profit AtlantiCare health system, but it was restructured in 2006 to become independently owned by physicians in the for-profit AtlantiCare Physician Group.²³⁴ HealthRite contracts with AtlantiCare for billing and other services.²³⁵ This model is not without limit, however. For example, HealthRite cannot advertise its affiliation with AtlantiCare health system, nor can the two entities link to each other's websites.²³⁶ Through the "captive physician" model, New Jersey RMC

227. TAKACH & WITGERT, *supra* note 1944, at 16.

228. CHCF 2007, *supra* note 9, at 26.

229. TAKACH & WITGERT, *supra* note 1944, at 17.

230. *Id.* at 10.

231. *Id.*

232. *Id.*

233. *Id.*

234. *Id.*

235. *Id.*

236. *Id.*

operators have found a way to fit within the existing state health care system.

e. Texas: Regulating retail medical clinics through CPOM and nurse practitioner oversight

Texas is another state that utilizes the corporate practice of medicine doctrine to regulate retail medical clinics. The state's laws prohibit for-profit corporations from directly employing physicians, though corporations can employ other types of clinicians such as NPs.²³⁷ Corporation-owned RMCs are thus structured to directly employ NPs but enter into independent contractor arrangements with physicians.²³⁸

Texas' strict regulation of NP supervision varies by region. Generally, a physician must be at a retail medical clinic fifty percent of the time for the clinic's nurse practitioners to have prescribing authority.²³⁹ In medically underserved areas, however, the physician is only required to visit the clinic once every ten business days.²⁴⁰ Texas recently attempted to further loosen requirements for NP supervision, though to date no such bill has been successful.²⁴¹ Texas legislators hope that loosened regulations will encourage the expansion of RMCs, which they believe provide convenient care and discourage inappropriate use of emergency departments.²⁴²

f. Florida: A unique licensure structure for retail medical clinics

Florida's unique licensing structure for RMCs is the result of an anti-fraud investigation involving the automobile and personal injury insurance industry.²⁴³ Soaring insurance premiums due to inappropriate diagnostic testing, inflated charges, and over-utilization of treatments initiated the investigation.²⁴⁴ The resulting law, the Health Care Clinic Act, established a unique licensing structure for corporate-owned clinics—not exclusive to RMCs—with the intent to prevent fraudulent business practices, further costs, and harm to consumers.²⁴⁵ RMCs owned by licensed health care practitioners (NPs included) are exempt from licensure.²⁴⁶ However, all clinics that employ NPs are subject to the bill. The bill limited the number

237. *Id.* at 11.

238. *Id.*

239. TEX. OCC. CODE ANN. § 157.053 (Vernon 2010); TAKACH & WITGERT, *supra* note 1944, at 11.

240. TEX. OCC. CODE ANN. § 157.052; TAKACH & WITGERT, *supra* note 1944, at 11.

241. TAKACH & WITGERT, *supra* note 1944, at 11.

242. *Id.*

243. *Id.* at 14.

244. *Id.*

245. FLA. STAT. § 400.900 (2007).

246. *Id.*

of NPs a physician may supervise to no more than four NPs per supervising physician.²⁴⁷

Clinics that are subject to licensure must pay a \$2,000 application fee, a \$2,000 renewal fee every two years, and must consent to field visits and inspections.²⁴⁸ Further, clinic applicants must “provide evidence of sufficient assets, credit, and protected revenues to cover liabilities and expenses” for the first year of operation.²⁴⁹ Chief operating officers, clinic staff, and board members are subject to criminal background checks during the licensure process.²⁵⁰ All concerns involving the medical operations of the clinic are referred to the state medical board, while the recently established Health Care Clinic Unit within Florida’s Bureau of Health Facility Regulation oversees the business operations of the RMC.²⁵¹ Florida’s strict anti-fraud environment makes it expensive and demanding, though necessary, for Florida RMCs to practice transparent and ethical business practices.

*g. New Hampshire and Oklahoma:
Failed first attempts at passing legislation*

In June 2008, the governor of New Hampshire established a commission to study RMCs and develop legislation in order to regulate the licensure and operation of RMCs in the state.²⁵² The commission’s proposed legislation, introduced in January 2009, would have required RMCs to limit their scope of services to preventive care and wellness promotion.²⁵³ RMCs would also have been required to post hours of operation including nearby sites at which care may be sought during hours when the clinic was not open, and post a “well-defined menu of its services.”²⁵⁴ RMCs would have to maintain a transfer agreement with local hospitals, and ensure continuity of care by making appropriate referrals for follow up care and treatment.²⁵⁵ Finally, the bill would have required retail medical clinics to encourage all patients to have a medical home.²⁵⁶ However, the state House Committee on Health, Human Services and Elderly Affairs judged the bill as “inexpedient to legislate.”²⁵⁷ No action on the bill has been taken since March 2009.

247. FLA. STAT. ANN. § 458.347(3) (West 2010).

248. FLA. STAT. ANN. § 400.9925; TAKACH & WITGERT, *supra* note 1944, at 14.

249. TAKACH & WITGERT, *supra* note 1944, at 14

250. *Id.*

251. *Id.*

252. NCSL, *supra* note 2033, at 2.

253. H.B. 422, 2009 Leg., 161st Sess. (N.H. 2009).

254. *Id.*

255. *Id.*

256. *Id.*

257. H.B. 422, N.H. Gen. Ct. Bill Status Sys., http://www.gencourt.state.nh.us/bill_

Similarly, Oklahoma's Retail Health Clinic Act (S.B. 1523) attempted to require physician ownership of retail medical clinics and impose supervisory requirements limiting physician supervision.²⁵⁸ The Act would have required written protocols for patient referral, the transmission of medical records to RMC patients' primary care physicians, and required RMC employees to disclose to patients certain details regarding the qualifications of practitioners and limitations of the clinic.²⁵⁹ This Act and another similar bill brought in 2008 sought to impose certain scope of practice and supervisory requirements.²⁶⁰ Neither bill passed by the end of the 2008 session.²⁶¹ Interestingly, both bills died in committee due to the opposition of several hospital systems that were interested in opening retail medical clinics.²⁶²

Led by Massachusetts, a handful of states have considered or are considering legislative avenues through which to regulate retail medical clinics in their state health care environment. A lesser number of states have attempted to indirectly control the growth of retail medical clinics through the authority to regulate the sale of alcohol and tobacco.

h. Indiana: Studying regulation of retail medical clinics

With the support of the Indiana State Medical Association, the Indiana legislature is considering a bill that would regulate retail medical clinics. While the bill as introduced would require RMCs to meet specified standards and implement certain policies for the monitoring of quality of care, it was amended to provide for a study on the regulation of RMCs.²⁶³ The purpose of the study is to determine the number of health clinics (as defined by the statute) that are already regulated and those that are not, adequacy of the regulations of clinics, and a determination about whether any additional standards need to be included.²⁶⁴ The report is due October 1, 2009. As of July 2009, the bill had passed a second reading in the state senate, and had been "ordered engrossed."²⁶⁵

status/bill_status.aspx?lsr=711&sy=2009&sortoption=billnumber&txtsessionyear=2009&txtbillnumber=hb422 (last visited Mar. 24, 2010).

258. AM. MEDI. ASS'N, ADVOCACY RES. CTR., PHYSICIAN BUSINESS ISSUES: RETAIL HEALTH CLINICS 2008 LEGISLATIVE SUMMARY (2008) [hereinafter "ARC"].

259. *Id.*

260. *Id.*

261. *Id.*

262. *Id.*

263. S.B. 216, 116th Gen. Assem., Reg. Sess. (Ind. 2009), available at <http://www.in.gov/legislative/bills/2009/SB/SB0216.1.html>.

264. *Id.*

265. *Id.*

2. States with strategy of prohibiting stores with retail medical clinics from selling tobacco or alcohol products

Several states have taken the approach of effectively forcing retailers to choose between support of health and wellness and products whose use undermines health and wellness. Illinois House Bill 5372, which was introduced by the ISMS, includes a prohibition on the sale of alcohol or tobacco products for stores hosting retail medical clinics.²⁶⁶ Similarly, Tennessee House Bill 3502/Senate Bill 3205 would prohibit cigarette sales at any place of business where medical services are also offered to the public.²⁶⁷ The bill did not move far in the legislature due to strong criticism from the business community.²⁶⁸ Rhode Island's Senate Bill 2356/House Bill 7676, which would amend the state's cigarette tax statute by prohibiting licensure of a facility that maintains a health care facility and pharmacy in the same location, was held in committee for further study.²⁶⁹ While these laws have not yet proven successful, the idea of making retailers choose between the financial incentives of RMCs and alcohol and tobacco sales is an interesting approach that will warrant further study.

As retail medical clinics continue to expand in number and become established in a growing number of states throughout the country, state legislators will increasingly have to take on the task of regulating RMC operation and scope of practice. Presumably many will follow Massachusetts' lead in drafting legislation, though, as shown by the diverse means through which states have directly or indirectly regulated RMCs thus far, states have a variety of choices through which to assert their authority over this particular model of health care delivery.

B. Corporate Practice of Medicine

Retail medical clinics in several states are subject to the corporate practice of medicine (CPOM) doctrine. The legal doctrine prohibits anyone who is not a licensed medical provider from interfering with a physician's professional medical judgment and often bans corporations from directly employing physicians.²⁷⁰ The intent of the doctrine is to ensure that physician professional medical judgment and treatment decisions are not influenced by lay control.²⁷¹ CPOM is driven by a concern that the practice of medicine by a corporation leads to the commercialization of the medical

266. ARC, *supra* note 258.

267. *Id.*

268. *Id.*

269. *Id.*

270. TAKACH & WITGERT, *supra* note 1944, at 9.

271. *Id.*; Welk, *supra* note 191, at 235.

profession to the public's detriment.²⁷² CPOM doctrines vary from state to state, and enforcement is rare and inconsistent among the states.²⁷³

Retail medical clinic operators assert that CPOM laws make it "fundamentally untenable" to do business in states that employ the doctrine since they cannot employ physicians directly and thus control the quality or standard of care that is central to the RMC model.²⁷⁴ RMC operators also complain that because of CPOM laws, they cannot own equity in clinic operations, a significant detractor given the amount of investment required.²⁷⁵ Conversely, critics of RMCs argue that those businesses that host these clinics exploit the medical services provided to support the corporation's non-health related interests, and that such corporations may attempt to improperly control the clinical practice and diagnoses provided by RMC's professional staff.²⁷⁶

To avoid violating the CPOM doctrine, retail medical clinic operators have adopted such "various ownership configurations" as the "captive physician" model, in which a RMC is legally owned by a physician or a group of physicians but is closely tied to a corporation by a series of management or other contracts.²⁷⁷ For regulatory purposes, these clinics' operations are considered the private practice of medicine.²⁷⁸ Given the inconsistent and diminishing force of state CPOM laws, this doctrine is not likely to hold back the overall expansion of retail medical clinics. Antitrust considerations, on the other hand, are far more significant.

C. Antitrust

Federal antitrust laws regulate commerce and prevent anticompetitive conduct that discourages competition in the market. States attempts at regulating retail medical clinics have attracted the attention of the FTC. The FTC investigates the competitive effects of restrictions on business practices and has specifically undertaken research and advocacy directed at health care advertising issues.²⁷⁹ The FTC claims that its activities in this area seek to limit the anticompetitive and anti-consumer effects of unnecessary restrictions on truthful and non-misleading advertising by,

272. Welk, *supra* note 191, at 235.

273. *Id.* at 237.

274. CHCF 2007, *supra* note 9, at 22-23.

275. *Id.*

276. Belfort, *supra* note 36.

277. *Id.*; TAKACH & WITGERT, *supra* note 1944, at 9.

278. TAKACH & WITGERT, *supra* note 1944, at 9.

279. Letter from the FTC, Office of Policy Planning, Bureau of Econ., Bureau of Competition and Bureau of Consumer Prot., to the Honorable Elaine Nekritz, Ill. State Repr. (May 29, 2008) [hereinafter "FTC"].

among others, physicians, chiropractors, and optometrists.²⁸⁰ The Commission has examined and weighed in on the RMC market through analysis of Illinois and Massachusetts legislation specific to retail clinics.²⁸¹

1. Illinois

The FTC's comments pertaining to Illinois law were in response to House Bill 5372, the details of which are discussed in Section A(1)(a), above. While the FTC "commended Illinois in its efforts to open new points of access to health care through new models of delivery," the Commission expressed concern over provisions of the bill that may have "caused undue burden on retail clinics, thereby limiting their ability to compete."²⁸² The FTC studied several of the bill's potential anti-competitive provisions, including those that would prohibit the sale of alcohol or tobacco products by a host retailer and provisions on advertising, facility, and operating requirements.²⁸³

The FTC ultimately concluded that, because several of the bill's requirements that appeared to impose burdensome restrictions would pertain only to RMCs, and not to other health care facilities offering the same service or staffing, the bill "would put retail clinics at a competitive disadvantage without offering countervailing consumer benefits" for Illinois consumers.²⁸⁴ Illinois' proposed bill would thus work as a substantial barrier to the entry of RMCs in Illinois, which in turn might restrict the supply of or raise the prices of basic health care services.²⁸⁵

H.B. 5372's advertising restrictions on retail medical clinics were the subject of harsh criticism from the FTC, which interpreted the provisions as having the potential to prohibit or chill consumer access to truthful and non-misleading information about prices for basic medical services.²⁸⁶ The bill would prohibit RMCs from advertising comparisons of its fees with the fees of other licensed facilities.²⁸⁷ The FTC reasoned that if "commercial speech is not false or misleading, and does not concern unlawful activities, restrictions on that speech must satisfy two conditions."²⁸⁸ First, the restriction must serve a substantial government interest, and second, the restriction must not be more extensive than necessary to serve that interest. The FTC concluded that Illinois' interest in isolating its own consumers

280. *Id.*

281. Deloitte, *supra* note 31, at 11.

282. TAKACH & WITGERT, *supra* note 1944, at 13

283. Deloitte, *supra* note 31, at 11

284. FTC, *supra* note 279.

285. *Id.*

286. *Id.*

287. *Id.*

288. *Id.*

from objective and truthful price information was unclear.²⁸⁹ Though false or misleading marketing information could harm Illinois consumers, the Commission stressed the importance of access to truthful and non-misleading information to consumers' "effective participation in their health care and health care expenditures."²⁹⁰

The Commission also took issue with the bill's requirement that a physician be the medical director of no more than two clinics, reasoning that this requirement may be an undue and potentially costly limitation on the organization and operation of retail medical clinics.²⁹¹ The FTC found the reasoning behind such a provision to be unclear. The provision also had the potential to give an unfair advantage to large healthcare providers with the capability to leverage existing physician staff.²⁹² The bill also seemed to impose stricter requirements for supervision on those mid-level practitioners who practiced in RMCs than on those providers who practiced in a non-retail setting.²⁹³ The FTC concluded that special requirements could restrict competition, as they might tend to suppress supply or raise prices without conveying countervailing benefits to Illinois health care consumers.²⁹⁴

The FTC went on to analyze H.B. 5372's insurance provisions. Under the bill's "nondiscrimination" provisions, retail medical clinics would have to subject insured customers to the same "co-payment, deductible, or co-insurance requirements" that the insured would pay for a visit to a physician, NP, or PA.²⁹⁵ The FTC read this provision as restricting the ability of RMCs to negotiate favorable terms with third-party payors and to pass on savings to clinic customers.²⁹⁶ Further, to undercut the ability of third-party payors to negotiate favorable rates would diminish the power of payors to manage costs for services, consequently having a harmful effect on consumer health care costs.²⁹⁷ Therefore, this provision had the potential to limit competition in Illinois.

Illinois' proposed bill also included a prohibition against locating a retail medical clinic in any store that sold alcohol or tobacco to the public. Though the FTC recognized the public policy interest in safeguarding the health and welfare of Illinois citizens, such as prohibiting the sale of alcohol and tobacco to minors, the FTC ultimately found no rationale for limiting

289. *Id.*

290. FTC, *supra* note 279.

291. *Id.*

292. *Id.*

293. *Id.*

294. *Id.*

295. *Id.*

296. FTC, *supra* note 279.

297. *Id.*

alcohol and tobacco sales in only those retailers that house RMCs.²⁹⁸ As the FTC noted, Illinois law contains no general restriction that applies to health care services other than RMCs, such as on the placement of pharmacies in retail stores.²⁹⁹ Further, the bill's exemption of hospital- or physician-owned hospitals from this requirement would place significant restrictions on certain competitors but not others within the same market.³⁰⁰ Therefore, the provision would act as a barrier to competition among providers of basic medical services, to the detriment of Illinois consumers.³⁰¹

In sum, while the FTC commended the Illinois legislature for attempting to provide guidance for this new model of healthcare delivery, it ultimately found that several of H.B. 5372's provisions would harm health care competition and the emergence of retail medical clinics without providing countervailing benefits for health care consumers.³⁰² The FTC left open the possibility that provisions currently considered anti-competitive may become acceptable in the future, should the Illinois legislature be presented with evidence that specific health, safety or other risks to consumers are associated with retail clinics.³⁰³ If this should be the case, the FTC warned that remedial regulations should be narrowly tailored to address such problems.³⁰⁴

The FTC concluded that, under Illinois' current healthcare environment, H.B. 5372 as presented would "substantially limit the potential benefit of retail medical clinics to Illinois healthcare consumers, especially those with inadequate access to basic medical services, by making it more difficult to open and operate such clinics, or by raising their costs of doing so, which likely raise the cost of their services to consumers."³⁰⁵ Given the Illinois legislature's persistence in attempting to pass legislation specific to retail medical clinics, it is likely that further bills will be presented with strong safeguards for RMCs that do not quite rise to the anticompetitive nature of past legislative attempts.

2. Massachusetts

As discussed above, Massachusetts legislators sought the FTC's comment on the state's initiative to facilitate the emergence of retail medical clinics. Legislative discussions began in 2006, when MinuteClinic

298. *Id.*

299. *Id.*

300. *Id.*

301. *Id.*

302. FTC, *supra* note 279.

303. *Id.*

304. *Id.*

305. *Id.*

sought entry into the Massachusetts market by applying for a clinic license. Massachusetts' regulations did not speak to the RMC model at that time. To remedy the situation, Massachusetts legislators drafted legislation that would fit RMCs into existing regulations pertaining to medical clinics. The regulation recognized that new models of health care delivery could make basic health care more accessible to consumers.³⁰⁶

The FTC supported the goal of the regulation, but expressed concern that a proposed requirement that all retail medical clinic advertising (but no other clinic advertising) be pre-screened and pre-approved could deprive consumers of useful information about available care and act as a barrier to entry into the market.³⁰⁷ Using language parallel to that used in its analysis of Illinois law, the FTC noted that singling out RMCs would put such clinics "at a competitive disadvantage without offering countervailing consumer benefits."³⁰⁸ Massachusetts adopted the Commission's suggestions in its final regulations.

D. *Mid-Level Practitioner Quality, Scope of Practice and Supervision*

The success of retail medical clinics is dependent on mid-level practitioners providing care that is equal or superior to that of physicians when providing the same care for the same problems. Physician groups have expressed doubt over the quality of care offered by mid-level practitioners. The AMA has expressed its belief that mid-level practitioners "fundamentally lack the comprehensive medical knowledge that is obtained through medical school."³⁰⁹ However, evidence has shown that these providers are as qualified as physicians to deliver those services that retail medical clinics offer.³¹⁰

Authors of a meta-analysis of thirty-five studies published in the British Medical Journal found that not only was there no difference in health status found, but also that patients were *more* satisfied with care provided by a NP.³¹¹ NPs also often have longer consultations which partly accounted for

306. *Id.*

307. Cecilia M. Assam & Peyton M. Sturges, *Provider Regulation: FTC Sees Benefits To Massachusetts Rules for Store-Based Clinics; Ad Screening Nixed*, 16 BNA HEALTH LAW REP. 1201 (2007); FTC, *supra* note 279.

308. Assam & Sturges, *supra* note 307, at 1201.

309. Letter from the Am. Med. Ass'n to James Bolton, Chair of the Special Comm. on Scope of Practice, Fed'n of State Med. Bds. (Aug. 9, 2004) (on file with the Am. Med. Ass'n) [hereinafter Bolton letter].

310. AM. ACAD. OF NURSE PRACTITIONERS, STANDARDS FOR NURSE PRACTITIONER PRACTICE IN RETAIL-BASED CLINICS 1 (2007), <http://www.aanp.org/NR/rdonlyres/9429B4BC-AB09-4CB6-A699-EB5AC43852D6/0/RetailBasedClinics.pdf>; Sage 2008, *supra* note 1, at 1239-40.

311. Sue Horrocks et al., *Systematic Review of Whether Nurse Practitioners Working in Primary Care Can Provide Equivalent Care to Doctors*, 324 BRIT. MED. J. 819, 819 (2002).

this satisfaction.³¹² While the average physician office visit lasts 8-10 minutes, the NPs who staff retail clinics often spend double that amount of time with each patient. While many factors contribute to quality, being able to spend an extra ten minutes with a patient may count for a lot.³¹³ The study's authors concluded that the increasing availability of NPs in primary care is likely to lead to high levels of patient satisfaction and quality care.³¹⁴

Similarly, the Munding study published by the Journal of the American Medical Association hailed as the "most ambitious and well-executed comparison of NPs with physicians" found that there were no significant differences in the outcomes between NPs and physicians.³¹⁵ Patients reported no statistical difference in overall satisfaction or communications factors, or in their willingness to refer the NP to others.³¹⁶ The study's authors concluded that the study "strongly support[ed]" the hypothesis that, using the traditional model of primary care, patient outcomes for NP and physician delivery of primary care are similar.³¹⁷

Retail medical clinics claim that the quality of care produced by NPs at the clinics are a result of strict adherence to evidence-based medicine, as rigorous adherence to clinical guidelines can improve rates of appropriate treatment.³¹⁸ One study found RMCs that used an electronic clinical decision support tool provided high quality of care with 99.15% overall adherence to evidence-based guidelines.³¹⁹ In contrast, according to a study conducted by RAND, Americans receive evidence-based medicine only 55% of the time at other health care providers.³²⁰ However, to date no independent study of overall quality of care provided by retail medical clinics has been done.³²¹

In part, the quality of care provided by RMCs is dependent upon the clinics keeping within an appropriate scope of practice, in consideration of the purpose of the retail medical clinic and the qualifications of the practitioners who staff the clinics. To the extent that RMCs go beyond this purpose and scope of practice, they risk losing the public confidence in

312. *Id.*

313. *Id.* at 822.

314. Horrocks et al., *supra* note 311, at 819.

315. Mary O. Munding et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A Randomized Trial*, 283 JAMA 59, 64 (2000); Harold C. Sox, *Independent Primary Care Practice by Nurse Practitioners*, 283 JAMA 106, 107 (2000).

316. Munding et al., *supra* note 315, at 64.

317. *Id.* at 68.

318. James D. Woodburn et al., *Quality of Care in the Retail Health Care Setting Using National Clinical Guidelines for Acute Pharyngitis*, 22 AM. J. MED. QUALITY 457, 461 (2007), available at <http://ajm.sagepub.com/cgi/content/abstract/22/6/457>.

319. *Id.*

320. CHCF 2007, *supra* note 9, at 21.

321. *Id.*

RMCs and the midlevel practitioners who staff them.

1. Scope of Practice

The scope of practice (SOP) of nurse practitioners and physician assistants varies by state and is constantly changing to meet unique or differing circumstances. Scope of practice—the activities that a health care practitioner may perform within his or her profession—is increasingly expanding through legislative, regulatory and administrative processes, and is warranted due to advancements in mid-level practitioner education and training.³²² Health care practitioner groups who argue that there is a consumer demand for allied health professional services due to an undersupply of health care practitioners and a problem of access in rural communities have fueled this legislation.³²³

An expanded SOP will enable retail medical clinics to provide greater services through its non-physician clinicians. However, RMC operators say that some state rules are too burdensome and, as a result, hinder growth.³²⁴ As mid-level practitioners' scope of practice expands, RMCs must adapt to ensure that their employees are practicing within state standards.

2. Supervision of Mid-Level Practitioners

Traditionally, the states set standards for allied health professional education and supervision through their respective licensure laws and professional boards. Licensing requirements define what is necessary for mid-level practitioners to practice medicine safely.³²⁵ The supervising physician and mid-level practitioners typically develop jointly written protocols that become the basis for the supervision arrangement.³²⁶ The supervising physician must provide “professional oversight and direction sufficient to assure the safety of the patient and the delivery of appropriate care.”³²⁷ The supervisory services must be provided within the context of an

322. Statement of the Am. Med. Ass'n to the Fed. Trade Comm'n/Dep't of Justice Joint Hearing Re: Health Care Competition Law and Policy – Quality and Consumer Protection: Market Entry (June 10, 2003) (on file with the American Medical Association).

323. FED'N OF STATE MED. BDS., *ASSESSING SCOPE OF PRACTICE IN HEALTH CARE DELIVERY: CRITICAL QUESTIONS IN ASSURING PUBLIC ACCESS AND SAFETY* 6 (2005) [hereinafter *ASSESSING SCOPE*].

324. Hsu, *supra* note 7, at 19.

325. ADVOCACY RES. CTR., AM. MED. ASS'N, *SCOPE OF PRACTICE DATA SERIES: NURSE PRACTITIONERS* 44 (2009), http://www.acnpweb.org/files/public/08-0424_SOP_Nurse_Revised_10_09.pdf [hereinafter *SCOPE OF PRACTICE*].

326. Yarnell Beatty, *Retail-Based Clinic Oversight Draws TMA's Attention*, 100 J. TENN. MED. ASS'N 16, 16 (2007).

327. *ASSESSING SCOPE*, *supra* note 323, at 7.

established relationship between physician and allied health professional.³²⁸

Physician supervision of mid-level practitioners can be direct, where the supervisor is on the premises and readily available, or indirect, where the supervisor is available electronically or telephonically, but able to be on the clinic site within a certain time frame.³²⁹ Most RMCs utilize indirect methods of physician supervision.

While no state requires the continuous presence of the supervising physician, the physician must at a minimum be available for consultation and must make occasional site visits.³³⁰ Laws also generally require the supervising physician to review a certain percentage of the allied health professional's charts within a delineated time frame.³³¹ Often supervisory arrangements establish written guidelines for who and what services are to be supervised, the geographical proximity of the supervisor to the supervisee, and the designation of an alternate supervisor in the absence of the primary supervisor.³³² Moreover, statutes may restrict the number of mid-level practitioners a physician may supervise.³³³ State requirements for supervision vary considerably among the states and differ based on which category of mid-level provider—physician assistant or nurse practitioner—the standards apply to.³³⁴

a. *Physician Assistants*

Regulations relating to physician supervision of allied health professionals generally apply to two categories of health professionals: nurse practitioners (NPs) and physician assistants (PAs). The main difference between physician assistants and nurse practitioners is that NPs practice under their own license and are independent, while PAs are not.³³⁵ PAs by definition are licensed to practice medicine only under the direction and within the scope of practice of a licensed physician, although that supervision may be intermittent and from a remote location.³³⁶

The requirements for physician involvement in PA practice vary widely. Again, while no state requires the constant physical presence of a physician, all states require the physician to be easily available for consultation through telecommunication or electronic means. For those arrangements

328. *Id.*

329. *Id.*

330. Beatty, *supra* note 326, at 16.

331. *Id.*

332. ASSESSING SCOPE, *supra* note 323, at 7.

333. Belfort, *supra* note 36, at 7.

334. *Id.*

335. Hansen-Turton et al., *supra* note 15, at 9.

336. Richard A. Cooper, *Health Care Workforce for the Twenty-First Century: The Impact of Nonphysician Clinicians*, 52 ANN. REV. MED. 51, 54 (2001).

wherein the PA practices at a satellite location, some states delineate the number of hours per week the physician must be physically present at the location. For instance, the time span ranges from no physical requirement,³³⁷ to weekly meetings,³³⁸ to at least one direct personal contact visit every four months for at least four hours,³³⁹ to physical presence seventy-five percent of the time each month the PA is providing patient care.³⁴⁰ Others require the physician to be no more than an hour away from the PA.³⁴¹ Many states provide that a physician must find an alternate physician to cover supervision duties when the primary physician-supervisor is unavailable.³⁴²

As stated above, a supervising physician must review and sign within a certain time frame the medical records of all or a percentage of patients cared for by the physician assistant. Each state has a different requirement for the number or percentage of patient charts the physician must review and sign off on. The most vague is a Utah statute, which provides that “a physician. . . shall cosign a sufficient number of charts.”³⁴³ Some states require physician to cosign all charts. Similarly, each state has a different time frame for the amount of time a physician may take to review and sign. For example, for osteopathic physician assistants, the range is from twenty-four hours,³⁴⁴ to one week,³⁴⁵ to 30 days,³⁴⁶ to “in a timely manner.”³⁴⁷

Some state supervision requirements differ based on the physician assistant’s experience. For example, Colorado requires a PA to practice on-site with a physician for the PA’s first thousand working hours.³⁴⁸ Kentucky PAs must practice with on-site physician supervision for 18 months before practicing in an off-site location.³⁴⁹ In Alaska, PAs in remote locations with less than two years of experience must work 160 hours in direct patient care under the immediate supervision of collaborating physician within 90 days of starting practice in remote location.³⁵⁰ The PA must complete the first 40

337. ALA. CODE § 34-24-290 (2009).

338. CONN. GEN. STAT. § 20-12a (2007).

339. ALASKA ADMIN. CODE tit. 12, § 40.430 (2007).

340. S.C. CODE ANN. § 40-47-955 (2009).

341. OHIO ADMIN. CODE § 4730:1-03 (2007).

342. CONN. GEN. STAT. § 20-12a (2003); IDAHO CODE ANN. §§ 22.01.03.010, 22.01.03.030 (2010); N.H. CODE ADMIN. R. ANN. MED. 603.01 (2006).

343. UTAH ADMIN. CODE r. 156-70a-501 (2009).

344. GA. COMP. R. & REGS. 360-5-.08 (1998).

345. WASH. ADMIN. CODE § 246-854-015 (2007).

346. FLA. STAT. ANN. § 458.348 (LexisNexis 2010).

347. 263 MASS. CODE REGS. 5.05 (1993).

348. 3 COLO. CODE REGS. § 713-7-106 (2006).

349. KY. REV. STAT. ANN. § 311.860 (LexisNexis 2008).

350. ALASKA ADMIN. CODE tit. 12, § 40.415 (2007).

hours before working in the remote location.³⁵¹

All state statutes and regulations provide that the supervising physician accepts responsibility for the medical services provided by the PA and is legally liable for the PA's activities. The PA is generally presumed to be the physician's agent.³⁵² Nurse practitioners, as is discussed below, practice with more independence.

b. Nurse Practitioners

Nurse practitioners practice autonomously and in collaboration with health care professionals to assess, diagnose, treat and manage a range of primary and specialty care services.³⁵³ Most have obtained a master's degree level of education.³⁵⁴ NP care emphasizes prevention, case management, counseling and patient education—all areas of care through which retail medical clinics aim to attract customers.³⁵⁵ NPs are trained in various areas of primary care, such as adult health, pediatrics, family health, women's health, or gerontology.³⁵⁶

Nurse practitioners enjoy greater clinical freedom than other mid-level practitioners. While twenty-eight states require NPs to practice pursuant to a collaborative arrangement with a licensed physician, the remaining twenty-two states grant NPs complete autonomy for the diagnosing and treating aspects of practice.³⁵⁷ As a result, in many states NPs have wide latitude to diagnose and care for patients within their training and expertise, including ordering and interpreting diagnostic tests and performing minor procedures.³⁵⁸ This autonomy is not without limit, however; NPs still must complete education and other requirements to be able to prescribe the different classes of drugs. Those states that require collaboration between NP and physicians, set prescribing authority and dictate what kind of prescriptions an NP can write.³⁵⁹

Most states call for some degree of physician oversight or delegation over the nurse practitioner.³⁶⁰ Such oversight may extend from a few days to two weeks in some states, with greater independence when NPs practice

351. *Id.*

352. ALA. CODE § 34-24-292 (2009).

353. American Academy of Nurse Practitioners, *Statement on Scope of Practice for Nurse Practitioners* (1993).

354. Cooper, *supra* note 336, at 52.

355. *Id.*

356. *Id.*

357. American Medical Association, *Scope of Practice Data Series: Nurse Practitioners* (2008), at 105-129.

358. *Id.* at 61.

359. CHCF 2007, *supra* note 9, at 25.

360. Cooper, *supra* note 336, at 52.

in rural or underserved communities.³⁶¹ The collaborative arrangement also must often include standardized procedures that are approved by the nurse practitioner, the supervising physician, and a “facility administrator before the NP can perform anything that might be considered the practice of medicine.”³⁶² Other regulations for physician supervision or collaboration with nurse practitioners include issues such as the amount of supervision, the location for supervision, the type and frequency of chart review, and limits to the number of NPs a physician can simultaneously supervise.³⁶³

Though allied health professionals play an increasingly important role in the delivery of health care, particularly when it comes to retail medical clinics, the physician’s role in patient care is still important. For this reason, the AMA believes that scope of practice expansions must be coupled with safeguards to protect the level of care provided by mid-level practitioners.³⁶⁴ Nevertheless, with these safeguards, and with expanded scope of practice allowances, allied health professionals can help drive the success and quality behind retail medical clinics, to the benefit of the public.

E. Stark Law

Stark law prohibits physicians from referring patients to an entity for certain designated health services (DHS) for which Medicare or Medicaid payment may be made if the physician has a financial relationship with the entity.³⁶⁵ Violations can result in refunding of the prohibited payment and, in cases of knowing violations, exclusion from the federal health care programs.³⁶⁶ Knowing violations for the physician self-referral law can also form the basis for liability under the False Claims Act.

Ten categories of services are subject to Stark law.³⁶⁷ To date, retail medical clinics offer none of these services. As such, RMCs are not subject to Stark law. However, the range of services RMCs have to offer may expand in the future as HIT progresses and states grant mid-level practitioners broader scopes of practice. Moreover, Medicare and Medicaid are now providing reimbursement for many of the services RMCs offer.

Further, mid-level practitioners are not subject to Stark, though any physician who staffs the retail medical clinic is subject to the law. Physicians can have a financial relationship with a RMC through being

361. *Id.*

362. CHCF 2007, *supra* note 9, at 25.

363. *Id.* at 25.

364. Bolton letter, *supra* note 309.

365. Social Security Act, 42 U.S.C. § 1395nn(a) (2006).

366. Social Security Act, 42 U.S.C. § 1395nn(g) (2006); OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 56,832, 56,841 (Sept. 30, 2008).

367. 42 C.F.R. § 411.351 (2009).

directly employed or contracted out by the clinic operator, or by owning a share of the clinic, even if this share is through the physician's stake in a physician organization. If the physician is employed by, or is an independent contractor of the RMC, and wants to refer patients to the clinic, the arrangement must meet a direct compensation exception to Stark, such as the exception for personal services.³⁶⁸

More important is the latter situation, where a physician has an indirect financial interest in the retail medical clinic through the physician's ownership of the physician organization that owns the clinic. Under the recent Phase III Stark rules, a physician who has an ownership or investment interest in a physician organization will be deemed to "stand in the shoes" of that physician organization for purposes of determining whether the physician's relationship with the DHS entity is an indirect or direct compensation arrangement.³⁶⁹ CMS newly defined "physician organization" to include solo physicians, group practices, and physician practices.³⁷⁰

A physician who "stands in the shoes" of her physician organization is deemed to have the same compensation arrangement as the physician organization itself. Therefore, if a physician organization has a direct compensation with the retail medical clinic, any physician who has an ownership or investment interest in the physician organization is deemed to have a direct compensation arrangement with the clinic as well. In order for the physician to refer patients to the RMC, the relationship between the physician organization and the clinic must meet one of the afore-mentioned exceptions to Stark.

F. *Anti-Kickback Statute*

The Federal anti-kickback statute places constraints on business arrangements related directly or indirectly to items or services reimbursable by federal health care programs, including Medicare and Medicaid.³⁷¹ The statute criminalizes certain practices the health care industry that are common in other business sectors, such as offering or receiving gifts to reward past or current referrals.³⁷² In sum, the anti-kickback statute prohibits offering or paying anything of value in return for paying, leasing,

368. 42 C.F.R. §§ 411.357(a), (b), (d) (2009)

369. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51,012, 51,028 (Sept. 5, 2007) (to be codified at 42 C.F.R. § 411.354).

370. Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III), 72 Fed. Reg. at 51,028

371. OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. at 56,841.

372. *Id.*

ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable in whole or in part by a federal health care program.³⁷³ To receive protection, an otherwise suspect arrangement must comply with one of the enumerated safe harbors.³⁷⁴ However, as the statute takes into account the circumstances of each arrangement, such as intent of the parties, failure to comply with a safe harbor does not mean that an arrangement is illegal *per se*.³⁷⁵ Nevertheless, facilities should structure arrangements to fit within a safe harbor whenever possible.

Because retail medical clinic operators and pharmacies owned by the “host” retailer may refer federal health care program patients to each other, the anti-kickback statute may be triggered under the provision of anything of value by either party to the other.³⁷⁶ Remuneration exchanged between a RMC operator and pharmacy or host retailer may include safe harbors such things as rent, service or practice management fees.³⁷⁷ New York state regulators have taken note of this risk and are investigating the business relationship between host retailers or pharmacies and RMC operators to determine whether the clinics are being misused to add business or attract patients into pharmacies that house the clinics.³⁷⁸

A retail medical clinic can mitigate risk, however, by structuring any arrangements with host stores to fit within the safe harbors for space and equipment rental, and the personal services exception.³⁷⁹ RMC operators may also exclude a revenue share common with other retail leases of space for specialty services (e.g. Starbucks, banks) to avoid the perception that the clinic is paying the host store in exchange for referrals.³⁸⁰ In addition, EHR or electronic prescribing items and services (e.g. software or information technology and training services) may fall within an anti-kickback statute safe harbor and, if so, would not be considered “remuneration.”³⁸¹

Moreover, retail medical clinics typically arrange for physicians to provide medical director, quality assurance, and other services.³⁸² While

373. *Id.*

374. OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. at 56,842.

375. *Id.*

376. Belfort, *supra* note 36.

377. *Id.*

378. Hsu, *supra* note 7, at 21.

379. 42 C.F.R. § 1001.952(b), (c), (d) (2009). These safe harbors generally require that the space or equipment rental or personal service agreement be set out in writing, signed by the parties, for specified period of time no less than one year, and with payment set in advance and based on fair market value. 42 C.F.R. § 1001.952(b), (c), (d).

380. See CHCF 2006, *supra* note 2, at 19.

381. 42 C.F.R. § 1001.952(x)-(y).

382. OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 56,832, 56,843 (Sept. 30, 2008)

this allows the physicians to increase the quality of care furnished to RMC patients, these physicians may also be in a position to garner federal health care program business for the retail clinic.³⁸³ For instance, they may order items and services. As such, RMC operators must monitor physician arrangements to ensure that the RMCS are not being utilized to pay physicians for referrals.³⁸⁴ To avoid the perception that the clinic is a vehicle for referrals to and from physicians, the host store or pharmacies, a RMC operator may consider implementing a business conduct rule that promotes and enforces good referral behavior among the clinic's physician and nonphysician employees.

G. Liability

Medical malpractice is “an act or omission by a health care provider that deviates from accepted standards of practice in the medical community and results in injury, damage, or loss to the patient.”³⁸⁵ The unique way that retail medical clinics deliver care – through licensed nurse NPs and PAs – has the potential to complicate the liability environment. The AMA says that RMCs interrupt the relationship between patients and their doctors making it difficult to determine who is accountable when problems arise.³⁸⁶ The primary issue is that no patient-physician relationship is created when a patient visits a RMC (unless the patient actually sees a physician). Since some states require patients to have a formal relationship with their physician before the patient can file a medical malpractice claim, this lack of a relationship would hinder a potential plaintiff's ability to file suit directly against the physician.³⁸⁷

However, liability may be found through the acts of the supervising physician. Supervising practitioners can be held liable for the acts of those under their supervision if they fail to provide adequate and reasonable supervision (negligent supervision).³⁸⁸ Moreover, as PAs or NPs practicing under a physician's supervision are generally presumed to be the physician's agent, a physician is liable for negligent acts committed by allied health professionals while practicing under the physician's supervision.

This does not mean that supervised allied health professionals are free from risk of liability. Independent practitioners can be liable for incorrect

383. OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. at 56,844.

384. *Id.*

385. Kershaw Cutter Ratinoff LLP, Medical Malpractice, <http://www.kcrlegal.com> (last visited Apr. 9, 2010).

386. Hsu, *supra* note 7, at 21.

387. *Id.*

388. ASSESSING SCOPE, *supra* note 323, at 2.

diagnosis and treatment recommendations and for failure to necessarily refer patients.³⁸⁹ In addition, supervised practitioners may also be held independently liable for negligence. The standard for determining malpractice is whether the healthcare provider exercised the specific knowledge and skill of similar professionals.³⁹⁰ Therefore, NPs or PAs who work in RMCs are legally responsible for actions that fail to meet the standard of care.³⁹¹

At least one state—Texas—has specified statutorily that different standards of care apply to physicians than those applied to allied health providers. The statute provides that an allied health provider is accountable for advanced practice nursing care, but not a doctor's care, even when making diagnoses, since diagnoses are considered to be made within the confines of a physician's written authorization.³⁹² The delegating physician may remain responsible for delegated medical acts.³⁹³

Particularly if retail medical clinic operators expand the scope of care offered beyond basic medical necessity, the liability issue may complicate the clinics' growth and popularity. Retail clinics will cease to exist if they can be sued for failing to detect and diagnose serious medical conditions most properly suited for a primary care physician or specialist. To stay true to their purpose and minimize liability, RMCs must be transparent about their purpose and limitations. Patients must know exactly what to expect in terms of diagnostic care and treatment.

CONCLUSION

In this era of consumer-driven health care, retail medical clinics are well positioned to become a permanent fixture in the United States' system of health care delivery. As health care spending in the United States zooms past \$2 trillion annually, and the underlying cost of medical services and insurance premiums increase, RMCs offer quality medical care at a reasonable cost. Consumers who use retail clinics appropriately instead of emergency rooms or physician offices may reduce not only individual out-of-pockets costs, but overall health system costs as well.

Quality, cost-effective health care is an enticing proposition, particularly in the current economic climate. Many Americans have reported changing their consumption of health care services to curb costs, such as by skipping necessary health care.³⁹⁴ Many acknowledge that lower prices for health

389. *Id.* at 11.

390. Hsu, *supra* note 7, at 21.

391. *Id.*

392. *See generally id.*

393. *See generally id.*

394. *Id.* at 3.

care and insurance would make a difference in families' financial situation.³⁹⁵ RMC's lure of affordable basic health care services makes them well poised to grow as a participant in the health care delivery system.

To be successful, routine and preventive care must be available without disrupting activities of daily life. RMCs are a friendly reminder to shoppers about routine and preventive care, and may be able to better help patients manage their chronic conditions through convenient access to health care technology and services. Retail medical clinics also have the potential to increase access to basic health care in rural or underserved communities. While not every person lives close to a primary care provider or hospital, half of Americans live within five miles of a Wal-Mart, and ninety percent live within fifteen miles of the superstore.³⁹⁶ As one commentator noted, "If you are trying to put care where people are, following large retailers is not a bad strategy."³⁹⁷

To date, however, this potential has not yet been realized. A 2009 study of geographic accessibility of retail medical clinics found that retail clinics are more likely to be found in areas with higher resident income and less likely to be located in medically underserved areas.³⁹⁸ The authors suggested that, if policy makers decide that retail clinics should be an important component of health care accessibility, they may need to actively address the location given the community's health care needs.³⁹⁹

Though promising, retail clinics are not without legal challenge. The few states that have attempted to directly regulate retail medical clinics been met with criticism by the FTC due to the proposed legislations' anticompetitive undertones. The relationship between retail medical clinics and the host stores or pharmacies that house them has the potential to spark fraud and abuse concerns, whether perceived or legitimate. Retail medical clinics must abide by state-specific regulation on scope of practice of the various mid-level practitioners who work for the clinics, particularly to minimize exposure to litigation and keep within the clinics' intended purpose of a supplement, not replacement, to primary care physician offices.

These legal obstacles have not slowed retail medical clinic operators. The consumer benefits of cost and convenience, combined with the potential for growth and expanded consumer base from a retailers' perspective, make the legal challenge inherent in running a retail medical clinic well worth the effort.

395. *Id.* at 4.

396. Sage 2008, *supra* note 1, at 1242.

397. Sage 2007, *supra* note 146, at 515.

398. Craig Evan Pollack & Katrina Armstrong, *The Geographic Accessibility of Retail Clinics for Underserved Populations*, 169 ARCHIVES OF INTERNAL MED. 945, 947 (2009).

399. *Id.* at 949.