

# DEALING WITH THE EMERGENCE OF CONVENIENT CARE RETAIL CLINICS:

A Guide for Health Centers



NATIONAL ASSOCIATION OF  
Community Health Centers

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## INTRODUCTION

This document will acquaint Health Centers (also known as Federally Qualified Health Centers, or FQHCs) with convenient care ‘retail’ clinics. These clinics are providing limited health care services under a new delivery model. Some analysts have identified the development of convenient care ‘retail’ clinics as an innovative development that has the potential to change the way primary care delivery works. Convenient care retail clinics are opening at an increasing rate all across the country - currently there are over 800 clinics in at least 37 states.

Convenient care clinics have generally opened as a business strategy, sometimes in response to access issues – inconvenient hours of service or geographical locations, long delays for appointments and service – issues common today in primary care and indeed all of mainstream medicine.

In this context, the development of convenient care clinics can represent both a challenge and an opportunity to FQHCs and other community-based primary care providers: they may impact mission and finances positively or negatively.

**The following questions will be addressed in this guidance:**

- **What is a convenient care ‘retail’ clinic?**
- **What makes convenient care clinics different from safety net primary care providers?**
- **What have been the various responses to the emergence of convenient care clinics — by governments, providers, and customers?**
- **What impact can a local convenient care clinic have on an existing FQHC?**
- **Are convenient care clinics likely to be an enduring provider model?**
- **How can an FQHC respond to the emergence of convenient care clinics?**
- **How can I determine whether or how my FQHC should respond to convenient care clinic developments in my community**
- **What kinds of challenges can be expected in FQHC ownership and/or operation of a convenient care clinic?**
- **Can an FQHC operate a convenient care clinic and have all the benefits of FQHC status for that clinic?**
- **Can a center operate a convenient care clinic as a ‘separate line of business’ and keep its existing center’s FQHC status?**
- **What kinds of involvement with the convenient care model are FQHCs experiencing?**

## What is a convenient care 'retail' clinic?

A typical convenient care retail clinic is a health care facility offering:

- ...a limited, posted set of primary health care services,
- ...that is not comprehensive care,
- ...and that does not include ongoing chronic disease care,
- ...but does include preventative services,
- ...that can be delivered quickly,
- ...in high volume,
- ...at a low price (which is posted),
- ...in limited space,
- ...with little likelihood of complications or required follow-up,
- ...typically by nurse practitioners or physician assistants,
- ...who support the 'medical home' concept, and therefore,
- ...will require outside primary care providers for consultation and referral.

These kinds of health care facilities were initially called 'retail' clinics, probably because they were typically located in retail locations (often in leased space), and because they sold health care services for a profit much as other goods and services are sold in stores. However, this is no longer necessarily true. Now such clinics may be located in a range of sites, including freestanding facilities. And some of these clinics are operated as non-profit enterprises. All stress rapid service with no appointments and little or no waiting. The industry has chosen to identify these clinics instead by the feature that they all continue to share: the promise of quick, local episodic care. Thus they refer to these clinics by the term "convenient care".

Convenient care clinics do not provide comprehensive, ongoing care, by design. In addition to limited acute primary care, convenient care clinics

typically provide preventive services, including screening for conditions such as diabetes, hypertension, cholesterol, and obesity, as well as vaccines.<sup>1</sup>

The limited set of services that can be profitably and quickly provided in the convenient care clinic setting precludes comprehensive care. Similarly, chronic disease care requires ongoing care management and thus is regarded as not appropriate in the convenient care clinic setting.

Of note, convenient care clinic companies and Convenient Care Association (CCA) policies support the 'medical home' concept, and require that patients be referred to other providers for comprehensive care<sup>2</sup> and for services not included in the clinic 'menu'. Convenient care clinics which are members of the CCA use standardized clinical protocols grounded in evidence-based medicine. CCA members also support a set of quality and safety standards that seek to address concerns raised by other providers and health care regulators.<sup>3</sup> More information is available at the CCA website, [www.convenientcareassociation.org](http://www.convenientcareassociation.org).

Individual convenient care clinics can vary somewhat from the above description, and can have one of several organizational structures (which will be discussed in a later section of this brief.) Since convenient care clinics exist in a competitive environment where their competitors are each seeking to build a unique 'brand identity,' each company that operates these clinics can be expected to 'tweak' the clinic model to give it a competitive advantage.

## What makes convenient care clinics different from safety net primary care providers?

Convenient care clinics have **developed along a different path from safety net primary care delivery systems.** Whereas primary care providers, groups and systems (including FQHCs) typically form in response to an assessment of community health and the need to provide care to address community primary care shortfalls, convenient care clinics developed from a business strategy that focuses on increasing the convenience of primary care to the public in order to be profitable and self-sustaining. This gives the convenient care industry a different perspective on health care delivery, although with similar outcomes, i.e. improved access to primary care, albeit limited in scope. Rather than being developed within local primary health care delivery systems, convenient care clinics have been developed outside these systems, and have only recently begun seeking to achieve integration with other healthcare partners.

Convenient care clinics **have generally operated in a comparatively unregulated environment, at least until recently.** Due to their small size, limited menu of services, and typical use of nurse practitioners for care delivery, these convenient care clinics are specifically designed to operate under minimal constraints and with minimal complexity.

Unlike most primary care providers who are locally or regionally-based, many commercial convenient care clinic companies are **designed to operate on a multi-state or even a national scale,** using a common model across widely different communities.

Although the convenient care clinic model can be used by any kind of primary care organization, the industry **leaders thus far have been commercial firms dependent on profitability,** and thus may be perceived as less committed to the communities they serve than existing primary care providers.

Unlike safety net primary care providers, convenient care clinics **do not offer comprehensive care.** Rather than offering to treat the 'entire patient', convenient care clinics provide only episodic care and services which allow for low cost and easy access. They must rely on other providers, including FQHCs, to address their customers' need for comprehensive care.

## **What have been the various responses to the emergence of convenient care clinics — by governments, providers, and customers?**

### **Governments**

Governments at the Federal, state, and local level have generally not yet addressed regulation of convenient care clinics. One exception has been the state of Massachusetts, where state health regulators assessed the request by CVS/Minute Clinics to waive certain state regulations in order to support the operation of convenience care clinics. The state did waive the regulations, and the state health commissioner endorsed the convenient care clinic model. However, the mayor of Boston went on record as opposing the development of convenient care clinics. The Health Resources and Services Administration (HRSA), of the Federal Department of Health and Human Services, which manages the FQHC program, has not yet issued policy on convenient care clinics. It is reportedly examining the issue in response to numerous FQHC requests.

### **Provider Organizations**

Despite the novelty of the convenient care clinic model and the potential financial threat it might pose to some primary care providers, health care industry response – which at first was stridently negative, has lately softened somewhat. The American Association of Family Physicians (AAFP), the American Medical Association (AMA), and the American Association of Pediatricians (AAP) have all questioned the appropriateness of convenient care clinics, but they have also acknowledged their reality and likely future. The AAP, for example, has expressed concern over:

- Fragmentation and possible effects on quality of care,
- Care for children with special needs,
- Lack of access to a central health record,
- Use of tests for diagnosis without proper follow-up, and –
- Public health issues surrounding exposure to contagious diseases in a retail environment.

All three organizations have issued guidelines for appropriate convenient care clinic operations, which the convenient care clinic industry has embraced.<sup>4</sup> In the case of the AMA, the organization adopted the following principles for such clinics (which it refers to as “store-based clinics”):

- 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 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 those with medical degrees (MD and DO) 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 any 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 continuity of care.

Anecdotal reports suggest that primary care physicians are becoming less worried about the impact of convenient care clinics on their practices. Some providers may even be pleased with the referrals they receive.

### **Customers**

To date customer response has been positive and sufficient to grow the industry, and is likely to increase as more clinics become available and customers become familiar with them. The industry reports more than 500,000 U.S. households have used convenient care clinics. Harris/Wall Street Journal surveys in 2005 and 2007 reported high levels of patient satisfaction. And a survey in April 2007 reported that 12% of convenient care clinic patients with primary care physicians claim that "retail clinics have mostly or completely replaced my primary care physician for the type of treatments offered at convenient care clinics."

## **What impact can a local convenient care clinic have on an existing FQHC?**

A convenient care clinic can potentially have negative impacts on an FQHC. Among the impacts, such a clinic can hurt FQHC finances by:

- Reducing FQHC visit volume by providing services at the convenient care clinic that is also provided at the FQHC clinic,
- Changing the FQHC patient payer mix by attracting existing patients (especially those with coverage), and by
- Referring predominantly low-income, uninsured patients to the FQHC (i.e. “dumping”).

Convenient care clinics can also potentially:

- Disrupt FQHC patients’ continuity of care due to poor linkage of FQHC and convenient care clinic care.
- Place unanticipated burdens on FQHC clinical staff related to care management, with patients potentially receiving fragmented care from multiple providers.
- Disrupt FQHC growth plans, and even current operations.
- Increase competition for mid-level providers.

Local convenient care clinics can also potentially have positive effects on an FQHC. Referrals from the convenient care clinic can (assuming availability of resources and capabilities at the FQHC):

- Increase FQHC overall visit volume.
- Increase the number of registered FQHC patients.
- Reduce episodic care levels, allowing FQHC clinical staff to concentrate on more pressing and chronic conditions.
- Allow the FQHC to treat additional populations.

While FQHC patients may choose to obtain some of their care at the convenient care clinic, if communication between the clinic and the FQHC is appropriate, assuming the clinic provides quality care, an overloaded FQHC may be able to provide more timely and effective care for those patient conditions beyond the limited scope of the convenient care clinic.

## **Are convenient care clinics likely to be an enduring provider model?**

Since the convenient care industry's history is brief and still in the development phase, it is not yet clear whether convenient care clinics are likely to survive over time as significant providers. However, some evidence of the industry's prospects can be documented.

- The convenient care industry continues to expand rapidly from the first clinic in 2000 to over 800 at the beginning of 2008, with an expanding number of clinic companies.
- The convenient care clinic industry requires a modest capital investment.
- So far, the convenient care clinics have received:
  - a. Guarded acceptance, and even some vocal opposition, from other provider organizations
  - b. Approval and support from many employers
  - c. General support from insurers
  - d. Strong customer approval<sup>5,6</sup>
  - e. Some government approval.

Note that convenient care clinics may change their services and methods of operation over time as a result of market forces and future government regulation.

## How can an FQHC respond to the emergence of convenient care clinics?

An FQHC can respond to the emergence of convenient care clinics in a number of different ways. The responses can range from passive or active resistance to cooperative relationships to FQHC ownership and operation of convenient care clinics.

Models of FQHC response to the emergence of convenient care clinics include:

### A. Non-Engagement Responses

**1. Resistance** -- An FQHC can resist the introduction or presence of convenient care clinics in its target communities. Organizations have sought to block convenient care clinics by lobbying for imposition or enforcement of legal or regulatory restrictions. To date, these efforts have generally not been effective.

**2. Avoidance** -- An FQHC can seek to avoid adverse impacts from convenient care clinics. While an FQHC should always strive to locate its facilities within easy reach of its target population, it might wish to avoid locating facilities where it might be in direct competition with convenient care clinics and/or discourage its patients from utilizing the services of convenient care clinics already in the FQHC target areas.

**3. Competition** -- An FQHC may choose to address the market forces driving convenient care clinics to minimize convenient care clinic impacts. FQHCs can seek to provide care that is sufficiently convenient, with extended hours of operation and with prompt visit scheduling and short waits at the clinic, such that convenient care clinics have no special appeal for the FQHC's patients.

**4. Start your own.**

### B. Partnership Responses Involving Cooperative Arrangements

An FQHC can partner with convenient care clinics without clinic ownership through cooperative arrangements involving referrals and clinical oversight services.

Convenient care clinics do not provide a medical home, so they will need to refer patients to other providers for follow-up and comprehensive care. A convenient care clinic is free to refer patients to an FQHC for follow-up without an agreement. However, a negotiated agreement can reduce the risk that only certain patients (e.g., low-income, uninsured) will be referred, and can help the FQHC serve as a medical home for the referred patients. According to the

Convenient Care Association, more than one-third of all convenient care clinic patients have indicated that they have no regular source of health care.

**1. Receive referrals** -- An FQHC can arrange to accept referrals from a convenient care clinic, and offer to provide a 'medical' home for those patients.

**2. Provide clinical oversight/medical records review** -- An FQHC can provide physician oversight to the convenient care clinic non-physician staff, and/or conduct medical records review (*but* see later discussion of liability and scope of project concerns).

### C. Ownership Responses

If FQHCs choose to secure partial or complete ownership of a convenient care clinic, they will need to provide one or more of the three services necessary for convenient care clinic operation:

- **Clinical services**
- **Administrative services**
- **Clinic site ownership and management services.**

**1. Staffing** -- An FQHC can partner with a convenient care clinic company by providing clinical staffing, while the convenient care clinic company provides administrative services, and a retailer provides clinic space. Clinic management and branding would be negotiated. The new Wal-Mart model combines the clinical staffing, administrative services and site management in one company.

**2. Franchising** -- An FQHC can contract to operate a convenient care clinic. It would assume responsibility for providing the clinical services, providing or leasing space, and handling administrative and billing functions, although it could contract with an outside company to provide clinic design, guidance, and some administrative services unique to operating the convenient care clinic model.

**3. Leasing retail store space** -- An FQHC can directly operate a convenient care clinic by managing the clinical and administrative services, but renting space in an existing retail store. This is the 'classic' convenient care clinic model.

**4. Complete ownership/operation** -- An FQHC can establish and operate a convenient care clinic, providing all clinical and administrative services either at an existing site or at a leased/purchased freestanding site.

**To assess its own capabilities, the FQHC needs to:**

- ✓ Review available capital, payer mix, clinical mix and excess capacity, administrative resources and skill set, and existing strategic plans.
- ✓ Assess organizational willingness to undertake additional risk, demands on staff, and involvement in a new business venture.
- ✓ Review available technical assistance resources, and how they may be accessed using FQHC, PCA and/or NACHC resources.

Then the FQHC can determine if partnering with, or owning/operating, a convenient care clinic is a worthwhile strategy.

**Possible benefits to an FQHC's patients of partnership or ownership include:**

- ✓ Improved patient access: reduced travel and reduced appointment and visit waiting times for some patients for some services.
- ✓ Reduced costs for some self-pay patients with incomes above 200% of the poverty level.
- ✓ Improved access and reduced costs may encourage some patients to seek more timely care.

**Possible benefits to the FQHC include:**

- ✓ More patients.
- ✓ Improved center finances (but only if revenues equal or exceed expenses).
- ✓ Access to new populations and communities within the FQHC target area at minimal cost.
- ✓ Potentially improved patient perception of customer service.
- ✓ Improved payer mix.
- ✓ Extended influence on community primary care delivery.

**Note that:**

- Other business entities may seek an FQHC as a partner. The FQHC needs to be prepared for serious negotiations (and to say 'no' to unacceptable conditions.)
- Right now, every locality has unique local conditions that will determine whether, and how, an FQHC can be successfully involved with convenient care clinics.
- Ramp-up: since achieving "break-even" for a new convenient care clinic can take a year or more, provision must be made for covering possibly significant ramp-up costs.
- FQHCs need to do a pro forma analysis of the viability of a proposed convenient care development in or out of their Federally-approved scope of project.

## How can I determine whether or how my FQHC should respond to convenient care clinic developments in my community?

The model of convenient care clinic participation that is best for a particular FQHC is a function of the mission and resources of the FQHC, the nature and goals of the partner, if any, and conditions and developments within the local community. FQHCs need to determine what convenient care clinic model best matches their resources and mission, what the current needs of the target population are, and what new or expanded services, including convenient care clinics, other providers may be planning. To do this, an FQHC should assess the local environment and the FQHC's capabilities (which are best done as part of the individual FQHC's strategic planning process).

- **Review the history of any convenient care clinics in the local or nearby communities.** Find out if any convenient care clinics are, or have been, in operation in the area. Research their ownership, history, and what their success has been. (Given the competitive nature of some convenient care clinic enterprises, some information may be difficult to secure). Visit the clinic(s) to see their site location, clinic layout, services offered, method of operation, and level of utilization.
- **Research whether to become involved with large local retailers and pharmacy chains in the operation of convenient care clinics.** These businesses are currently the most common sites for convenient care clinics, and their desire to increase customer traffic, combined with their awareness of their own lack of expertise in managing a health care delivery system, may lead them to seek a knowledgeable local provider to operate an on-site convenient care clinic. Information on the larger chains is most commonly available through corporate headquarters. The FQHC should seek to be on the distribution list of any future requests-for-proposals to operate convenient care clinics.
- **Identify prospective convenient care clinic companies and their operations** both to see if any local convenient care clinics are planned, and if so, whether partnership opportunities exist. Commercial convenient care clinic companies may be reluctant to reveal expansion plans, but may be willing to work with a well-regarded provider like an FQHC.
- **Determine whether local hospitals are planning to develop convenient care clinics in your community.** Hospitals have

begun to explore and undertake convenient care clinic strategies. Local hospitals involved with convenient care clinic strategies should be contacted for insights that can be gained from their experience, and as investigated as possible competitors or partners.

- **Assess local Medicaid managed care organizations (MCOs) to determine if any would be interested in supporting an FQHC convenient care clinic.** Medicaid MCOs in a competitive MCO marketplace that cover many of an FQHC's patients might be willing to subsidize a convenient care clinic. The MCO may see such a clinic as a way to improve existing customer satisfaction, to reduce after-hours use of local emergency rooms, and to recruit additional members for enrollment.

### **What kinds of challenges can be expected in FQHC ownership and/or operation of a convenient care clinic?**

Challenges will be a function of the specific structure of the convenient care clinic and local conditions. Possible challenges include:

- Working with convenient care clinic partners whose business goals are primarily market-driven.
- Working with convenient care clinic partners that have different organizational cultures and public images.
- Maintaining an acceptable level of FQHC influence/control over convenient care clinic operation (negotiating appropriate contract language is essential).
- Possible incompatibility of the convenient care clinic's goals and the FQHC's mission to serve all in the community and to make its care affordable for low-income uninsured populations (see following section for more discussion of these issues).
- Maintaining a manageable clinical case mix.
- Maintaining a financially stable payer mix.
- Finding locations that serve the health center's target populations.
- Establishing and maintaining adequate clinical reporting between the convenient care site and the FQHC site.
- Establishing and maintaining compatible electronic health records systems between the convenient care site and the FQHC site (software can be used as an interface to link the two systems).
- Accepting that in a partnership, the convenient care companies may not wish to make long term commitments that don't provide a profitable potential volume.
- Working with clinic partners that may not have any long-term commitment to the target populations and communities.



## **Can an FQHC operate a convenient care clinic and have all the benefits of FQHC status for that clinic?**

An FQHC is subject to Federal regulations and policy as administered by the Bureau of Primary Health Care (BPHC) within the Federal Health Resources and Services Administration (HRSA) for activities performed within its approved scope of project. BPHC has not yet issued clear policy relating to FQHCs and convenient care clinics. NACHC's General Counsel has advised that it should be possible for FQHCs to operate convenient care clinics within the health center's approved scope of project (i.e. with the benefits and protections uniquely afforded to the FQHC) under certain circumstances. For example, the convenient care clinic would have to operate in accordance with the health center's Board approved policies and procedures and under the direction of the health center's management team. However, these policies and procedures may impede an FQHC in operating a successful convenient care clinic in a competitive environment. *A copy of counsel's memorandum is attached.*

BPHC's initial response to inquiries from health centers, *a redacted copy of which is attached to this document*, has indicated that, in its view, in order for a convenient care retail clinic site to be eligible for inclusion within a health center's Federal scope of project, all current Health Center program requirements would have to be met, in particular:

- Services for those below 200 percent of the Federal poverty level (FPL) would have to be available on a sliding fee scale;
- Discounts using the section 330 funds or related program income could not be provided to those above 200 percent of the FPL;
- No patient could be denied care based on inability to pay; and –
- All patients must have reasonable access to the full complement of services offered by the health center (even if some of those services are available only at other health center sites).

BPHC can be expected to provide more comprehensive convenient care guidance to FQHCs in the foreseeable future.

While operating a convenient care clinic within its scope of project extends FQHC benefits and protections to the health center and its patients, doing so may also come with restrictions that make the expansion non-viable (such as the requirement to use the FQHC's sliding fee scale system for low-income patients with limited or no health insurance), especially if there are no additional funds to support otherwise uncompensated care costs.

## **Can a center operate a convenient care clinic as a ‘separate line of business’ and keep its existing center’s FQHC status?**

NACHC’s general counsel memorandum indicates that an FQHC may be able to operate a convenient care clinic as a separate line of business, i.e., outside of the scope of project, without jeopardizing its FQHC status. In such cases, the health center’s convenient care clinic site would not have to meet the requirements listed in the previous section; however, the convenient care clinic site would not be eligible for any of the benefits and protections of FQHC status, including:

- Federal Tort Claims Act (FTCA) coverage for the clinical activities of staff working at the convenient care sites;
- Special Medicare and Medicaid all-inclusive per-visit FQHC payment rates and “wrap-around” payments for care provided to Medicare and Medicaid beneficiaries at the convenient care sites;
- Access to 340B discounted-price pharmaceuticals for those served at the convenient care sites; and –
- Use of Vaccines for Children (VFC) vaccines for under-insured children receiving care at the convenient care sites (note: VFC vaccines could still be used for uninsured children and for Medicaid and SCHIP beneficiaries).

Moreover, convenient care clinic operating funds would need to be separated from FQHC operating funds. Equally important, operating a convenient care clinic as a separate line of business would expose the FQHC to the risks of a relatively unregulated market.

## What kinds of involvement with the convenient care model are FQHCs experiencing?

- An FQHC multi-site network is partnering with a Medicaid MCO to set up a convenient care clinic in a regional supermarket site serving one of the FQHC's target populations. In a competitive Medicaid managed care environment, the MCO seeks to maintain and expand its Medicaid market share by providing increased convenience and customer satisfaction to its Medicaid recipients served by the FQHC. The supermarket company is eager to generate additional visitors to its store. The FQHC seeks to provide additional, convenient care to existing patients, and recruit new patients. The FQHC has negotiated financial support for ramp-up from the MCO and clinic site build-out support from the supermarket chain. The FQHC intends to operate the convenient care clinic as part of its FQHC scope of project with the applicable FQHC benefits, and is seeking BPHC approval. The FQHC also plans to open in-house convenient care-modeled services at its existing FQHC sites. The in-house convenient care clinic model adopted by the FQHC will provide the same rapid care for a limited range of services.
- An FQHC reports that a convenient care clinic in the FQHC's area was able to recruit one of the FQHC's Nurse Practitioners. The Nurse Practitioner was apparently attracted by the working hours. However, the Nurse Practitioner subsequently rejoined the FQHC, indicating dissatisfaction with the convenient care clinic's "quality of care". The convenient care clinic site subsequently closed.
- A multi-site rural FQHC applied to operate convenient care clinics in response to a request-for-proposals from Wal-Mart. The FQHC has not yet received a response. In the interim, Wal-Mart has announced a new corporate approach to their convenient care clinic modeling, which includes partnering and co-branding with outside providers. An analysis by the FQHC suggested that the convenient care clinics would only be financially feasible if conducted within the scope of project. The FQHC has made a request to BPHC to allow incorporation of the convenient care sites into the FQHC's scope of project, and has received an initial response similar to that indicated earlier (on page 17). The FQHC is waiting for a Wal-Mart response, and is seeking a re-consideration of its request by BPHC.
- FQHCs in a region are observing the aggressive introduction of a new primary care services chain which is incorporating some elements of the convenient care clinic model: promises of low cost and little waiting, but with more comprehensive primary care for a monthly fixed fee.

## Summary Considerations

Convenient care clinics are an expanding and evolving primary care provider model nationally. They are popular among customers and many insurers; accordingly, primary care providers are examining how the convenient care model can affect them. Convenient care clinics are likely to affect many FQHCs, whether the FQHCs choose to partner or not. In any event, FQHCs should consider whether to adopt certain features of the convenient care clinic model in their operation. These opportunities have different benefits and risks. FQHCs can examine these models and determine if any of them are a good fit.

*A table of convenient care clinic sites by state and sponsoring company, as of January 2008, is attached.*

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<sup>1</sup> MinuteClinic website, February 2008.

<sup>2</sup> Press release. *Convenient Care Association Issues Industry-Wide Quality and Safety Standards Leading Retail Health Care Operators to Accept and Support Mandatory Standards for Growing Industry.* Convenient Care Association... March 28, 2007.

<sup>3</sup> *Convenient Care Association* website, February 2008

<sup>4</sup> See for example, the American Academy of Family Physicians' stance, at <http://www.aafp.org/online/en/home/membership/initiatives/retailclinics.html>; or the American Academy of Pediatrics' position at [http://www.aap.org/sections/soapm/RBC\\_home.html](http://www.aap.org/sections/soapm/RBC_home.html).

<sup>5</sup> PR Newswire, United Business Media, April 2, 2007.

<sup>6</sup> Wall Street Journal Online. *Most Adults Satisfied with Care at Retail-Based Health Clinics.* 6:6, April 11, 2007.[Online] Available [http://www.lharrisinteractive.com/news/newsletters/Wsjhealthnews/HI\\_WSJ\\_HealthCarePoll\\_v06\\_i06.pdf](http://www.lharrisinteractive.com/news/newsletters/Wsjhealthnews/HI_WSJ_HealthCarePoll_v06_i06.pdf).



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**TO:** Malvise Scott, SVP for Partnership and Resource Development  
Jason Patnosh, Director of Partnership Development  
National Association of Community Health Centers, Inc.

**FROM:** Jacqueline Leifer *JL*

**DATE:** August 16, 2007

**RE:** Retail Based Clinics

This memorandum is written in response to your request for legal guidance regarding questions raised by health centers as to the permissibility of operating retail based clinics.

**1. ~~Can a health center operate a retail based clinic (RBC) as a federally qualified health center (FQHC) or as an "other line of business" (OLB)?~~**

The following response is subject to restrictions that may be imposed: (1) by State law, *e.g.*, licensure limitations, certificate of need requirements, *etc.*, and/or (2) by contract, *e.g.*, the retail store may require a RBC operator to provide particular services which a FQHC may or may not be able legally to provide; the store may require the health center to provide proof of commercial professional liability insurance, which a health center deemed eligible for coverage under the Federal Torts Claims Act (FTCA) may or may not be willing to procure.

Nothing in Section 330 of the Public Health Service Act (42 U.S.C. § 254b), the implementing regulations (42 C.F.R. Part 51c), and/or related Health Center Program Expectations (Policy Information Notice [PIN] # 98-23 [August 17, 1998]) or other policies issued by the Health Resources and Services Administration (HRSA), restricts the location(s) at which a FQHC may offer services. In the FY 08 Service Area Competition Guidance (Announcement # HRSA-08-005, 08-006, 08-007, 08-008; issued March 22, 2007, at p. 126), HRSA includes a very broad definition of "Service Site," defining it as "any place where [a health center], either directly or through a subrecipient or contract arrangement, provides primary health care services to a defined service area or target population." In order to be considered a health center site, the following conditions must be met:

- Encounters are generated by documenting in the patients' medical record face-to-face contacts between patients and providers;
- Providers exercise independent judgment in the provision of services to the patient;
- Services are provided directly by or on behalf of the grantee, whose governing board retains control and authority over the provision of the services at the location; and
- Services are provided on a regularly scheduled basis (*e.g.*, daily, weekly, first Thursday of every month). However, there is no minimum number of hours per week that services must be available at an individual site/location.

Further, a health center may request a change in its approved scope of project to add a site that meets the aforementioned definition which is not located in, or serving, a medically underserved area or population, provided that in adding that site the health center will not diminish its commitment to the target population(s) currently in scope. *See* PIN # 2002-07: Scope of Project Policy (December 31, 2001) at p. 8. However, HRSA is currently reviewing its policies regarding scope of project, and particularly is evaluating whether certain locations (*e.g.*, corrections institutions, nursing homes) should continue to be approvable within scope. (See the discussion under Question # 2 below for the implications of HRSA approving the operation of a clinic in a retail establishment as part of the health center's scope of project).

If HRSA decides to establish a more restrictive policy, a health center remains free (subject to State law and contractual terms) to operate a RBC as an "other line of business," outside of its HRSA-approved scope of project. Of course, if the clinic is operated as an OLB, the health center will have to establish a separate cost center to account for revenues and expenses associated with the clinic(s). Because the OLB would be outside of the approved scope of project, the health center will not be able to:

- Use Section 330 grant funds, program income pledged to the Section 330 project or grant-supported resources to support the direct or indirect expenses of operating the clinic(s) [HRSA expects that there will be sufficient non-Section 330 related revenue to support the costs of operation of the OLB];
- Bill the Medicaid and Medicare programs for the enhanced payment rates it receives for services rendered to Medicaid and Medicare beneficiaries within the scope of project;
- Dispense Section 340B drugs to individuals served at these clinics, unless they are registered patients that receive primary care at health center sites within scope; or
- Avail itself (or its practitioners) of FTCA coverage for claims related to services rendered at the RBC(s). [Query: given the limited scope of services typically offered by RBCs (*i.e.*, no prenatal care or deliveries, no complex tests), what would the cost of malpractice insurance or an expanded gap policy likely be?]

*See* PIN # 2002-07 at pp. 3 – 4.

If operated as an OLB, it is possible that the revenues generated by a RBC might be considered "unrelated business income" of the health center (pursuant to Internal Revenue Service (IRS) rules) and, therefore, may be taxable. If this income is substantial, the health center's tax exemption might be threatened. For this and other reasons (*e.g.*, to separate the liabilities and thereby shield the health center's assets; to create "distance" so as to address issues regarding different fee schedules and a different scope of services), it may make sense to establish a separate corporation to operate the RBCs (but licensure and other State law issues would need to be considered).

**2. If a health center is permitted to operate a RBC within its HRSA- approved scope of project, what are the requirements, given that the health center will not furnish its full scope of services at the RBC site?**

Health centers are not required to provide every service at every site. *See* PIN # 2002-07 at p. 5. The question is whether the full scope of services offered by the health center as a whole is readily available and reasonably accessible to all of the health center's patients, either at another site within the health center's scope of project or through an established arrangement(s) with another provider. Accordingly, the health center would have to analyze whether it has a site reasonably close by or whether it can establish an arrangement with another local provider, which would be available to all of the health center's patients. In assessing whether a site or an arrangement is "reasonably accessible," there is no specific mileage standard; transportation could be arranged from the RBC to a full-service health center site (or another provider) if necessary in order to assure access. Public transportation may also be an option.

Other concerns include:

- The health center will have to assure that it (or the other provider) has the capacity necessary to accommodate additional patients, as it would be expected to provide health promotion and outreach to the RBC patients and their families, encouraging them to make full use of the health center's broader services array.
- The retail establishment may require the health center to establish particular schedules of charges and discounts which are inconsistent with the health center's regular charge and discount schedules. Health centers are required to establish a schedule of charges designed to cover their costs of operation and consistent with locally prevailing charges, as well as a corresponding schedule of discounts which is applied to charges and is adjusted based on the patient's ability to pay for services. *See* 42 U.S.C. § 254b(k)(3)(G)(i); 42 C.F.R. § 51c.303(f). Whether HRSA would authorize health centers, for purposes of these locations only, to use a contractually agreed-upon rate structure should be determined. Even if this were authorized, having different charge structures for patients served at the RBC (as opposed to patients served at other health center sites) might present confusion and or local political problems for a health center.

- Similarly, the retail establishment may require the health center to provide discounts to families/individuals with annual incomes above 200% of the Federal Poverty Guidelines. The health center implementing regulations require health centers to charge full fees to such patients. *See* 42 C.F.R § 51c.303(f). Accordingly, Section 330 funds (and pledged program income) cannot be used to support discounts to individuals/families earning above 200% of the Federal Poverty Guidelines. Unless the health center secures another source of revenue to support discounts deeper than those permitted by law (*e.g.*, private donations, other State/local funding), whether HRSA would authorize health centers, for purposes of these locations only, to use a contractually agreed-upon discount structure that differs from the regulatory requirements should be determined. Even if this were authorized, having different discount structures for patients served at the RBC (as opposed to patients served at other health center sites) might present confusion and or local political problems for a health center.
- Most RBCs operate seven days a week and offer extended hours. Whether a health center has the clinical and administrative capacity and financial wherewithal to operate in accordance with such scheduling expectations is questionable.

**3. If the health center is permitted to operate the RBC only as an OLB, how might the arrangement be structured?**

We would expect many of these arrangements to be contractual in nature. In other words, the health center and the retail establishment would execute a standard lease agreement that contains several additional contractual terms designed to assure, among other things, that the retail establishment is held harmless from the liability exposures attendant to a clinic operation, as well as prescribing the service scope and charge approach, and possibly a required schedule of hours open to the public. Other terms might include: (1) use of a particular electronic health record (EHR) system; and/or (2) physical space design/signage use.

Internally, the health center would have to establish appropriate safeguards to ensure that its Section 330 grant funds, program income pledged to the Section 330 project and grant-supported resources are not used to support the direct or indirect expenses of operating the clinic(s). As discussed under Question # 1 above, HRSA expects that there will be sufficient non-Section 330 related revenue to support the direct costs of operating the OLB as well as a proportionate share of administrative overhead (if the RBC and the Section 330 project share the costs of certain functions, such as billing and other administrative tasks).

**4. If the retail establishment decides to operate the RBC under its own auspices, how can an arrangement between the health center and the RBC be structured?**



Alternatively, the retail establishment might operate its own clinics or contract with non-FQHCs to operate the RBC, rather than operating the RBC under the FQHC's auspices. Under this scenario, the health center could still be involved with the RBC by establishing a referral arrangement, executing a purchase of capacity agreement, or both.

In particular, RBC operators might seek to establish referral arrangements with local FQHCs to provide, for example, follow-up care that cannot be furnished at the RBC. Because FQHCs offer the full range of preventive and primary care services (including oral and behavioral health services), as well as case management and other enabling services, they can serve as a complement to the health care services provided at the RBC. However, insofar as health centers are intended to be medical homes, agreeing to refer patients to the RBC for services that can be provided by the health center directly in exchange for the RBC's referrals could be troubling. In addition, referring a patient to another provider who may charge less than the health center for particular services, while not offering deep discounts or nominal fees to the lowest income uninsured or underinsured patients would be problematic.

At a minimum, the health center should seek assurance, in a formal referral agreement, that:

- The RBC will provide high quality, culturally competent services;
- The RBC will accept any patient regardless of ability to pay or insurance status and, subject to patient freedom of choice and each clinician's independent medical judgment, will refer all patients for follow-up care (not only the uninsured and underinsured patients);
- All RBC clinicians are properly licensed and credentialed, not excluded from participating in Federal health care programs, and, as may be legally required, supervised;
- The RBC and its clinicians are properly insured against professional liability;
- Upon referral to the health center, the RBC will provide appropriate information regarding services provided and follow-up recommendations;
- There are no quid pro quos – no inducements for referrals of Federal health care program beneficiaries or for the purchase or lease of goods or services paid for, all or in part, by any Federal health care program.

In addition, the RBC might wish to contract with an FQHC to provide certain services, e.g., translation services, at the RBC. The RBC would purchase capacity from the health center to provide services to the RBC's patients, on behalf of the RBC. The RBC would remain the provider of the contracted services (assuming that the services are within the RBC's scope of services and licensure), and patients could receive follow-up care not provided by the RBC at the health center.



NOV 7 2007



Dear [REDACTED]:

Thank you for your email requesting clarification from the Bureau of Primary Health Care (BPHC) regarding the operation of a Retail-Based Clinic (RBC) within the Federal scope of project. The central question presented in your proposal is whether statutory and regulatory requirements of the Health Center Program pose any barriers to [REDACTED]

[REDACTED] operation of RBCs in your service area. Although Health Center Program requirements would not apply if [REDACTED] operated the RBCs as a separate line of business, you made clear in your email that you are not interested in this option. Without more specific information and a formal change in scope request, we cannot provide you with a formal BPHC decision on your proposal; however, we can suggest questions and issues to consider as [REDACTED] positions itself to operate RBCs in local Wal-Mart stores.

We appreciate your interest in taking advantage of a business opportunity that has the potential to help subsidize care to additional medically underserved patients. However, in order for RBC sites to be eligible for inclusion within the Federal scope of project, all Health Center Program requirements must be met. These requirements include:

1. services for those below 200 percent of the Federal poverty level (FPL) must be available on a sliding fee scale;
2. discounts using the section 330 funds or related program income cannot be provided to those above 200 percent of the FPL;
3. no patient will be denied care based on the inability to pay;

4. the governing board must have a consumer majority and be representative of the population served; and
5. all patients must have reasonable access to the full complement of services offered by the health center as a whole.

A request to add a RBC as a health center service site will be considered using the same criteria currently applied to all change in scope requests (see Policy Information Notice (PIN) 2002-07 and PIN 2007-14). If [REDACTED] decides to submit a request to add RBC sites to its Federal scope of project, you and your staff should be prepared to answer questions such as:

1. What is [REDACTED] plan for providing RBC patients with access to primary care services not offered at the RBC site? How will [REDACTED] staff ensure appropriate follow-up and coordination of care with staff at more comprehensive [REDACTED] sites?
2. How will [REDACTED] ensure that the RBC addresses the needs of special populations, such as the elderly, chronically ill, or children?
3. What is [REDACTED] plan for creating medical records for its RBC patients?
4. Considering that most RBCs charge a flat rate for services, what is [REDACTED] plan for instituting its sliding fee scale at the RBC sites? Does Wal-Mart have an established schedule of charges and discounts? If so, would it effect [REDACTED] ability to establish a sliding fee scale?
5. What role will Wal-Mart play in the operation of the RBCs? Will they pay for the clinic's overhead costs? Will they have any control of the fee scale, clinical protocols, hours, or the supervision of staff? Do they understand the health center model and the governing board requirements?
6. Describe the business relationship between [REDACTED] and Wal-Mart. Provide copies of documents that formalize the relationship.
7. If [REDACTED] participates in the 340B Drug Pricing Program, will Wal-Mart's existing fees have implications for [REDACTED] ability to meet the requirements of this program (i.e., the 340B Drug Pricing Program)?

Again, we support your efforts to act strategically in a competitive market. If you would like to talk further about the issues or questions listed above, please contact Shannon Dunne-Faltens in the Office of Policy and Program Development at (301) 594-4065.

Sincerely,

*Donald L. Wheeler, M.D.*

*for* James Macrae  
Associate Administrator

Convenient Care 'Retail' Clinic Sites by State and Clinic Company - January 2008																					
Clinic company	States																				
	AL	AK	AZ	AR	CA	CO	CT	DE	FL	GA	HI	ID	IL	IA	IN	KS	KY	LA	ME	MD	
Aurora Quick Care																					
CareWorks																					
CheckUps	9							3											5		
Christus Convenient Clinic																					
Corner Care Clinics						2						4			5						
Curquick												1									
Early Solutions Clinic																					
ExpressHealth Clinic																					
HealthPartners HealthStation																					
Lindora Health Clinic					1																
The Little Clinic			3					17	8								5				
MedBasics			3																		
MediMin			4																		
MedPoint Express			1												3						
MeD thru Express Clinic																					
MedXpress (Trinity)																					
MinuteClinic			17		54		16	46	30			17		11	15						27
My Healthy Access																					1
Now Medical Centers																					
Paragon Family Practice																		3			
PLAN – Planned Parenthood																					
QuickClinic																					
QuickHealth													1								
RediClinic				2																	
Roadside Medical									1												
SmartCare Family Medical Ctrs						15															
Solantic								15													
Sutter Express Care																					
Take Care Health Systems								20	16			34									
Target Clinic (Target Stores)																					5
<b>TOTALS</b>	<b>9</b>	<b>0</b>	<b>28</b>	<b>2</b>	<b>75</b>	<b>15</b>	<b>18</b>	<b>0</b>	<b>101</b>	<b>55</b>	<b>0</b>	<b>1</b>	<b>55</b>	<b>1</b>	<b>19</b>	<b>15</b>	<b>8</b>	<b>5</b>	<b>0</b>	<b>33</b>	

Note: Wal-Mart has hosted convenient care clinics operated by other organizations, so it is not included above.  
 (Note that due to the volatility of the convenience care clinic industry, data may not be exact.)

**Convenient Care 'Retail' Clinic Sites by State and Clinic Company - January 2008**

Clinic company	States																				
	MA	MI	MN	MS	MO	MT	NE	NV	NH	NJ	NM	NY	NC	ND	OH	OK	OR	PA	RI	SC	
Aurora Quick Care																					
CareWorks																					
CheckUps				6																	5
Christus Convenient Clinic																					
Corner Care Clinics										1		2	1		6					3	1
Curaquick								2													
Early Solutions Clinic			6																		
ExpressHealth Clinic																					
HealthPartners HealthStation			2																		
Lindora Health Clinic																					
The Little Clinic															10						
MedBasics																					
MediMin																					
MedPoint Express																					
MeD thru Express Clinic																					
MedXpress (Trinity)																					
MinuteClinic	17	28						8		23		7	37		14	3	1				19
My Healthy Access																					
Now Medical Centers			15								1										
Paragon Family Practice																					
PLAN – Planned Parenthood			3																		
QuickClinic																					
QuickHealth															5						
RediClinic																					2
Roadside Medical																					
SmartCare Family Medical Ctrs																					
Solantic																					
Sutter Express Care																					
Take Care Health Systems												14									8
Target Clinic (Target Stores)			15																		
<b>TOTALS</b>	<b>0</b>	<b>23</b>	<b>63</b>	<b>6</b>	<b>12</b>	<b>0</b>	<b>2</b>	<b>8</b>	<b>0</b>	<b>24</b>	<b>14</b>	<b>9</b>	<b>38</b>	<b>0</b>	<b>35</b>	<b>5</b>	<b>1</b>	<b>35</b>	<b>0</b>	<b>1</b>	

Note: Wal-Mart has hosted convenient care clinics operated by other organizations, so it is not included above.  
 (Note that due to the volatility of the convenience care clinic industry, data may not be exact.)

Convenient Care 'Retail' Clinic Sites by State and Clinic Company - January 2008													
Clinic company	States												
	SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	DC	TOTALS	
Aurora Quick Care									19				19
CareWorks													5
CheckUps													23
Christus Convenient Clinic													0
Corner Care Clinics													25
Curquick	1												4
Early Solutions Clinic													6
ExpressHealth Clinic		3											3
HealthPartners HealthStation													2
Lindora Health Clinic													1
The Little Clinic		4											47
MedBasics				4									7
MediMin													4
MedPoint Express													3
MeD thru Express Clinic													1
MedXpress (Trinity)													0
MinuteClinic		25	37			16		6					474
My Healthy Access				6									7
Now Medical Centers													16
Paragon Family Practice													3
PLAN – Planned Parenthood													3
QuickClinic													5
QuickHealth													15
RediClinic							9						34
Roadside Medical		1											2
SmartCare Family Medical Ctrs													15
Solantic													15
Sutter Express Care													6
Take Care Health Systems		8	7						10				128
Target Clinic (Target Stores)													20
<b>TOTALS</b>	<b>1</b>	<b>41</b>	<b>75</b>	<b>0</b>	<b>0</b>	<b>25</b>	<b>0</b>	<b>6</b>	<b>29</b>	<b>0</b>			<b>893</b>

Note: Wal-Mart has hosted convenient care clinics operated by other organizations, so it is not included (Note that due to the volatility of the convenience care clinic industry, data may not be exact.)