Memorandum

To: Health Center, Network and Primary Care Association Executive Directors

From: Malvise A. Scott, Senior Vice President, Partnership and Resource Development

Date: September 19, 2007

Subject: Legal Guidance – Health Centers and Retail Based Clinics

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NACHC has received numerous questions regarding how Health Centers may relate to the Retail Based Clinic phenomenon. Attached is related legal guidance prepared by Jacqueline C. Leifer, NACHC's General Counsel. I hope this is helpful. You may expect to receive additional guidance and updates as issues arise.

If you have questions, please contact me (MSCOTT@NACHC.COM) or Jason Patnosh (JPATNOSH@NACHC.COM).

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

FROM: Jacqueline Leifer

DATE: September 29, 2008

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 "<u>any place</u> 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 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.