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HENRY McMASTER
ATTORNEY GENERAL

January 24, 2006

The Honorable Darrell Jackson
Senator, District No. 21
P.O. Box 142
Columbia, South Carolina 29202

Dear Senator Jackson:

We issue this opinion in response to a letter you submitted to our Office expressing your concerns as to the State Board of Pharmacy's (the "Pharmacy Board") interpretation of certain provisions under the Pharmacy Practice Act (the "Act"). You state: "It appears that the Act allows for the dispensing of medication to patients by private physicians and Free Medical Clinic physicians, but prohibits physicians working in a federally funded health center from dispensing medication to their patients—because they do not 'own' the medication." You focus your concern in particular on sections 40-43-60(I) and (K) of the Act. "As stated in Section I, these health centers are 'institutions authorized to possess medication.' These health centers qualify to receive medications for their indigent patients through the 340B pricing Program and the Pharmacy Assistance Program (or Patient Assistance Program) so why are their physicians prohibited from dispensing." Thus, you request "an opinion as to what appears to [you] to be discriminatory language or possibly a discriminatory interpretation of the language in the Pharmacy Practice Act."

In addition to your letter, this Office has been in communication with federally funded health centers located in South Carolina. These centers confirmed the Pharmacy Board's interpretation of the Act has affected the activities of their physicians. According to representatives of the centers we spoke with, the Pharmacy Board has not provided the centers with a written statement of its position on the ability of physicians working in the centers to dispense drugs. However, the centers stated they were told by the Pharmacy Board that their physicians did not have the legal authority to dispense drugs to patients of the centers.

Upon review of the Act, in our opinion, it allows physicians working in federally funded health centers, under certain circumstances, to dispense drugs to patients of the center.

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physician working in a federally funded health center to determine the Act's impact on the activities of those physicians in administering and dispensing prescription drugs.

One instance in which a physician is allowed to transfer drugs to patients is in section 40-43-60(H) of the Act. This statute provides:

(H) Nothing in this chapter shall be construed to require a permit of or to prevent a licensed practitioner as defined under Section 40-43-30(45) from possessing or administering drugs or devices, or compounding drugs used for administration in the regular course of professional practice.

S.C. Code Ann. § 40-43-60(H) (2001) (emphasis added). The Act defines "administer" as "the direct application of a drug or device pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion, topical application, or any other means." S.C. Code Ann. § 40-43-30(1). Pursuant to this statute, the Act clearly does not prohibit a licensed physician, working in a federally funded health center or elsewhere, from possessing or administering drugs to patients.

Section 40-43-60(I) of the Act (Supp. 2005) also provides an exception for physicians.

This chapter does not require a permit of or prevent a licensed practitioner, as defined under Section 40-43-30(45), from dispensing drugs or devices that are the lawful property of the practitioner or a partnership or corporate entity which is fully owned by licensed practitioners or from dispensing a free complimentary trial supply of drugs owned by a person or institution authorized to possess medication under state or federal law for indigent patients with guidelines equal to or equivalent to Section 340B of the Public Health Service Act. Drugs or medicine dispensed must comply with the labeling requirements of state and federal laws and regulations.

S.C. Code Ann. § 40-43-60(I). Under this provision of the Act, a physician may dispense drugs (1) in which he or she owns or (2) drugs constituting "a free trial supply" and are owned by the physician or by an institution serving indigent patients.

In our conversation with one of the centers in question, we learned the Pharmacy Assistance Programs or Patient Assistance Programs you referred to in your letter are programs created by private drug manufacturers, which generally seek to provide pharmaceuticals to uninsured or underinsured patients. The drug manufacturers create the guidelines for these programs and we understand from speaking with one of the participating centers, the drug manufacturers only distribute drugs to licensed physicians, not to the health centers. Therefore, if the physicians working in the centers are the physicians receiving the drugs under these programs, presumably

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these physicians are the owners of the drugs for purposes of section 40-43-60(I). However, we must note that the determinations of ownership of the drugs is a factual determination. Therefore, this determination is not appropriate in an opinion of this Office. Op. S.C. Atty. Gen., November 28, 2005 (“[T]he Attorney General cannot investigate or determine facts.”).

According to your letter, the centers in question qualify to participate in the federal 340B Pricing Program. As we understand it, this program, which is covered under the Public Health Services Act, allows qualifying health centers to purchase pharmaceuticals at a discount. See 42 U.S.C.A. § 256b. Assuming, as you state, these centers qualify for such a program, section 40-43-60(I) allows physicians working in the centers to dispense free complimentary trial supplies of drugs owned by the center. However, again we must note whether the drugs dispensed are free complimentary trial supplies is a factual determination, not appropriately made in opinion of this Office. Op. S.C. Atty. Gen., November 28, 2005.

Lastly, section 40-43-60(K) of the Act (2001) states: “A physician may dispense noncontrolled prescription drugs at an entity that provides free medical services for indigent patients if no pharmacist is available. All such drugs must be labeled as required by this chapter.” (emphasis added). This provision of the Act does not describe the level of free medical services the entity must provide before a physician may dispense noncontrolled prescription drugs. Under the plain wording of this provision, presumably if the entity provides any free medical services for indigent patients, this exception to the Act applies. Arguably, section 40-43-60(K) could be read to require performance of all medical services free of charge. However, because the Act imposes criminal penalties on those who unlawfully engage in the practice of pharmacy, we will construe this statute against the State, finding our initial interpretation more persuasive. S.C. Code Ann. § 40-43-160(B) (2001); State v. Hill, 361 S.C. 297, 305, 604 S.E.2d 696, 700 (2004) (providing penal statutes must be strictly construed against the State).

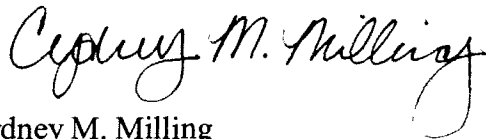
Again, in our conversations with a federally funded health center, we were informed that these types of centers often provide free medical services to their patients although most patients are charged some type of fee. A representative of one center informed us that approximately 10% to 15% of the center’s patients receive medical services at no charge due to patients’ inability to pay and because that center receives funding from an HIV grant, which prohibits charging patients under 3% of the poverty level. Additionally, in a limited review of the Public Health Services Act, we discovered only “covered entities” are entitled to receive medication under the 340B Pricing Program. 42 U.S.C.A. § 256b. Covered entities include federally qualified health centers, which in turn include centers qualified to receive federal grant funds. 42 U.S.C.A. § 256b(a)(4)(A); 42 U.S.C.A. § 1396d(l)(2)(B). As a condition of receiving such funds, the centers are prohibited from denying health care services to patients based on their inability to pay. 42 U.S.C.A. § 254b(k)(3)(G).

Thus, under our reading of the statute, if the center provides free medical services to indigent patients, a physician would be allowed to dispense noncontrolled drugs at the center.

Conclusion

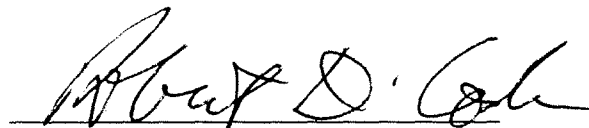
In summary, under the Act, we find physicians working in federally funded health centers may conduct the following activities with respect to the administration and disbursement of drugs to patients of the center: (1) physicians may possess and administer drugs in the course of their practice; (2) physicians may, assuming a factual determination is made that they own the drugs, dispense drugs received by way of a Pharmacy Assistance Program; (3) physicians may dispense any drugs determined to be a "complimentary trial supply of drugs," which are owned by the health center or by the physician; and (4) if the center provides free medical services to indigent patients, the physicians may dispense any noncontrolled prescription drugs. Again as noted above, each of these exceptions depend upon the relevant facts and circumstances involved, and thus, a determination of the application of these exceptions is beyond the scope of this opinion.

Very truly yours,



Cydney M. Milling
Assistant Attorney General

REVIEWED AND APPROVED BY:



Robert D. Cook
Assistant Deputy Attorney General