

Emergency Contraception

Common Legal Questions About Prescribing, Dispensing, Repackaging, and Advertising

In the United States, emergency contraceptive pills (EC) are distributed both "on-label" and "off-label." With respect to "on-label" distribution, two designated EC products—Preven and Plan B—are currently available and have been approved by the FDA for EC marketing. In addition, some health-care providers continue to provide patients with regular oral contraceptive pills (OCs) for EC use, despite the fact that the OC manufacturers have refused to label their products for postcoital use. This "off-label" use of OCs as EC was long employed before the emergence of designated EC products, and it was given the FDA's explicit "stamp of approval" on February 25, 1997, when the FDA announced that Levlen and Tri-Levlen, manufactured by Berlex Laboratories, and Ovral, Lo/Ovral, Nordette, and Triphasil, manufactured by Wyeth Laboratories, were safe and effective for use in emergency contraceptive regimens.¹

This briefing paper will answer common legal questions about dispensing, repackaging, and advertising oral contraceptives as "off-label" EC. It will also address questions about prescribing, and liability related to the provision of, both "off-label" EC and designated EC products.

PRESCRIBING EMERGENCY CONTRACEPTIVE PILLS

As a preliminary matter, health-care providers, health centers, and family planning programs must identify which medical personnel may prescribe EC and when they may do so. Because many providers are interested in increasing EC accessibility due to the importance of the treatment and because of the short time frame for its effective use, programs often use physician assistants, advanced practice nurses, or other non-physician health-care providers to prescribe EC. In addition, some programs are working to develop collaborative agreements with pharmacists to enable them to dispense EC to particular patients without a prescription in appropriate circumstances. Finally, some providers prescribe EC prophylactically for their clients' future emergency use.

1. May a physician prescribe oral contraceptives as EC to a patient with a present need for emergency contraception?

Yes. Medical doctors may legally prescribe oral contraceptives for postcoital use. Neither the federal Food, Drug, and Cosmetic Act (FDCA), its regulations, nor state law limit a physician's authority to prescribe an approved drug for an off-label use.² In addition, as discussed in the introduction, the FDA has specifically endorsed the off-label use of oral contraceptive pills as emergency contraception. Of course, like any other aspect of the practice of medicine, prescribing EC must be medically appropriate for the particular patient.

2. May a non-physician health-care provider prescribe oral contraceptives or a designated EC product to a patient with a present need for emergency contraception?

It depends on state law.³ Non-physician health-care providers (such as physician assistants, nurse practitioners, and midwives) with prescribing authority from their state may prescribe "off-label" EC or designated EC products without violating the FDCA or its attendant regulations.⁴

Nonetheless, states vary widely in the extent to which they grant prescribing authority to particular types of non-physician health-care providers and impose limits on that authority. For example, in Florida, midwives have no prescribing authority, advanced registered nurse practitioners may prescribe under a protocol approved by a committee of nursing and medical board members, and physician assistants have dependent prescribing authority (i.e. supervising physicians may delegate such authority to physician assistants) to prescribe from a limited formulary.⁵ In New Mexico, certified nurse midwives have independent prescribing authority, while physician assistants have only dependent prescribing authority.⁶

Health care providers in doubt as to their prescribing authority should speak to their state board of pharmacy, local professional group, or attorney. Like any other aspect of the practice of medicine, the provision of a prescription for EC must be medically appropriate for the particular patient.

3. May a pharmacist fill a health-care provider's prescription for oral contraceptive pills as EC?

Yes. The FDCA does not prevent a pharmacist from filling a prescription for an off-label use. In addition, the FDCA exempts retail pharmacies that fill prescriptions in accordance with local law from many of the requirements applicable to drug manufacturers and repackagers.⁷ Similarly, we are aware of no state law preventing pharmacists from filling off-label prescriptions.⁸

4. May a pharmacist dispense EC without a prescription?

It depends on state law. In some states, pharmacists have authority to initiate EC therapies pursuant to established protocols or a collaboration agreement with a physician with prescribing authority. Currently five states permit such pharmacy dispensing of EC without a prescription—Alaska,⁹ California,¹⁰ Hawaii,¹¹ New Mexico,¹² and Washington.¹³

Because each of these laws requires conformance with established protocols or a collaboration agreement with a physician, pharmacists interested in providing EC in these states should consult with their local pharmacy board about the particular requirements of state law.

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5. May a physician or other health-care provider with prescribing authority prescribe EC for future use?

Yes, where appropriate. We are aware of no law preventing a health-care provider from prescribing drugs to a patient for a future need. Prescribing EC in advance has the significant benefit of ensuring that a patient will have the pills available when and if she needs them. The short window of opportunity for using emergency contraception makes this accessibility particularly important. As with the provision of any other prescription or medical service, the provider should exercise his or her professional medical judgment in determining whether an advance prescription is appropriate for a particular patient.

DISPENSING EMERGENCY CONTRACEPTIVE PILLS

In some circumstances, health-care providers and health programs may wish to dispense designated EC products or OCs as EC directly from their facilities, rather than through a prescription filled by a separate pharmacy. For example, programs that buy OCs in bulk at discount rates may be able to offer them to patients at a lesser cost than that offered by the patient's pharmacy. In addition, direct dispensing can reduce the amount of time between the act of unprotected intercourse and the beginning of EC treatment.

1. May a physician dispense EC directly to his or her patients?

It depends on state law. The FDCA does not regulate a doctor's authority to dispense medications to his or her patients.¹⁴ State law in the vast majority of states grants physicians broad authority to dispense drugs to their patients.¹⁵ Thus, doctors in those states may directly dispense EC to their patients. Some states, however, limit a physician's dispensing authority in various ways. For example, in Arkansas, doctors need special permission to dispense directly to patients.¹⁶ Doctors in Maryland and Michigan may dispense only to their own patients.¹⁷ Because the state laws in this regard are quite diverse, doctors who are unsure of their authority to dispense prescription drugs to patients should seek the guidance of their state board of pharmacy, local professional group or attorney.

Doctors who directly dispense EC should follow their state dispensing requirements, which generally include specific mandates as to drug labeling and/or packaging, including the contents of labels, the inclusion of instructions, and the types of containers that must be used.¹⁸ For example, in California, a health-care provider who dispenses prescription drugs must fulfill all of the labeling and packaging requirements imposed on pharmacists, including the use of childproof containers.¹⁹ In Arkansas, a dispensing physician must personally dispense drugs to his or her patients, maintain records of that activity, and label the dispensed drugs with specified information that includes the names and addresses of the physician and patient, the date of dispensing, and any warnings and instructions required by law.²⁰

Some states also impose other types of dispensing requirements on medical practitioners. In Illinois and Iowa, for example, a dispensing physician must offer to provide his or her patient with a written prescription for a drug prior to dispensing that drug directly.²¹ In Michigan, dispensing providers must store drugs so as to preserve their stability and prevent contamination or adulteration.²² In Florida, dispensing physicians who charge a fee for the dispensed drugs must register with a professional licensing board.²³ Because these laws vary significantly, medical personnel with doubts as to the specific dispensing requirements should seek the guidance of their state board of pharmacy, local professional group or attorney.

Federal law requires that any dispenser of oral contraceptive drugs provide the patient (or their agent) with the standardized labeling known as the patient package insert.²⁴ Although the FDA does not regulate the dispensing of approved drugs by a physician to his or her patients and has not indicated whether it will attempt to assert its authority over this matter, dispensing health-care providers who wish to avoid any risk of being challenged in this regard should provide patients with the patient package insert (or a copy thereof) for the particular oral contraceptive dispensed, in addition to EC instructions and information.

When preparing patient labeling and instructions for OCs as EC, health-care providers should use both the FDA Notice on EC and the American College of Obstetricians and Gynecologists's Practice Pattern on Emergency Oral Contraception.²⁵

2. May a non-physician health-care provider dispense EC directly to his or her patients?

It depends on state law. Many states grant certain non-physician health-care providers authority to dispense drugs to patients. This authority exists for different types of providers in different states. For example, in Colorado, physician assistants may dispense certain medications, but advanced practice nurses may not dispense drugs other than samples.²⁶ By contrast, in New Hampshire, physician assistants and advanced registered nurse practitioners may dispense only to provide for the immediate needs of patients.²⁷ In New Mexico, both physician assistants and certified nurse practitioners may dispense drugs in accordance with specified limitations.²⁸

Even the states that permit certain non-physician health-care providers to dispense drugs place various limitations on that authority. For example, in Missouri, a registered professional nurse may dispense drugs only pursuant to a collaborative agreement with a physician.²⁹ In Wyoming, physician assistants can be delegated authority to dispense prepackaged drugs, but only when pharmacy services are not physically available.³⁰ Because the state laws in this area vary widely, health-care providers should seek the guidance of their state board of pharmacy, local professional group, or attorney if they are unsure of their authority to dispense prescription drugs to patients.

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The packaging and labeling issues discussed above in connection with dispensing by physicians are fully applicable to, and should be considered by, non-physician health-care providers who dispense EC.

REPACKAGING ORAL CONTRACEPTIVE PILLS AS EC

Many health-care providers, health clinics, and family planning programs have expressed interest in repackaging OCs for use as emergency contraception. Repackaging ensures that the patient receives only the pills that she needs in a container that bears appropriate labeling and instructions. To date, health programs have used a variety of repackaging methods. These have included placing cut up strips of blister-packed pills in prescription bottles or labeled envelopes, as well as removing pills from blister packs and placing them in bottles or envelopes. Of these methods, the former has the very significant advantage of minimizing concerns about the stability and possible contamination of the medications.

1. May health-care providers with dispensing authority repackage oral contraceptive pills to dispense to their own patients?

It depends on state law. Although the FDCA imposes a range of restrictions on drug repackagers,³¹ we do not believe that these restrictions apply to medical personnel who are authorized to dispense drugs and repackage them for their own patients.³² Nor do we believe that the FDCA places restrictions on health-care providers who repackage in bulk for future distribution to their own patients. In our opinion, both of these actions constitute the "practice of medicine," which the FDA does not regulate.

State laws also impose significant requirements on drug repackagers. Many of these laws do not apply to physicians with prescribing authority who repackage for their own patients in the course of their medical practice. For example, Texas excludes such health-care providers from the reach of a statute that authorizes government inspection of establishments in which prescription drugs are processed or packaged.³³ Similarly, North Carolina exempts such health-care providers from the registration requirements that the state imposes on drug repackagers.³⁴ Nonetheless, some state regulations may not explicitly exempt health-care providers and thus might arguably apply to repackaging actions.³⁵ Moreover, other state laws explicitly regulate repackaging by health-care providers. For example, Arizona law permits physician assistants to dispense drugs (when delegated to do so by a supervising physician), but precludes them from packaging or repackaging those drugs.³⁶ Because the state laws in this area vary widely, health-care providers should seek the guidance of their state board of pharmacy, local professional group, or attorney if they are unsure of the applicable repackaging regulations of their states.

The considerations discussed above in connection with dispensing are equally relevant to the dispensing of repackaged drugs and should be considered by any health-care provider who repackages oral contraceptives for EC use.

2. May health-care providers with dispensing authority repackage oral contraceptive pills for dispensing by other health-care providers within their practice?

This also depends on state law. Repackaging, without charge, by one health-care provider for another with whom the repackager shares the duties and responsibilities of a medical practice would probably be considered by the FDA to be within the medical practice of the repackager and outside of the scope of federal regulation.³⁷ We are not aware of any state law that would treat such repackaging differently than repackaging by one provider solely for distribution to his or her own patients. Nonetheless, because state laws in this area vary widely, health-care providers should seek guidance if they are unsure of their state's applicable repackaging regulations.³⁸

3. May pharmacists repackage oral contraceptives in bulk for doctors, other medical personnel or clinics for dispensing as EC?

This may be possible in certain circumstances. Nonetheless, before undertaking such a project, the dispensing providers and pharmacy should seek individualized legal advice because this situation presents a number of fact-specific legal issues. For example, the pharmacy should inquire as to whether its actions might subject it to federal or state regulation as a drug repackager, wholesale distributor or manufacturer and, if so, whether its activities comply with regulations that govern these activities.³⁹

ADVERTISING EMERGENCY CONTRACEPTIVE PILLS

1. May health-care providers, clinics or health programs advertise the availability of postcoital contraceptive services and drugs at their facilities?

Yes. Truthful, accurate advertising campaigns by health-care providers, clinics, or other health programs to raise awareness of EC are generally legal.⁴⁰ In contrast, the FDCA prohibits manufacturers from advertising a product for a use that has not been approved in the product's labeling.⁴¹ Thus, an advertisement that is sponsored by an oral contraceptive manufacturer and that promotes the use of oral contraceptives for EC would be illegal.

2. May health-care providers, clinics or health programs advertise the availability of particular brands of oral contraceptives at their facilities for EC use?

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Maybe. Health-care providers or programs wishing to use specific product names in their advertisements should seek legal guidance because the issues arising from the use of brand names will be fact specific and may depend on a variety of factors governed by state law, such as whether the provider sells a particular product directly.⁴² Laws attempting to limit such advertising may be susceptible to a successful First Amendment challenge, so long as the advertising is not fraudulent or misleading.⁴³

3. May health-care providers, clinics or health programs include the names of particular brands of oral contraceptives in their patient instructional and educational materials?

Yes. Providers and programs may include specific brand names and doses in educational or instructional materials that they distribute to patients.⁴⁴ Providers are encouraged to quote from the FDA's Notice on EC in their patient materials.

CIVIL LIABILITY FOR PRESCRIBING OR FAILING TO PRESCRIBE EMERGENCY CONTRACEPTIVE PILLS

In addition to questions about authority to prescribe, dispense, repack and advertise EC, some providers have questions about potential civil liability for providing, or not providing, access to emergency contraception. As the provision of EC continues to become a common and widely accepted medical treatment, there are increased risks of liability for failing to provide access to EC treatment where it is indicated.

1. May health-care providers be exposed to malpractice liability for prescribing OCs as EC?

The threat of malpractice liability is no greater with OCs as EC than with the provision of any other drug for an off-label use. Indeed, the threat is likely lesser with EC because the FDA has explicitly recognized the safety and efficacy of using OCs for EC.⁴⁵ Further, we know of no case in which liability has been imposed against a health-care provider in connection with the provision of OCs as EC. Of course, in providing any drugs, health-care providers should follow the appropriate standard of care with respect to screening, prescribing, dispensing, and counseling practices. We believe that medical providers can demonstrate that they have satisfied the proper standard of care with respect to appropriate patients seeking to avoid an unwanted pregnancy by demonstrating that they have complied with the practices recommended by the FDA's Notice on EC and by ACOG's Practice Pattern on emergency oral contraception.⁴⁶

2. May health-care providers be exposed to malpractice liability for not prescribing EC?

Potentially. If health-care providers do not provide access to EC to medically suitable patients who have had unprotected intercourse and do not wish to get pregnant, they may be open to malpractice liability. Even prior to the FDA's Notice on EC, the issuance of ACOG's Practice Pattern, and the FDA's approval of designated EC products, a California court ruled that a hospital could be held liable for failing to provide a rape victim with information about and access to emergency contraception.⁴⁷ The court reached this result even though the hospital had a religious affiliation and state law exempted health-care facilities with religious affiliations from liability for refusing to perform abortions or refusing to permit the performance of abortions in their facilities. The court concluded that this immunity did not apply to the provision of emergency contraception, which is a "pregnancy prevention" treatment, rather than an abortion. The issuance of the FDA Notice on EC, ACOG's publication of a practice pattern on EC, and the availability of two designated EC products all bolster the conclusion that provision of EC to appropriate patients is the standard of care, and that failure to meet that standard of care may lead to malpractice liability.

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Endnotes

1. Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8609, 8610 (1997) [hereinafter FDA Notice on EC]. Copies of the FDA notice may be obtained at www.fda.gov/opacom/fedregister/cd96107.htm.
2. Federal courts have repeatedly stated that the FDA does not have authority to regulate the "practice of medicine" and that the federal Food, Drug and Cosmetic Act (FDCA) was not intended to reach the practice of medicine as between a doctor and his or her patients. *See, e.g., Linder v. U.S.* 268 U.S. 5, 18 (1925); *Chaney v. Heckler*, 718 F.2d 1174, 1179-80 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985). In addition, for over twenty years, the FDA has expressed and reaffirmed its policy that physicians may prescribe approved drugs for off-label uses. *See* Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices, 59 Fed. Reg. 59820, 59821 (1994); Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16503 (1972); Use of Approved Drugs for Unlabeled Indications, Vol. 12, No. 1 FDA Drug Bulletin 5. (1982). Finally, with respect to state regulation, we are aware of no state law limiting a medical doctor's ability to prescribe an approved drug for an off-label use. States that have considered the matter appear to have concluded that physicians may prescribe for off-label uses and pharmacists may furnish drugs for those uses pursuant to prescriptions. Peter B. Hutt & Richard A. Merrill, *Food and Drug Law* 621 (1991). *See, e.g., Op. Att'y Gen. of CA, CV 76-212, CV 77-236* (1978) (finding that drug dispensed by pharmacist for an off-label use pursuant to a physician's prescription was not a "new drug").
3. State laws governing the practice of medicine and pharmacy vary widely; the examples of particular state laws provided in this document are only illustrative. These examples do not fully describe the applicable regulatory scheme of any state; nor do they provide a comprehensive list of the various state that impose a particular kind of law on the practice of medicine or pharmacy.
4. The "practice of medicine" exception discussed in endnote 2 is based on the principle that the states, rather than the federal government, have authority under the general police power to protect health and welfare, and thus, to directly regulate the practice of medicine. *See, e.g., Linder*, 268 U.S. at 18; *Chaney*, 718 F.2d at 1180. To the extent that the states have delegated prescribing authority (or other authority to provide medical care) to non-physician health care providers, the exercise of that authority falls within the regulatory reach of the state, but not the federal, government.
5. Fla. Stat. Ann. §§ 467.015 (3) (midwives), 464.003 (3)(c) (advanced registered nurse practitioners), 464.012 (3)(a) (same); 458.347 (4)(e) (physician assistants) (West 1996).
6. N.M. Stat. § 24-1-4.1 (certified nurse midwives), N.M. Stat. § 61-6-7(D) (physician assistants)
7. *See, e.g., 21 U.S.C. §§ 360 (g)(1)* (excluding such pharmacies from registration requirements), 353 (b)(ii) (exempting such pharmacies from many labeling and packaging requirements) (1972 & Supp. 1996).
8. *See, e.g., Op. Att'y Gen. of CA, CV 76-212, CV 77-236*, at 197-202 (1978) (finding that pharmacist may dispense a drug for an off-label use pursuant to a physician's prescription).
9. 12 Alaska Admin. Code § 52.240;
10. California Business and Professions Code Section 4052 (8)
11. Hawaii House Bill 123 (signed by Governor June 24, 2003, text available at http://www.capitol.hawaii.gov/sessioncurrent/sessioncurrent/bills/hb123_hd1_.htm)
12. New Mexico Administrative Code § 16.19.26.9.
13. Revised Code of Washington § 18.64.011(11).
14. Although the FDCA does not directly address this issue, the Act clearly assumes the existence of direct dispensing by doctors. For example, the Act exempts from its registration requirements practitioners who "prepare, propagate, compound, or process drugs . . . for use in the course of their professional practice." 21 U.S.C. § 360 (g) (Supp. 1996). Moreover, we believe that the dispensing of approved drugs falls within the "practice of medicine" which, as discussed above in connection with prescribing, lies beyond the scope of the FDA's authority. *See, supra*, endnote 5.
15. *See, e.g., Or. Rev. Stat. § 677.089* (1995); 63 Pa. Cons. Stat. § 390-8 (2) (1996).
16. Ark. Code Ann. § 17-95-102 (d) (Michie 1995).
17. Md. Code Ann., Health Occupations § 12-102 (c)(2)(ii) (1996); Mich. Comp. Laws Ann. § 333.17745 (2) (West 1996).
18. *See, e.g., Conn. Gen Stat. § 20-14e* (1995); 225 Ill. Comp. Stat. 60/33 (West 1996); Md. Code

- Ann., Health Occupations § 12-102 (c)(2)(iv)(1) (1996).
19. Cal. Bus. & Prof. Code § 4170 (4) (Deering 1996).
20. Ark. Code Ann. § 17-95-102 (c) (Michie 1995).
21. 225 Ill. Comp. Stat. 60/33 (West 1996); Iowa Code § 147.107 (2) (1996).
22. Mich. Comp. Laws Ann. § 333.17745 (4) (West 1996).
23. Fla. Stat. Ann. § 465.0276 (2)(a) (West 1996).
24. 21 C.F.R. § 310.501 (1996).
25. To obtain free copies of the FDA notice, *see* endnote 1, to obtain free single copies of ACOG's Practice Pattern Emergency Oral Contraception, contact ACOG's Resource Center, 409 12th Street, SW, Washington, DC 20024-2188, (202) 863-2518 (tel), (202) 484-1595 (fax).
26. Colo. Rev. Stat. §§ 12-36-106 (5)(a) (physician assistants), 12-38-111.6 (10) (advanced practice nurses) (1996).
27. N.H. Rev. Stat. Ann. § 318:42 (II) (1996).
28. N.M. Stat. Ann. §§ 61-6-7 (C) (physician assistant), 61-3-23.2 (B)(2), (D) (certified nurse practitioner) (Michie 1996 & 1997).
29. Mo. Rev. Stat. § 334.104 (1) (1996).
30. Wyo. Stat. Ann. § 33-26-510 (c) (Michie 1996).
31. *See, e.g.*, 21 U.S.C. §§ 351 (a)(2)(B) (compliance with current good manufacturing practices), 360 (a)(1), (b) (registration with FDA) (Supp. 1996); Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulations, FDA Compliance Policy Guide 7132c.06 (1991) (regulations regarding FDA approval after repackaging of approved drugs).
32. Although the courts have not directly addressed this issue, we believe that these activities fall within the scope of the "practice of medicine." As discussed above, *see* endnote 5, the FDCA does not reach the "practice of medicine." Further, the FDCA appears to define certain activities — such as the preparation of drugs by a practitioner for use in his or her own practice — as outside of activities that the FDCA regulates. *See* 21 U.S.C. § 360 (g)(2) (Supp. 1996). In addition, for the same reasons, we believe that the FDCA also does not apply to non-physician health care providers who repackage in accordance with their authority under state law.
33. Tex. Health & Safety Code Ann. § 431.042 (a), (e)(2) (West 1997).
34. N. C. Gen. Stat. § 106-140.1 (a), (f)(2) (1996).
35. *See, e.g.*, Fla. Stat. Ann. §§ 499.003 (37), (38) (defining repackager as one who "repackag[es] or otherwise chang[es] the container, wrapper, or labeling to further the distribution of the drug"), 499.01(d)(1) (requiring permit for drug manufacturer), 499.013(2)(a)(2) (requiring manufacturer to follow federal and state good manufacturing practices) (West 2003).
36. Ariz. Rev. Stat. § 32-2532 (G) (1996).
37. *See*, 21 U.S.C. § 360 (g)(2) (Supp. 1996) (exempting from group of entities that must register with the FDA practitioners who prepare drugs "solely for use in the course of their professional practice"). The use of the broad language "in the course of their professional practice" rather than a term such as "by their own patients" supports our interpretation. *Cf.* Iowa Code § 147.107 (2) (1996) (allowing physicians to delegate nonjudgmental dispensing functions to staff assistants as long as physicians can verify the accuracy and completeness of the prescription).
38. *Cf., e.g.*, Conn. Gen. Stat. § 21a-70 (1995) (requiring registration of drug wholesaler).
39. *See, e.g.*, 21 U.S.C. § 360 (a)(1) (Supp. 1996) (manufacturer); 21 C.F.R. § 205.3 (g) (1996) (wholesale distributor); Va. Code Ann. § 54.1-3401 (Michie 1996) (wholesale distributor); Ala. Code § 34-23-1(23) (2003) (repackager).
40. We are unaware of any federal or state laws that prohibit such advertisements. We believe that such laws would be subject to a successful First Amendment challenge. *See* *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977) (attorneys' commercial speech receives First Amendment protection); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) (commercial speech of pharmacist receives First Amendment protection); *Bigelow v. Virginia*, 421 U.S. 809 (1975) (commercial speech of out-of-state abortion clinic receives First Amendment protection). *See generally* 3 Am. Jur. 2d Advertising § 17 (1996).
41. 21 C.F.R. § 202.1 (e)(4)(iii) (1996).
42. These actions may make the federal or state government perceive the providers as distributors to whom advertising limitations might apply. *See, e.g.*, statutory definitions cited in endnote 39. *See also* 21 C.F.R. § 202.1 (e)(4)(iii) (1996).
43. *See* endnote 40.
44. Any restriction on that ability would certainly be subject to a First Amendment challenge. *See* cases cited in endnote 40.
45. *See* note 1.
46. *See* note 25.
47. *Brownfield v. Daniel Freeman Marina Hospital*, 208 Cal. App. 3d 405, 413-14 (1989).