

# **A Proposal for State Regulation of Physicians' Office Procedures: Expanding the Reach of the Clinical Laboratory Improvement Amendments**

## **I. QUALITY ASSURANCE AND THE NEED FOR REGULATION OF PHYSICIANS' OFFICE PROCEDURES**

Mary Smith is forty-five years old. After experiencing intermittent sharp abdominal pain for one week, she went to see her family physician, Dr. Jones. Dr. Jones examined Ms. Smith and performed an electrocardiogram (EKG) and a chest X-ray. Because Dr. Jones did not find the source of Ms. Smith's pain, he recommended that she return to the office in three days for an abdominal ultrasound. Ms. Smith continued to have pain. She returned in three days, and Dr. Jones's office staff performed the ultrasound. Unfortunately, Dr. Jones still did not find the source of Ms. Smith's pain.

Dr. Jones next recommended that Ms. Smith return to the office in two days for a cholecystogram, or gallbladder X-ray. Ms. Smith returned in two days, and Dr. Jones's office staff performed the cholecystogram. Again, Dr. Jones did not find the problem. That night, Ms. Smith experienced excruciating abdominal pain. She went to a local hospital emergency room. At the emergency room, a physician found that Ms. Smith's gallbladder was infected and inflamed. The infection had also spread to her abdominal wall causing peritonitis. A surgeon removed Ms. Smith's gallbladder. Ms. Smith stayed in the hospital beyond her expected recovery time to receive intravenous antibiotics.

Ms. Smith lost over three weeks of work and suffered extreme pain. She is angry that, after three office visits, Dr. Jones did not find the source of her pain. She hired an attorney, and intends to sue Dr. Jones for negligently performing the ultrasound and cholecystogram. Unfortunately, the state where Ms. Smith and Dr. Jones live does not have a statute regulating physicians' office procedures. In fact, no state has such a statute. If such a statute existed, Ms. Smith could check with a regulatory committee to determine whether Dr. Jones registered his office to perform diagnostic procedures. Dr. Jones could also prove that he meets the state's requirements for performing procedures in his office.

Like Ms. Smith, consumers demand quality health care. Yet, physicians, not health care consumers, control health services delivery.<sup>1</sup> One

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1. See Alexander M. Capron, *Containing Health Care Costs: Ethical and Legal Implications of Changes in the Methods of Paying Physicians*, 36 CASE W. RES. L. REV.

commentator stated, "In their office practice [physicians] view themselves as individual entrepreneurs, solely responsible to themselves for the diagnosis and treatment of patients."<sup>2</sup> When physicians fail to provide quality care, the state must regulate their behavior.

This Note proposes state regulation of physicians' office procedures. Part I describes physician control in health care and the quality of care provided in physicians' offices. Part I also describes the current increase in outpatient services and physicians' office procedures. Part II describes federal and state laws designed to ensure medical care quality and safety. Part III discusses why state legislatures are the appropriate forum for implementing physicians' office procedure regulations. Finally, Part IV proposes a statute for the regulation of physicians' office procedures to ensure quality and safety for health care consumers.

### A. *Physician Control in the Health Care Field*

Physicians benefit from professional autonomy and self-regulation. Physicians regulate themselves through education, socialization, certification, and accreditation.<sup>3</sup> This self-regulation tends to be based on limited clinical studies, unverified beliefs about treatment methodologies, and professional traditions, rather than empirical data.<sup>4</sup> As a result, standards based on scientific evidence are not available to settle disputes over medical treatment methods.<sup>5</sup> Because physicians define and apply their own standards, they cannot know how their colleagues treat patients in their offices. Unfortunately, office practices that do not meet a reasonable standard of care are usually not discovered until after a

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708, 734 (1986) (the consumer selects a physician who makes choices for him); Gail R. Wilensky & Louis F. Rossiter, *The Relative Importance of Physician-Induced Demand in the Demand for Medical Care*, 61 MILBANK MEMORIAL FUND Q. 252, 271 (1983) ("The less the individual pays for medical care, the more likely is the physician to initiate visits and related expenditures."); Bruce A. Hunter, Recent Case, 52 U. CIN. L. REV. 253, 262 n.79 (1983) (the demand for health care services is often controlled by providers). *But see* Roger Feldman & Frank Sloan, *Competition Among Physicians, Revisited*, 13 J. HEALTH POL. POL'Y & L. 239, 258 (1988) (physicians do not generate demand to avoid price controls).

2. Richard L. Johnson, *Revisiting "The Wobbly Three Legged Stool"*, in HOSPITAL ORGANIZATION AND MANAGEMENT 38, 43 (Kurt Darr & Jonathan S. Rakich eds., 4th ed. 1989).

3. Timothy S. Jost, *The Necessary and Proper Role of Regulation to Assure the Quality of Health Care*, 25 HOUS. L. REV. 525, 535 (1988) [hereinafter Jost, *Regulation*].

4. *See* Richard E. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 CALIF. L. REV. 1483, 1484 (1989).

5. Mary T. Koska, *Hospital, Patient Input Key to Quality Reforms*, HOSPITALS, Oct. 20, 1989, at 77, 77.

patient is harmed.<sup>6</sup> Physicians with minimal qualifications are more likely to harm patients within their offices because an office is not a regulated setting. Consequently, state legislation to regulate physicians' office procedures will help to identify physicians who deviate from accepted practices.

### B. *Defining Quality Health Care*

State legislatures cannot implement effective quality standards for physicians' office procedures without first defining the word quality. Quality is a term that is difficult to define, particularly in the health care field.<sup>7</sup> To define quality care, medical professionals have used outcome standards which measure patient care results.<sup>8</sup> These standards are guidelines for treatment, documentation, and evaluation.<sup>9</sup>

Mortality and severity-adjusted death rates are widely accepted outcome standards;<sup>10</sup> however, outcome standards also include "patient response in terms of . . . symptoms, ability to work or perform daily activities, and physiologic measurements."<sup>11</sup> For example, the expected outcomes for a gallbladder surgery patient include the absence of pain or pneumonia and the ability to return to work, to ambulate, and to eat.<sup>12</sup> State legislatures can help to ensure quality by incorporating outcome standards into physicians' office procedure regulations.

### C. *The Movement Toward Increased Outpatient Services*

Regulating physicians' office procedures is important because medical services are increasingly provided outside the inpatient hospital setting.<sup>13</sup>

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6. See *Voss v. Adams*, 259 N.W. 889 (Mich. 1935) (patient suffered surgical shock and was left alone after he had 16 teeth extracted); *Barbire v. Wry*, 183 A.2d 142 (N.J. Super. Ct. App. Div. 1962) (physician lost the tip of an irrigating syringe in the patient's ear).

7. AVEDIS DONABEDIAN, *THE METHODS AND FINDINGS OF QUALITY ASSESSMENT AND MONITORING: AN ILLUSTRATED ANALYSIS* 4 (1985); Koska, *supra* note 5, at 77.

8. Robert H. Brook & Francis A. Appel, *Quality-of-Care Assessment: Choosing a Method for Peer Review*, 288 NEW ENG. J. MED. 1323, 1323 (1973).

9. See Stephen Morgenstein et al., *Development of a Quality Assurance Program as an Integral Part of the Physical Therapy System*, 62 PHYSICAL THERAPY 464, 464 (1982).

10. Sandra R. Edwardson, *Revision and Testing of the Haersman and Hegyvary Outcome Measure for Myocardial Infarction*, in *MEASUREMENT OF NURSING OUTCOMES* 24 (Carolyn F. Waltz & Ora Strickland eds., 1988).

11. *Id.* at 25.

12. See JOAN LUCKMANN & KAREN C. SORENSEN, *MEDICAL-SURGICAL NURSING: A PSYCHOPHYSIOLOGIC APPROACH* 1520-21 (2d ed. 1980).

13. Barry R. Fittow, *The Changing Role of the Law in Promoting Quality in Health Care: From Sanctioning Outlaws to Managing Outcomes*, 26 Hous. L. Rev. 147, 154 (1989); James S. Roberts, *Reviewing the Quality of Care: Priorities for Improvement*, HEALTH CARE FINANCING REV. 69, 69 (Annual Supp. 1987).

The movement from inpatient to outpatient services resulted from changes in provider reimbursement. Today's increase in outpatient services began when Congress amended the Medicare statute in 1983 to include a prospective payment system.<sup>14</sup> Medicare's prospective payment system consists of 470 Diagnostic Related Groups (DRGs).<sup>15</sup> Under this reimbursement system, each hospitalized Medicare patient is assigned a DRG that is based on the average cost of his principal diagnosis.<sup>16</sup> DRG reimbursement rates, however, do not include actual patient costs.<sup>17</sup> If the patient's costs exceed the reimbursement rate, the hospital must absorb the cost.<sup>18</sup> If the patient's costs are below the reimbursement rate, the hospital may keep the excess.<sup>19</sup> As a result, Medicare's prospective payment system creates an incentive for hospitals to absorb excess reimbursements by decreasing lengths of stay.<sup>20</sup>

As hospitals attempt to decrease inpatient lengths of stay, physicians have an incentive to treat more patients in outpatient settings. For example, cholecystograms once performed in the hospital, are now performed in outpatient settings. As a result, prospective payment creates

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14. 42 U.S.C. § 1395ww (1988 & Supp. I 1989). *See generally* 48 Fed. Reg. 39,755 - 39,792 (1983) (summary of the Medicare Prospective Payment System as it was originally enacted).

15. 42 U.S.C. § 1395ww. *See generally* H. Lynda Kugel, Note, *The Medicare Rx: Prospective Pricing to Effect Cost Containment*, 19 U. MICH. J.L. REF. 743 (1986); Diana Vance-Bryan, Note, *Medicare's Prospective Payment System: Can Quality Care Survive?*, 69 IOWA L. REV. 1417 (1984); 1 Medicare & Medicaid Guide (CCH) ¶¶ 4203-4246.280 (1986).

16. 42 C.F.R. §§ 412.1 to -.10 (1990). Before the prospective payment system was introduced, Medicare reimbursed hospitals retroactively based on the actual cost of care provided to the patient. *See* Vance-Bryan, *supra* note 15, at 1417-18.

17. *See* 42 U.S.C. § 1395ww (1988 & Supp. I 1989); 42 C.F.R. §§ 412.1 to -.280 (1990); Susan C. Atkinson, Note, *Medicare "Cost Containment" and Home Health Care: Potential Liability for Physicians and Hospitals*, 21 GA. L. REV. 901, 902 (1987); Kugel, *supra* note 15, at 745-46.

18. Vance-Bryan, *supra* note 15, at 1420. *See also* Office of National Cost Estimates, *National Health Expenditures, 1988*, HEALTH CARE FINANCING REV., Summer 1990, at 1, 10 (one American Hospital Association panel study revealed that inpatient days decreased 16% between 1983 and 1988).

19. *See* Office of National Cost Estimates, *supra* note 18, at 9-10; Vance-Bryan, *supra* note 15, at 1420.

20. Office of National Cost Estimates, *supra* note 18, at 9. A hospital can receive reimbursement for "outliers" requiring longer lengths of stay, but specific criteria must be met. 42 U.S.C. § 1395ww(d)(5)(A)(i) (1988 & Supp. I 1989); 42 C.F.R. §§ 412.80 to -.86 (1990). *See also* Paul W. Eggers, *Prospective Payment System and Quality: Early Results and Research Strategy*, HEALTH CARE FINANCING REV. 29, 30 (Annual Supp. 1987); Dorothy R. Gregory, *DRGs: How the Government Requires You to Impose Life-Threatening Medical Restrictions*, LEGAL ASPECTS MED. PRAC., March 1986, at 1, 2 (1986); Atkinson, *supra* note 17, at 909.

a greater demand for physicians who perform procedures outside the hospital.<sup>21</sup>

Although prospective payment encourages outpatient care, Certificate of Need (CON) laws may impede outpatient service growth. Amendments to the National Health Planning and Resources Development Act of 1974 (NHPDA)<sup>22</sup> established state certificate of need programs which required state legislatures to determine the need for medical equipment and capital expenditures.<sup>23</sup> State legislatures made these determinations by reviewing capital expenditure proposals that exceeded a statutory threshold.<sup>24</sup>

Although Congress repealed the amendments that required certificate of need programs,<sup>25</sup> thirty-two states continue to review at least some health care expenditures.<sup>26</sup> Nineteen of these states specifically exclude

21. Physician contacts in settings outside the hospital increased 10.7% from 1983 to 1987. Furthermore, data from the Bureau of Labor Statistics show that employment in physicians' offices has grown since 1983. Office of National Cost Estimates, *supra* note 18, at 10. From this data one can infer that consumers are decreasing their use of hospital in-patient services. In addition, the proposed relative value scale for paying physicians under the Medicare program could lead to higher payments to physicians who perform procedures in their offices. See Fee Schedule for Physicians' Services, 56 Fed. Reg. 25,792 (1991) (to be codified at 42 C.F.R. pts. 405, 415).

22. 42 U.S.C. §§ 300k-1 - 300n-6 (repealed 1987).

23. *Id.* § 300m-6 (repealed 1987). See generally Roberta M. Roos, Note, *Certificate of Need for Health Care Facilities: A Time for Re-Examination*, 7 PACE L. REV. 491 (1987).

24. Capital expenditure thresholds vary from \$1,000,000 to \$4,000,000. Medical equipment thresholds range from \$400,000 to \$2,000,000. See Edward F. Shay, *Developments in Certificate of Need*, in HEALTH LAW HANDBOOK 187, 194-99 (Alice G. Gosfield ed., 1989).

25. 42 U.S.C. §§ 300k-1 - 300n-6 (repealed 1987).

26. See ALA. CODE §§ 22-21-260 to -276 (1990); ALASKA STAT. §§ 18.07.031 to -.111 (1986); ARK. CODE ANN. §§ 20-8-101 to -110 (Michie 1987 & Supp. 1991); CONN. GEN. STAT. ANN. § 19a-155 (West 1986 & Supp. 1991); DEL. CODE ANN. tit. 16, §§ 9301 - 9310 (1983 & Supp. 1990); GA. CODE ANN. §§ 31-6-40 to -50 (Michie 1991); HAW. REV. STAT. §§ 323D-41 to -54 (1991); ILL. ANN. STAT. ch. 111 1/2, para. 1153.1 (Smith-Hurd 1988); IOWA CODE ANN. § 135.63 (West 1989 & Supp. 1991); ME. REV. STAT. ANN. tit. 22, §§ 301 - 303 (West 1980 & Supp. 1991); MD. HEALTH-GEN. CODE ANN. § 19-115 (1990 & Supp. 1991); MASS. GEN. LAWS ANN. ch. 111, §§ 25B, 25C (West 1983 & Supp. 1991); MINN. STAT. ANN. §§ 144.551, 144A.071 (West 1989 & Supp. 1991) (moratorium on construction of hospitals and nursing home beds); MISS. CODE ANN. §§ 41-7-171 to -209 (1980 & Supp. 1991); MO. REV. STAT. §§ 197.300 to -.365 (1983 & Supp. 1991); MONT. CODE ANN. §§ 50-5-301 to -317 (1991); NEB. REV. STAT. §§ 71-5801 to -5872 (1990); NEV. REV. STAT. ANN. §§ 439A.010 - 439A.120 (Michie 1987); N.H. REV. STAT. ANN. §§ 151-C:1 to -C:15 (1990 & Supp. 1991); N.J. STAT. ANN. § 26:2H-1 to -18.3 (West 1987 & Supp. 1991); N.Y. PUB. HEALTH LAW § 2802 (Consol. 1985 & Supp. 1991); N.C. GEN. STAT. §§ 131E-175 to -190 (1988); N.D. CENT. CODE § 23-17.2-01 to -15 (1991); OKLA. STAT. ANN. tit. 63, §§ 1-851 to -860 (West 1984 & Supp. 1991); 35

physicians' offices from at least part of their certificate of need statutes.<sup>27</sup> In these states, physicians can purchase diagnostic equipment without state review.<sup>28</sup> Consequently, physicians can compete with hospitals to provide diagnostic services that once required inpatient care. For example, if Dr. Jones practices in a state with a certificate of need statute that excludes private physicians or that has a high medical equipment threshold, Dr. Jones may purchase a variety of medical equipment for his office. Likewise, if the state where Dr. Jones practices does not have a certificate of need statute, Dr. Jones can purchase any medical equipment that he would like to use in his office and that he can afford.

Yet, the use of medical equipment by private physicians is not always beneficial to patients. Medical practice is based on the philosophy that patients should receive all treatments of any conceivable benefit in an

PA. CONS. STAT. ANN. §§ 448.701 to -.712 (Supp. 1991); R.I. GEN. LAWS §§ 23-15-1 to -9 (1989 & Supp. 1991); S.C. CODE ANN. §§ 44-7-110 to -460 (Law. Co-op. 1985 & Supp. 1990); TENN. CODE ANN. §§ 68-11-101 to -113 (1987 & Supp. 1991); TEX. HEALTH & SAFETY CODE ANN. § 225.001 to -.005 (West Supp. 1991); VT. STAT. ANN. tit. 18, §§ 2400 - 2416 (1982 & Supp. 1991); VA. CODE ANN. §§ 32.1-102.1 to -102.11 (Michie 1985 & Supp. 1991); W. VA. CODE §§ 16-2D-1 to -15 (1991). Arizona, California, Colorado, Florida, Idaho, Indiana, Kansas, Kentucky, Michigan, New Mexico, Ohio, Oregon, South Dakota, Texas, Utah, Washington, Wisconsin, and Wyoming have repealed their CON laws.

27. ALA. CODE § 22-21-260(5) (1990); ALASKA STAT. § 18.07.111 (1986); DEL. CODE ANN. tit. 16, § 9302 (1983 & Supp. 1990); HAW. REV. STAT. § 323D-54 (1991); ILL. ANN. STAT. ch. 111 1/2, para. 1153 (Smith-Hurd 1988 & Supp. 1991); ME. REV. STAT. ANN. tit. 22, § 303 (West 1980 & Supp. 1989) (private physicians excluded from the definition of ambulatory surgical facility for certificate of need purposes); MD. HEALTH-GEN. CODE ANN. § 19-101(e)(2)(v)(1) (1990 & Supp. 1991); MISS. CODE ANN. § 41-7-173(9) (1980); MO. REV. STAT. § 197.305(7) (1983 & Supp. 1991); MONT. CODE ANN. § 50-5-101 (1991); NEB. REV. STAT. § 71-5810 (1990); NEV. REV. STAT. ANN. § 439A.015 (Michie 1987); N.H. REV. STAT. ANN. § 151-C:2 (1990) (ambulatory surgical facilities); N.C. GEN. STAT. § 131E-176 (1988) (ambulatory surgical facilities); 35 PA. CONS. STAT. ANN. § 448.103 (Supp. 1991); R.I. GEN. LAWS § 23-15-2(5) (1989 & Supp. 1991); TENN. CODE ANN. § 68-11-102 (1987 & Supp. 1991); VT. STAT. ANN. tit. 18, § 2401(1) (1982 & Supp. 1991) (ambulatory surgical facilities); W. VA. CODE § 16-2D-2(b) (1991) (ambulatory health care facilities). *But see* IOWA CODE ANN. § 135.61 (West 1989) (emphasis added) which provides: (19) "New institutional health service" or "changed institutional health service" means any of the following: . . .

(g) Any expenditure by or on behalf of an individual health care provider or group of health care providers, in excess of four thousand dollars, made for the purchase or acquisition of a single piece of new equipment which is to be installed and used *in a private office or clinic*, and for which a certificate of need would be required if the equipment were being purchased or acquired by an institutional health facility or health maintenance organization, and which is, under generally accepted accounting principles consistently applied, a capital expenditure.

28. *See generally* Roos, *supra* note 23.

attempt to achieve a cure.<sup>29</sup> Consequently, a physician may be tempted to use a new technology without achieving proficiency with the procedure. Furthermore, when physicians perceive that liability may result from failure to perform procedures, they will increase the number of procedures they perform to avoid lawsuits.<sup>30</sup> This practice, known as defensive medicine, results in unnecessary procedures and increased health care costs.<sup>31</sup> The regulation of physicians' office procedures will deter physicians from performing procedures simply to diminish a perceived legal threat. These regulations will require physicians to provide documentation supporting the procedure performed and will mandate certain safety and hygiene requirements. Physicians will then be able to prove that certain minimum standards were met, thereby decreasing their perceived liability.

## II. CURRENT METHODS OF QUALITY AND SAFETY CONTROL

### A. *The Need for Governmental Regulation*

Although a physician may be liable for failure to perform appropriate diagnostic or therapeutic procedures, courts have also reasoned that a physician's medical judgment should be protected from state and organizational interference.<sup>32</sup> Courts have reasoned that interfering with medical judgment is inappropriate because physicians are better qualified to make medical progress and risk determinations.<sup>33</sup> This reasoning implies

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29. Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 435 (1988).

30. See *Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974) (physician held liable for failing to perform glaucoma test).

31. Americans spend an estimated \$27 billion each year on lab tests, \$2 billion on chest X-rays, and \$1 billion on EKGs. Twenty to sixty percent of these tests are unnecessary. Paula Dranov, *The Medical Test Mess: How Many Screening Procedures Are Too Many?*, 20 HEALTH 69, 69 (1988).

32. See *United States v. Evers*, 453 F. Supp. 1141, 1150 (N.D. Ala. 1978) (FDA not empowered to limit physicians' ability to prescribe); *People v. Privitera*, 141 Cal. Rptr. 764, 774 (1977), *vacated*, 591 P.2d 919 (1979), *cert. denied*, 444 U.S. 949 (1979) (physician cannot be required to use only "state sanctioned" treatment methods); *Radiology Professional Corp. v. Trinidad Area Health Ass'n*, 577 P.2d 748, 751 (Colo. 1978) ("The ability of a physician to exercise his professional judgment in the diagnosis and care of his patients is well-established and should be protected against unreasonable interference."); *State ex rel. Walker v. Bergman*, 755 P.2d 557, 560 (Kan. Ct. App. 1988) (facility may coordinate and monitor patient care, but it does not have supervisory authority over the physician). See also Hall, *supra* note 29, at 467 ("From several sources in the law there is evident a nascent principle that potentially insulates individual clinical decisions from nonmedical interference of any source or magnitude.").

33. See *Evers*, 453 F. Supp. at 1144 (the decision to inform a patient of the risks associated with a drug must be made by the physician); *Privitera*, 141 Cal. Rptr. at 773 ("treating doctor . . . is at the cutting edge of medical knowledge").

that governmental agencies should also refrain from making quality of care determinations.<sup>34</sup> Consequently, legislators must decide whether physicians should continue to determine their own standards.<sup>35</sup> If a state legislature chooses to regulate physicians' office procedures, it should enact statutes that are broad enough to allow physicians to practice medicine without excessive restraint, but are also narrow enough to limit physician behavior within appropriate parameters. In addition, because consumers pay for health care through taxes and insurance premiums, they expect effective and appropriate medical care.<sup>36</sup> Governmental regulation will ensure that physicians will not perform procedures when the potential benefit to the patient is outweighed by the risk that the physician will not perform the procedure skillfully.<sup>37</sup> Overall, state regulation should reflect consumers' expectations for quality care in all health care settings, including the physician's office.

### *B. The Clinical Laboratory Improvement Amendments of 1988*

The Clinical Laboratory Improvement Act (CLIA) is the only significant regulation of physician behavior in the office setting.<sup>38</sup> Between four and six billion laboratory tests are performed each year at an annual cost of twenty to twenty-five billion dollars.<sup>39</sup> Improperly performed laboratory tests may result in improper treatment, increased patient anxiety, and higher health costs.<sup>40</sup> Congress enacted CLIA to ensure that patients are provided with accurate laboratory results.<sup>41</sup>

In 1988, Congress passed the Clinical Laboratory Improvement Amendments (Amendments) to modify CLIA.<sup>42</sup> Congress passed the

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34. See Roberts, *supra* note 13, at 69 ("the responsibility for assuring the quality of care rests with the organization providing that care").

35. See Robert C. Clark, *Why Does Health Care Regulation Fail?*, 41 MD. L. REV. 1, 22 (1981) (physicians have enormous autonomy in determining their own norms of practice).

36. Duncan Neuhauser, *Commentary: Medical Technology Assessment as Social Responsibility*, 36 CASE W. RES. L. REV. 878, 878-79 (1986).

37. See Leahy, *supra* note 4, at 1491.

38. 42 U.S.C. § 263a (1988).

39. HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. NO. 899, 100th Cong., 2d Sess. 10 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3831.

40. Many state clinical laboratory statutes include these consequences within the statutory purpose of the statute. See, e.g., FLA. STAT. ANN. § 483.021 (West 1991); KY. REV. STAT. § 333.010 (Michie/Bobbs-Merrill 1990); TENN. CODE ANN. § 68-29-102 (1987). See also HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. NO. 899, 100th Cong., 2d Sess. 10 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3831.

41. See Robert Crawley et al., *Regulation of Physicians' Office Laboratories: The Idaho Experience*, 255 JAMA 374, 381 (1986).

42. 42 U.S.C. § 263a (1988).

Amendments because laboratories failed to comply with CLIA's proficiency testing requirements.<sup>43</sup> One study showed that when a physician's office laboratory and a local hospital laboratory each tested the same specimens, the results from the physician's office laboratory varied significantly from the hospital laboratory's results.<sup>44</sup> In addition, the House Energy and Commerce Committee found that mobile laboratories in vans and in shopping malls provided unreliable test results.<sup>45</sup> Furthermore, cytologists were diagnosing slides at home.<sup>46</sup> Thus, serious questions were raised concerning the accuracy of laboratory tests performed in unregulated laboratories.

Prior to the enactment of the Amendments, CLIA regulated only those physicians' office laboratories performing interstate testing.<sup>47</sup> These regulations excluded laboratories "whose operations [were] so small or infrequent as not to constitute a significant threat to the public health"<sup>48</sup> and any physician's laboratory operated "solely as an adjunct to the treatment of his . . . own patients."<sup>49</sup> Furthermore, few states enacted clinical laboratory statutes that included physicians' office laboratories.<sup>50</sup>

The Amendments require certification for all office laboratories except those performing only simple procedures.<sup>51</sup> Simple procedures are defined as procedures with "an insignificant risk of an erroneous re-

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43. HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. No. 899, 100th Cong., 2d Sess. 12 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3833. See also Charles W. Griffin, III, et al., *Relationship Between Performance in Three of the Centers for Disease Control Microbiology Proficiency Testing Programs and the Number of Actual Patient Specimens Tested by Participating Laboratories*, 23 J. CLINICAL MICROBIOLOGY 246 (1986).

44. This study examined results of hemoglobin, hematocrit, glucose, urea nitrogen, creatinine, uric acid, cholesterol, and total protein testing. Crawley, *supra* note 41, at 374.

45. HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. No. 899, 100th Cong., 2d Sess. 15 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3836.

46. *Id.* at 17, reprinted in 1988 U.S.C.C.A.N. 3828, 3838.

47. Clinical Laboratories Improvement Act, Pub. L. No. 90-174, § 353(b)(1), 81 Stat. 536 (1967); Marsha A. Goldsmith, *Federal Proficiency Testing Requirements Set to Start for POLs*, 262 JAMA 2355, 2355 (1989).

48. Clinical Laboratories Improvement Act, Pub. L. No. 90-174, § 353(b)(2), 81 Stat. 536 (1967).

49. *Id.* § 353(i), 81 Stat. at 538.

50. These states included California, Florida, Idaho, Maryland, Massachusetts, Michigan, Nevada, New Jersey, Oregon, Pennsylvania, West Virginia, Wisconsin, and Wyoming. Carol Gorove et al., *State Regulation of Physician Office Laboratories*, 17 LABORATORY MED. 44, 45 (1986).

51. 42 U.S.C. § 263a(d)(2)(A) (1988); Paul M. Fischer & Darroll Loschen, *Federally Regulated Office Laboratories*, AM. FAM. PHYSICIAN, Nov. 1989, at 95, 95. See generally HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. No. 899, 100th Cong., 2d Sess. 22 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3843.

sult."<sup>52</sup> These procedures include tests approved by the Food and Drug Administration (FDA) for home use, tests that are "so simple and accurate as to render the likelihood of erroneous results negligible," and tests that "pose no reasonable risk of harm to the patient if performed incorrectly."<sup>53</sup>

Under the Amendments, proficiency testing is used to determine whether a laboratory meets certification standards.<sup>54</sup> A laboratory is not required to meet the Amendments' proficiency testing requirements if it meets the standards of an approved accrediting body.<sup>55</sup> Accreditation is available from the Commission on Office Laboratory Assessment (COLA), the College of American Pathologists, the American Association of Bioanalysts, and state agencies.<sup>56</sup>

The Amendments also require laboratory inspections.<sup>57</sup> Unannounced inspections are permissible if they are conducted during business hours.<sup>58</sup> In addition, the Amendments allow the states to enact clinical laboratory statutes and regulations.<sup>59</sup> Yet, as Part III of this Note demonstrates, state legislatures have not enacted statutes beyond laboratory regulations to ensure quality in physicians' office procedures.

### III. THE REGULATION OF PHYSICIAN BEHAVIOR

#### A. Current State Legislation

Through their general police power, state legislatures have the authority to regulate health care and consequently, physician behavior.<sup>60</sup>

52. 42 U.S.C. § 263a(d)(3) (1988). The Illinois clinical laboratory statute contains a more comprehensive definition of a simple procedure:

"Simple test" means a test . . . which generally [has] the following characteristics:

(a) interpretation of a visual signal by pattern recognition, color definition or numeric information using an established control example;  
 (b) the use of simple addition, subtraction, multiplication, or division; or  
 (c) the use of manufacturer-prepared reagents or solutions which are combined without requiring numerous specific calibrated volume measurements or sequential application.

ILL. ANN. STAT. ch. 111 1/2, para. 622-118 (Smith-Hurd 1988).

53. 42 U.S.C. § 263a(d)(3) (1988).

54. *Id.* § 263a(f)(3). See also Fischer, *supra* note 51, at 95.

55. 42 U.S.C. § 263a(e)(1)(A) (1988).

56. HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. No. 899, 100th Cong., 2d Sess. 15 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3836. See also Fischer, *supra* note 51, at 95; K. Michael Peddecord & Ronald L. Cada, *Clinical Laboratory Proficiency Test Performance: Its Relationship to Structural, Process and Environmental Variables*, 73 AM. J. CLINICAL PATHOLOGY 380 (1980).

57. 42 U.S.C. § 263a(g) (1988).

58. *Id.*; HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. No. 899, 100th Cong., 2d Sess. 34 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3855.

59. 42 U.S.C. § 263a(p) (1988).

60. Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905).

Without federal regulation of physicians' office procedures, the states may implement their own policies. Yet, regulation of physicians' office procedures may not be appropriate for all states. For example, a state with substantial physician activity may decide to implement strict regulations for physicians' office procedures. A state with a low physician population may fear that regulation will decrease physicians' desire to practice in that state and worsen its shortage of medical practitioners. Therefore, state legislatures concerned about their physician population may reject the implementation of physician regulation. For these states, risks in physician office practice may be a necessary cost of providing health care in rural areas. Because state regulation can be tailored to meet the needs of a particular consumer population, state regulation is preferable to federal control of physicians' office procedures.

### *B. The States' Role in Regulating Physician Behavior*

With the exception of laboratory performance, state legislatures have not extended governmental regulation into the physician's office. An examination of state health facility statutes reveals that private physicians are not included in the statutes or are specifically excluded. Ten states specifically exclude physicians' offices from their statutes authorizing the regulation of hospitals.<sup>61</sup> In addition, fifteen states specifically exclude physicians' offices from health facility regulations.<sup>62</sup> Of these fifteen states, six exclude physicians from their certificate of need statutes,<sup>63</sup> and four do not have a certificate of need statute.<sup>64</sup> Therefore, in ten states, physicians can purchase medical equipment without review and

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61. ALA. CODE § 22-21-20(1) (1990); ILL. ANN. STAT. ch. 111 1/2, para. 1153 (Smith-Hurd 1988 & Supp. 1991); IND. CODE § 16-10-1-6 (1988); LA. REV. STAT. ANN. § 40:2102(A)(1) (West 1977); MINN. STAT. ANN. § 144.50(2) (West 1989); MISS. CODE ANN. § 41-9-3(a) (1981 & Supp. 1991); NEB. REV. STAT. § 71-2017.01(2) (1981); N.H. REV. STAT. ANN. § 151:2 (1990); R.I. GEN. LAWS § 23-17-2(1) (1989 & Supp. 1990); W. VA. CODE § 16-5B-1 (1991).

62. ALA. CODE § 22-21-20(1) (1990); CAL. HEALTH & SAFETY CODE §§ 1206(a), 1206.1 (West 1990); GA. CODE ANN. § 31-7-1 (Michie 1990); ILL. ANN. STAT. ch. 111 1/2, para. 1153 (Smith-Hurd 1988 & Supp. 1991); IND. CODE § 16-10-4-2(b)(9) (1988); MD. HEALTH-GEN. CODE ANN. § 19-101(c)(2)(5) (1990 & Supp. 1991); MINN. STAT. ANN. § 144.50(2) (West 1989); MONT. CODE ANN. § 50-5-101(19) (1991); NEB. REV. STAT. § 71-2017.01(4) (1981); N.H. REV. STAT. ANN. § 151:2 (1990); 35 PA. CONS. STAT. ANN. § 448.802a (Supp. 1991); R.I. GEN. LAWS § 23-17-2(1) (1989 & Supp. 1990); UTAH CODE ANN. § 26-21-2(10) (1989 & Supp. 1991); WASH. REV. CODE ANN. § 70.37.020(3) (West 1975 & Supp. 1991); W. VA. CODE § 16-5B-1 (1991).

63. ALA. CODE § 22-21-20(1) (1990); ILL. ANN. STAT. ch. 111 1/2, para. 1153 (Smith-Hurd 1988 & Supp. 1991); MONT. CODE ANN. § 50-5-101(19) (1991); NEB. REV. STAT. § 71-5810 (1986 & Supp. 1990); 35 PA. CONS. STAT. ANN. § 448.103 (Supp. 1991); W. VA. CODE § 16-2D-2 (1991). *See generally supra* text accompanying notes 22-28.

64. These states are: California, Indiana, Utah, and Washington.

can operate that equipment in their offices without meeting the requirements of state health facility statutes.

Similarly, twenty-seven states specifically include outpatient surgical clinics in their health facility statutes,<sup>65</sup> yet eighteen of these states exclude physicians' offices from these same statutes.<sup>66</sup> In addition, twenty-four states regulate laboratories outside of the inpatient setting,<sup>67</sup> but despite

65. ALA. CODE § 22-21-20(1) (1990); ARIZ. REV. STAT. ANN. § 36-401(29) (Supp. 1990); ARK. CODE ANN. § 20-8-101(C) (Michie 1990); CAL. HEALTH & SAFETY CODE § 1204(b)(1) (West 1990) (surgical clinics); FLA. STAT. ANN. § 395.002(2) (West 1986 & Supp. 1991); HAW. REV. STAT. § 321-11 (1988 & Supp. 1989); ILL. ANN. STAT. ch. 111 1/2, para. 1153 (Smith-Hurd 1988 & Supp. 1991); IND. CODE § 16-10-1-6(b) (1988); KAN. STAT. ANN. § 65-425(f) (1985); KY. REV. STAT. ANN. § 216B.015(11) (Michie/Bobbs-Merrill 1989); LA. REV. STAT. ANN. §§ 40:2131 - 40:2141 (West 1977 & Supp. 1991); ME. REV. STAT. ANN. tit. 22, § 1812-E (West Supp. 1990); MD. HEALTH-GEN. CODE ANN. § 19-101(e)(1)(iii) (1990 & Supp. 1991); MICH. COMP. LAWS ANN. § 333.20104(b)(5) (West 1989); MINN. STAT. ANN. § 144.50(2) (West 1989); MISS. CODE ANN. §§ 41-75-1 to -29 (Supp. 1991); MONT. CODE ANN. § 505-5-101(4) (1991); NEV. REV. STAT. ANN. § 449.019 (Michie 1989); N.C. GEN. STAT. §§ 131E-145 to -152 (1988); 35 PA. CONS. STAT. ANN. § 448.802a (Supp. 1991); R.I. GEN. LAWS § 23-17-2(1) (1989 & Supp. 1990); S.D. CODIFIED LAWS ANN. § 34-12-1.1(1) (1986 & Supp. 1991); TENN. CODE ANN. § 68-11-201(1) (1987 & Supp. 1991); TEX. HEALTH & SAFETY CODE ANN. §§ 243.001 to -.014 (West Supp. 1991); UTAH CODE ANN. § 26-21-2(2) (1989 & Supp. 1991); W. VA. CODE § 16-5B-1 (1991); WYO. STAT. § 35-2-901(a)(ii) (Supp. 1991).

66. ALA. CODE § 22-21-20(1) (1990); CAL. HEALTH & SAFETY CODE §§ 1206(a), (i), 1206.1 (West 1990); FLA. STAT. ANN. § 395.002(2) (West 1986 & Supp. 1991); ILL. ANN. STAT. ch. 111 1/2, para. 1153 (Smith-Hurd 1988 & Supp. 1991); ME. REV. STAT. ANN. tit. 22, § 1812-E (West Supp. 1990); MD. HEALTH-GEN. CODE ANN. § 19-101(e)(2)(v) (1990 & Supp. 1991); MICH. COMP. LAWS ANN. § 333.20104(b)(5) (West 1989); MINN. STAT. ANN. § 144.50(2) (West 1989); MISS. CODE ANN. § 41-75-1(a) (Supp. 1991); MONT. CODE ANN. § 505-5-101 (1991); NEV. REV. STAT. ANN. § 449.019 (Michie 1989); N.C. GEN. STAT. § 131E-146(1) (1988) (physicians acting within their offices are excluded if they perform "incidental, limited ambulatory surgical procedures"); 25 PA. CONS. STAT. ANN. § 448.802a (Supp. 1991); R.I. GEN. LAWS 23-17-2(1) (1989 & Supp. 1990); S.D. CODIFIED LAWS ANN. § 34-12-1.1(1) (1986 & Supp. 1991); TENN. CODE ANN. § 68-11-201(1) (1987 & Supp. 1991); W. VA. CODE § 16-5B-1 (1991); WYO. STAT. § 35-2-901(a)(ii) (Supp. 1991).

67. ALA. CODE § 22-21-20(1) (1990); CAL. BUS. & PROF. CODE §§ 1200-13 (West 1990 & Supp. 1991); CONN. GEN. STAT. ANN. § 19a-30 (West 1986); FLA. STAT. ANN. §§ 483.011 to -.151 (West 1989); GA. CODE ANN. §§ 31-22-1 to -13 (Michie 1991); ILL. ANN. STAT. ch. 111 1/2, para. 621-101 to -123 (Smith-Hurd 1988 & Supp. 1991); IND. CODE ANN. § 16-9-7-1 (West Supp. 1991); KY. REV. STAT. ANN. §§ 333.010 to -.990 (Michie/Bobbs-Merrill 1990); ME. REV. STAT. ANN. tit. 22, §§ 2011 - 2039 (West 1980 & Supp. 1990); MD. HEALTH-GEN. CODE ANN. §§ 17-201 to -212 (1984 & Supp. 1990); MASS. GEN. LAWS ANN. ch. 111D, §§ 1-8 (West Supp. 1990); MICH. COMP. LAWS ANN. §§ 333.20501 to -.20554 (West 1980 & Supp. 1991); MONT. CODE ANN. § 50-5-191(12) (1991); 1990 Neb. Adv. Legis. Serv. 551; NEV. REV. STAT. ANN. §§ 652.070 to -.190 (Michie 1987); N.H. REV. STAT. ANN. § 151:2 (1990); N.J. STAT. ANN. §§ 45:9-42.1 to -.45 (West 1978 & Supp. 1991); N.Y. PUB. HEALTH LAW §§ 571 - 581 (Consol. 1990); OR. REV. CODE ANN. §§ 438.010 to -.990 (Baldwin 1989); 35 PA. CONS. STAT. ANN. §§

the Clinical Laboratory Improvement Amendments, eleven of these states continue to maintain statutes that exempt physicians' office laboratories from regulation.<sup>68</sup>

State regulation of physician behavior outside of a hospital or health facility is limited. For example, New York and Pennsylvania regulate physician behavior in shared health facilities.<sup>69</sup> A shared health facility is an office used by three or more practitioners who provide care to Medicaid patients and who share common waiting areas, examining rooms, equipment, and support staff.<sup>70</sup> These statutes require physicians within shared health facilities to ensure follow-up care, adequate documentation, twenty-four hour availability, and patient privacy.<sup>71</sup> The facility must also register and specify the services it provides.<sup>72</sup> These statutes, however, do not ensure that procedures are performed in accordance with medical standards. In addition, because these statutes regulate only those offices where physicians share facilities and provide services to Medicaid patients, they reach only a small group of physicians' offices. Similarly, the Tennessee legislature proposed a bill that required a board to determine the qualifications for X-ray operators in physicians' offices.<sup>73</sup> The Tennessee bill, however, did not refer to physicians themselves.<sup>74</sup> Consequently, the board could have excluded physicians from these regulations.

Even when state legislatures attempt to include physicians' offices within health facility statutes, physicians can escape regulation when they practice in a setting that is not a hospital, a health facility, an outpatient surgical clinic, or a shared health facility. As a result, to ensure that only competent physicians will perform invasive procedures in their

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2151-65 (1977 & Supp. 1991); R.I. GEN. LAWS §§ 23-16.2-2 to -10 (1988 & Supp. 1990); TENN. CODE ANN. §§ 68-29-102 to -135 (1987 & Supp. 1991); W. VA. CODE § 16-5J-1 to -10 (1991); WYO. STAT. §§ 33-34-101 to -109 (1987).

68. ALA. CODE § 22-21-20 (1990); CAL. BUS. & PROF. CODE § 1241(b) (West 1990); FLA. STAT. ANN. § 483.031 (West 1989); ILL. ANN. STAT. ch. 111 1/2, para. 621-103(c) (Smith-Hurd 1988 & Supp. 1991); KY. REV. STAT. ANN. § 333.040(2) (Michie/Bobbs-Merrill 1990); ME. REV. STAT. ANN. tit. 22, § 2013-A(1)(C)(1) (West Supp. 1990); MD. HEALTH-GEN. CODE ANN. § 17-201(b)(2) (1984 & Supp. 1990); MICH. COMP. LAWS ANN. § 333.20507 (West 1980); N.H. REV. STAT. ANN. § 151:2 (1990); R.I. GEN. LAWS § 23-16.2-3(a) (1988); TENN. CODE ANN. § 68-29-104(2) (1987 & Supp. 1991) (a physician is excluded only if the laboratory is for his own patients).

69. N.Y. PUB. HEALTH LAW §§ 4700 - 4714 (Consol. 1985 & Supp. 1991); 62 PA. CONS. STAT. ANN. § 1403 (Supp. 1991).

70. N.Y. PUB. HEALTH LAW § 4702(2); 62 PA. CONS. STAT. ANN. § 1401.

71. N.Y. PUB. HEALTH LAW § 4710; 62 PA. CONS. STAT. ANN. § 1403(c).

72. N.Y. PUB. HEALTH LAW § 4704(2); 62 PA. CONS. STAT. ANN. § 1403(a)(2).

73. S. Bill 2330, 1990 Tenn. Pub. Acts 726.

74. *Id.*

offices, state legislatures should enact statutes that regulate physicians' office procedures.

### C. Other Means of Assuring Quality

Statutory regulation is appropriate because physicians' offices are not included in nonstatutory quality assurance standards. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)<sup>75</sup> is a voluntary accrediting body for hospitals, extended care facilities, psychiatric centers, alcohol and drug abuse centers, community mental health services, and ambulatory care services;<sup>76</sup> however, JCAHO accreditation is not available for physicians' offices.<sup>77</sup>

JCAHO influenced the adoption of the outcome standards used by medical professionals to evaluate quality of care.<sup>78</sup> JCAHO evaluates documented health services data against predetermined standards.<sup>79</sup> In addition, although JCAHO is a consulting organization, not a regulatory body,<sup>80</sup> JCAHO accreditation may relieve a health facility from statutory regulation.<sup>81</sup>

Another quality assurance program that fails to reach physicians' offices are Professional Review Organizations (PROs). PROs are private contractors who work for the Medicare program.<sup>82</sup> Hospitals and clinics reimbursed under Medicare's prospective payment system must enter into an agreement with a PRO.<sup>83</sup> PROs ensure that Medicare reimbursement is given to providers that render complete, accurate, and appropriate medical services.<sup>84</sup> In addition, state legislatures may require similar peer

75. Formerly the Joint Commission on Accreditation of Hospitals (JCAH).

76. Timothy S. Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C. L. REV. 835, 841 (1983) [hereinafter Jost, *JCAH*]. See JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, ACCREDITATION MANUAL FOR HOSPITALS (1992) [hereinafter JCAHO].

77. JCAHO has, however, developed standards designed for ambulatory care clinics, ambulatory surgical centers, group practices, and primary care centers. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, AMBULATORY HEALTH CARE STANDARDS MANUAL (1990).

78. Edwardson, *supra* note 10, at 25. See *supra* text accompanying notes 8-12.

79. See generally JCAHO, *supra* note 76.

80. Jost, *JCAH*, *supra* note 76, at 839.

81. See *id.* at 844.

82. 42 U.S.C. §§ 1320c - 1320c-12 (1988 & Supp. I 1989). See generally Alice G. Gosfield, *PROs: A Case Study in Utilization Management and Quality Assurance*, in HEALTH LAW HANDBOOK 361 (Alice G. Gosfield ed., 1989); Vance-Bryan, *supra* note 15, at 1425.

83. 42 U.S.C. § 1320c-2. See generally 3 Medicare & Medicaid Guide (CCH) ¶¶ 12,855, 12,860 (1987).

84. 42 U.S.C. § 1320c-3; 42 C.F.R. § 466.71 (1990). See also 3 Medicare & Medicaid Guide (CCH) ¶ 12,865 (1987).

review programs for hospitals and clinics.<sup>85</sup> Because nonstatutory quality assurance schemes such as JCAHO accreditation and peer review programs do not include physicians' offices, a state statute regulating physicians' office procedures will help to ensure that quality medical care is provided in this setting.

#### IV. PROPOSED CHANGES FOR ENSURING QUALITY IN PHYSICIANS' OFFICES

This Note recommends the implementation of a state statute to regulate physicians' office procedures. As discussed in previous sections, a statute regulating physicians' office procedures will help to identify physicians who deviate from accepted practices, to provide uniform application of outcome standards, and to decrease the incidence of unnecessary procedures and treatments. The proposed statute is designed to be practical and flexible without imposing an undue burden on private medical practice. To ensure quality, it also incorporates JCAHO standards that are applicable to the office setting.

The proposed statute defines the term "office" broadly to ensure public protection. In the proposed statute, an office includes any space shared by physicians<sup>86</sup> or operated by a health maintenance organization. Emergency medical centers and clinics not otherwise subject to state regulation will also be included in the statute's definition of office. A broad definition of the term office prohibits physicians from dodging regulation by renaming their office or changing its ownership or management form.

##### A. *Classifying Physicians' Office Procedures*

Physicians' office procedures vary in scope, nature, and sophistication. Because physicians perform numerous procedures within their offices, the proposed statute will implement a classification system for office procedures. Classification systems such as the Medical Device Classification Amendments, which regulate the safety of new medical devices, are frequently used in medical regulation.<sup>87</sup> Under the Medical Device Classification Amendments, each new medical device is placed into one of three classes.<sup>88</sup> These classes are defined broadly. Ultimately, a classification panel reviews each device and assigns it to a class.<sup>89</sup>

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85. See ARIZ. REV. STAT. ANN. § 36-445 (1990).

86. For a discussion of statutes regulating shared office space under the Medicaid program, see *supra* notes 70-72 and accompanying text.

87. See 21 U.S.C. §§ 360c-360k (1988 & Supp. I 1989).

88. *Id.* § 360c.

89. *Id.* § 360c(c).

Class I devices “[do] not present a potential unreasonable risk of illness or injury.”<sup>90</sup> Class II devices require added assurance of their safety and effectiveness.<sup>91</sup> Class III devices include devices for which “insufficient information exists for the establishment of a performance standard to provide reasonable assurance of [their] safety and effectiveness.”<sup>92</sup> Class III devices also include those devices that present a potential unreasonable risk of illness or injury.<sup>93</sup>

The Pennsylvania Clinical Laboratory Act also uses a classification system.<sup>94</sup> Under the Pennsylvania Act, Level I laboratories must register and adhere to clinical laboratory regulations.<sup>95</sup> In contrast, Level II and Level III laboratories must register, follow clinical laboratory regulations, complete self-evaluation forms, and participate in a proficiency testing program.<sup>96</sup>

The proposed statute will implement a classification system similar to these statutes. The proposed classification system for physicians' offices provides flexibility and avoids the necessity of providing separate regulations for every imaginable procedure. For example, the proposed statute divides physicians' office procedures into three classes. Class I procedures include noninvasive procedures that do not require a physician's skill. Class I procedures also include procedures typically performed by nursing or ancillary staff. These procedures include electrocardiograms, vital signs measurements, ear cleaning and irrigation, throat swabs, urinary catheter placement, intravenous catheter placement, and glaucoma screening. Class I procedures are excluded from the pro-

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90. *Id.* § 360c(a)(1)(A). See also 21 C.F.R. § 860.3(c)(1) (1991).

91. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2). The FDA will consider the following factors in establishing performance standards for Class II devices and premarket approval of Class III devices: (1) the persons for whose use the device is represented or intended; (2) the conditions of use; (3) the probable health benefit weighed against any probable injury; and (4) the reliability of the device. 21 C.F.R. § 860.7(b) (1991).

92. 21 U.S.C. § 360c(a)(1)(C)(ii) (1988); 21 C.F.R. § 860.3(c)(3) (1991).

93. *Id.* § 360c(a)(1)(C)(ii)(II).

94. 35 PA. CONS. STAT. §§ 2151-2165 (1977 & Supp. 1991).

95. Level I laboratories may perform urinalysis, glucose, pregnancy, white blood cell, hemoglobin, hematocrit, sedimentation rate, primary culture, occult blood, pinworm, *Trichomonas vaginalis*, and sickle cell testing. 28 PA. CODE § 5.1(ii) (1989). Cf. ILL. ANN. STAT. ch. 111 1/2, para. 622-108 to -111 (Smith-Hurd 1988). See also Josephine Bartola, *Painless Office Laboratory Regulation*, 13 PRIMARY CARE 605, 609 (1986); Miriam M. Bloch et al., *Longitudinal Study of Error Prevalence in Pennsylvania Physicians' Office Laboratories*, 260 JAMA 230, 230 (1988).

96. Level II laboratories may perform differential cell counts, prothrombin times, mononucleosis testing, B-streptococcus throat cultures, urinary tract infection testing and cell counts, and Gram's stains. Level III laboratories are those laboratories performing Level II testing and any other laboratory testing not included in Level I or Level II. Bloch, *supra* note 95, at 230-31. See *supra* note 95.

posed statute because they include noninvasive procedures that require only general skill.

Class II procedures require a higher degree of physician skill. This class includes procedures routinely performed by physicians such as X-rays, Pap smears, nuclear medicine services, and ultrasounds.<sup>97</sup> Although the Clinical Laboratory Improvement Amendments are designed to ensure proficient Pap smear readings, laboratory personnel may misread Pap smear specimens because the clinician failed to properly prepare the slide.<sup>98</sup> For this reason, Pap smears are regulated as Class II procedures, rather than Class I procedures which are excepted from the statute.

Class III procedures include invasive procedures that require an even higher level of physician skill and training. Shunt and catheter placement are examples of Class III procedures. Peripheral intravenous catheter placement is excluded because it is performed by nurses. Other Class III procedures include pacemaker placement, cardiac catheterization, biopsies, thoracentesis,<sup>99</sup> paracentesis,<sup>100</sup> and bronchoscopic,<sup>101</sup> endoscopic,<sup>102</sup> cystoscopic,<sup>103</sup> and fluoroscopic procedures.<sup>104</sup> Class III procedures also include hemodialysis<sup>105</sup> and radiation therapy.<sup>106</sup>

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97. For descriptions of the diagnostic imaging procedures mentioned and others, see MARTIN P. SANDLER ET AL., *CORRELATIVE IMAGING* (1989); *TECHNIQUES IN DIAGNOSTIC IMAGING* (Graham H. Whitehouse & Brian Worthington eds., 2d ed. 1990).

98. See HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. NO. 899, 100th Cong., 2d Sess. 16-17 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3837.

99. Thoracentesis is a procedure in which the physician removes fluid from the pleural (lung) cavity using a needle or other hollow instrument. See *STEDMAN'S MEDICAL DICTIONARY* 1446 (24th ed. 1982).

100. Paracentesis is a procedure in which the physician removes fluid from a body cavity using a needle or other hollow instrument. See *id.* at 1024.

101. Bronchoscopic procedures are procedures in which the physician examines the interior of the tracheobronchial tree using an endoscope to diagnose, to obtain biopsy samples, or to remove foreign bodies. See *id.* at 195.

102. Endoscopic procedures include any procedure in which the physician uses a lighted tubular scope to examine a canal or hollow organ of the digestive, respiratory, urogenital, or endocrine system. See *id.* at 465, 1566.

103. Cystoscopic procedures are procedures in which the physician uses a lighted tubular scope to examine the bladder's interior. See *id.* at 357.

104. Fluoroscopic procedures are procedures in which tissues and deep structures of the body are examined by X-rays that are projected onto a screen. See *id.* at 543.

105. Hemodialysis is a procedure by which toxic agents and electrolytes are removed from and necessary solutes are added to the patient's blood as it flows through a membrane or "artificial kidney." See *LAWYERS' MEDICAL CYCLOPEDIA OF PERSONAL INJURIES AND ALLIED SPECIALTIES* § 44.26 (Charles J. Frankel ed., 1977). See generally ALLEN R. NISSEN ET AL., *CLINICAL DIALYSIS* (1990).

106. For a discussion of other procedures that may be classified as Class III procedures, see ARTHUR B. DUBLIN, *OUTPATIENT INVASIVE RADIOLOGIC PROCEDURES: DIAGNOSTIC AND THERAPEUTIC* (1989).

In addition, Class III procedures may be performed in settings that are subject to state health facility statutes. For example, twelve states specifically include independent dialysis centers within their health facility statutes.<sup>107</sup> Under the proposed statute, dialysis is a Class III procedure; therefore, the proposed statute prohibits physicians from moving these procedures from a clinic to an office setting to avoid regulation. Once the office's managing physician determines what class of procedures are performed, the office must meet the registration requirements outlined in the next section.

### *B. Registration*

Under the proposed statute, offices where Class II and Class III procedures are performed must be registered with the Physicians' Office Procedure Committee (the Committee); however, offices where only Class I procedures are performed are not included in the statute's mandates. Registration requires that the managing physician for any office where Class II and Class III procedures are performed submit an application that describes the procedures performed and the methodology used. The application will include a list of the qualifications of the personnel assisting with the procedures, the frequency or expected frequency of the performance of each procedure, and the physician's experience with the procedure. The managing physician must also agree to permit annual inspections by the Committee, provide records in accordance with the statute, and pay a registration fee. Registration and inspection will provide a means of identifying physicians who perform procedures or operate equipment in their offices without the additional skill required for their performance or operation.

### *C. Physician Responsibilities*

The proposed statute is similar to health facility and hospital regulations and is consistent with physicians' tort liability because it requires

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107. ALA. CODE § 22-4-2(7) (1990); CAL. HEALTH & SAFETY CODE §§ 417.1 to -.8 (West 1990); CONN. GEN. STAT. § 19a-269 (West 1986); IND. CODE § 16-1-3.4-1(3) (1988); KAN. STAT. ANN. § 65-4801(b) (1985); KY. REV. STAT. ANN. § 216B.015(12) (Michie/Bobbs-Merrill 1991); MD. HEALTH-GEN. CODE ANN. § 13-307 (1982 & Supp. 1990); MONT. CODE ANN. § 50-5-101(26) (1989); 35 PA. CONS. STAT. ANN. § 448.103 (Supp. 1991); R.I. GEN. LAWS § 23-17-2(1) (Supp. 1991); UTAH CODE ANN. § 26-21-2(5) (Supp. 1991); WYO. STAT. § 35-2-901(a)(x) (Supp. 1991). *Cf.* MD. HEALTH-GEN. CODE ANN. § 19-101(e)(2)(iii), (iv) (Supp. 1991) (excluding kidney disease treatment facilities).

that offices where Class II and Class III procedures are performed must be maintained in a safe and hygienic condition. Physicians must provide adequate personnel, equipment, and space for the number of procedures performed.<sup>108</sup> In addition, to ensure safety in the performance of these procedures, equipment must be maintained in safe condition through inspection, calibration, and maintenance in accordance with the manufacturer's recommendations.

Furthermore, Class II and Class III procedures tend to require blood or tissue contact; therefore, physicians who perform these procedures may generate infectious waste and linen. For this reason, infection control guidelines must be imposed. For example, physicians' office personnel must dispose of needles in impervious containers, provide a work area for waste and dirty linen, and maintain records of sterilization test results.<sup>109</sup>

Another essential requirement for Class II and Class III procedures is the availability of emergency services. Emergency equipment and physician training in cardiac life support are necessary to ensure that the physician can safely transport patients to a hospital emergency department if necessary. Physicians performing Class II procedures must be certified in Basic Cardiac Life Support, but physicians performing Class III procedures must be certified in Advanced Cardiac Life Support.<sup>110</sup> The distinction is made because Class III procedures are more likely to result in the need for emergency services. Each office in which Class III procedures are performed must also maintain an emergency cardiopulmonary equipment cart to be used if a patient's respirations or heart beat stops.<sup>111</sup>

Under the proposed statute, physicians must also maintain medical records that include the patient's relevant history, chief complaint, procedures performed, and any follow-up care provided.<sup>112</sup> These records ensure comprehensive patient care and provide the Committee with documentation. The Committee can also use these records to determine whether the physician chose procedures appropriate to the patient's symptoms, whether the patient experienced adverse effects with similar procedures, and whether the physician provided appropriate follow-up care.

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108. Cf. 42 U.S.C. § 263a(d) (1988); JCAHO, *supra* note 76, at PA.2.

109. Cf. IND. ADMIN. CODE tit. 410, r. 15-2-14(2), (3) (1988); MINN. R. 4675.2400(1) (1990).

110. See generally AMERICAN HEART ASSOCIATION, TEXTBOOK OF ADVANCED CARDIAC LIFE SUPPORT (1989).

111. Cf. JCAHO, *supra* note 76, at ER.6.8.2.

112. Cf. IND. ADMIN. CODE tit. 410, r. 15-2-8(1) (1988); JCAHO, *supra* note 76, at HO.5.2.

Finally, physicians and their office personnel are required to maintain continuing education related to the office procedures performed. The Physicians' Office Procedure Committee is responsible for determining these educational requirements.

#### *D. The Physicians' Office Procedure Committee*

The proposed statute will implement a Physicians' Office Procedure Committee that is designed to meet the characteristics of effective peer review. These characteristics include: (1) practitioners knowledgeable in the practice reviewed; (2) objective analysis; (3) a focus on the evaluation of quality; (4) protection from legal intrusion; and (5) removal from corrective action decisions.<sup>113</sup>

The Committee will be the regulatory body that will enact the rules and regulations necessary to implement the statute. These rules and regulations may describe Class II or Class III procedures. They may relate to physician or staff qualifications. They may also include regulations designed to maintain sanitary conditions and safe equipment.<sup>114</sup> The Committee will also ensure that Class II and Class III offices are inspected annually and will maintain a list of registered offices that will be available to the public.<sup>115</sup> The list will serve to: (1) assist physician referral; (2) deter behavior that violates the statute; and (3) allow consumers to assess physician performance.<sup>116</sup>

A clinical engineer, a nurse or ancillary medical professional, physicians, and health care consumers will participate in the proposed Physicians' Office Procedure Committee. To maintain an unbiased Committee, the appointing body will be separate from any organization that only represents the medical profession. The appointing body may be the legislature or an appropriate administrative agency.

The Committee may select its own officers.<sup>117</sup> The Director is responsible for office registrations and for employing any staff necessary to assist the Committee. The Secretary will publish the rules and regulations enacted by the Committee. The Treasurer will maintain the

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113. Roberts, *supra* note 13, at 73.

114. *Cf.* NEV. REV. STAT. ANN. § 652.130 (Michie 1987) (under the Nevada Medical Laboratory Certification and Improvement Act, the state board of health is required to publish regulations concerning sanitary conditions in the lab).

115. *Cf.* 42 U.S.C. § 263a(n) (1988); ARIZ. REV. STAT. ANN. § 36-463.01 (Supp. 1990).

116. *Cf.* HOUSE ENERGY AND COMMERCE COMMITTEE, H. REP. NO. 899, 100th Cong., 2d Sess. 38 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3859.

117. *See id.*

Physicians' Office Procedure Revolving Fund.<sup>118</sup> This fund includes gifts, grants, donations, workshop fees, and fines levied under the Act.<sup>119</sup> The Treasurer will also collect fines and fees, pay bills, and prepare an annual budget.<sup>120</sup>

### *E. The Physicians' Office Disciplinary Panel*

The Physicians' Office Disciplinary Panel (the Panel) is the disciplinary body under the proposed statute. As with the Committee, the appointing body may be the legislature or an administrative agency. Committee members may not serve on the Panel, and Panel members may not serve on the Committee. A Panel separate from the Committee is created to avoid collusion within a single administrative body. A physician is more likely to receive fair notice and hearing if the inspection and disciplinary bodies are separate. Thus, physicians' actions will be reviewed twice before any disciplinary action is taken.

The Panel will examine requests for hearings generated from Committee inspections and consumer complaints. The Panel will also ensure that physicians who receive unfavorable inspection results or complaints are given an opportunity for a hearing.<sup>121</sup> If the public safety is threatened, however, the Panel may suspend the office's registration and petition to enjoin the performance of procedures.<sup>122</sup> The physician, however, is entitled to an appeal.

After a hearing is held, the Panel may revoke, limit, or suspend an office's registration. Office registration revocation, limitation, or suspension is appropriate when a physician provides misleading infor-

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118. *Cf.* ARIZ. REV. STAT. ANN. § 36-468 (Supp. 1990).

119. *Cf. id.*

120. *Cf. id.*

121. *Cf.* N.Y. PUB. HEALTH LAW § 577(3) (Consol. 1990) (concerning laboratory services) which provides:

No permit or certificate shall be revoked, suspended, limited or annulled without a hearing. However, a permit or certificate may be temporarily suspended without a hearing for a period not in excess of thirty days upon notice to the permit or certificate holder following a finding by the department that the public health, safety or welfare is in imminent danger.

122. *Cf.* GA. CODE ANN. § 31-22-12 (Michie 1991) which provides:

The operation or maintenance of an unlicensed clinical laboratory in violation of this chapter is declared a nuisance, inimical to the public health, welfare, and safety. The commissioner in the name of the people of the state through the Attorney General may, in addition to other remedies provided in this chapter, bring an action for an injunction to restrain such violation or to enjoin the future operation or maintenance of any such clinical laboratory until compliance with this chapter or the rules or regulations promulgated under this chapter has been demonstrated to the satisfaction of the department.

mation to the Committee or Panel.<sup>123</sup> The Panel may also apply these remedies when the physician performs procedures without registering his office,<sup>124</sup> when a physician refuses a reasonable request for information by the Committee or the Panel, or when a physician helps another physician to violate the Act or refers patients to an office that performs Class II and Class III procedures without a registration.<sup>125</sup> In the alternative, the Panel may also recommend to the Attorney General that a physician who performs procedures in an unregistered office or who knowingly violates the Act be charged with a misdemeanor. The Panel is also required to generate a report to the state licensure board that identifies physicians who have violated the Act. The Panel may also impose a supervised correction plan or a monetary penalty before revoking, suspending, or limiting office registration.<sup>126</sup>

In summary, the proposed statute divides physicians' office procedures into three classes. The statute imposes personnel, office conditions, and equipment requirements for the two classes of procedures that are likely to result in harm to patients. In addition, the statute creates a Committee to register offices subject to the statute and to conduct inspections. Finally, the proposed statute creates a disciplinary Panel to hold hearings, sanction physicians performing procedures in unregistered offices, and address consumer complaints.

#### V. CONCLUSION

Under current state laws, physicians are free from quality assurance review when they practice medicine within their offices. Yet, with the increase in outpatient services, physicians are providing a wide variety of services within their offices. Like Dr. Jones, physicians can now purchase diagnostic equipment and perform procedures without referring patients to a hospital or clinic. State legislatures must ensure that patients are protected not only in hospitals, nursing homes, and clinics, but also within physicians' offices; thus, a compelling need exists for state statutes requiring office registration, routine inspections, and consumer complaint investigation to ensure patient safety. The proposed statute will help to ensure that patients receive quality medical care when they are treated in a physician's office.

ROLANDA MOORE HAYCOX

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123. *Cf.* 42 U.S.C. § 263a(i)(1)(A) (1988); GA. CODE ANN. § 31-22-2(d)(1) (Michie 1989); N.Y. PUB. HEALTH LAW § 577(1)(a) (Consol. 1990).

124. *Cf.* 42 U.S.C. § 263a(i)(1)(B).

125. *Cf.* 42 U.S.C. § 263a(i)(1)(C)-(F) (1988); GA. CODE ANN. § 31-22-2(d)(5) (Michie 1991); N.Y. PUB. HEALTH LAW § 577(1)(g) (Consol. 1990).

126. *Cf.* 42 U.S.C. § 236a(h)(2) (1988).

## Appendix

A Bill for an Act to Ensure Quality in Medical Services Delivery  
Within Physicians' Offices

Effective: Upon passage.

Be it enacted by the General Assembly:

Chapter 1. *Purpose.*

The Legislature finds that the treatment of illness is frequently provided through diagnostic and therapeutic procedures and that inaccurately performed medical procedures endanger the health and lives of this State's citizens. Diagnostic procedures provide essential services to patients by furnishing practitioners with information that is essential in identifying or treating a medical condition. Physicians' office procedures should be performed by physicians having sufficient expertise and experience to assure quality and accuracy. The Legislature therefore declares it to be a public policy of this State to register physicians' offices where diagnostic and therapeutic procedures are performed and to set necessary standards for the care rendered within those offices.<sup>127</sup>

Chapter 2. *Definitions.*

These definitions apply throughout this Act:

- (1) "Applicant" or "registrant" means anyone registering or in the process of registering an office in compliance with Chapter 4 of this Act.
- (2) "Direct supervision" means that a physician supervises the procedure and determines which drugs or devices will be used.
- (3) "Infectious waste" means waste originating from the diagnosis, care, or treatment of a person that has been or may have been exposed to an infectious disease. Such waste includes but is not limited to:
  - (a) wastes originating from persons placed in isolation for the control and treatment of an infectious disease;
  - (b) bandages, dressings, casts, catheters, tubing, and the like used to treat infectious or potentially infectious wounds, burns, or surgical incisions;
  - (c) anatomical waste, human parts, or tissues;
  - (d) discarded hypodermic needles and syringes, scalpel blades, and similar materials; and

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127. Cf. TENN. CODE ANN. § 68-29-102 (1989 & Supp. 1991); W. VA. CODE § 16-5J-1 (1991).

- (e) any waste that cannot be separated from infectious waste.<sup>128</sup>
- (4) "Nuclear medicine" means the administration of a radioactive substance for diagnostic purposes or the act of performing associated imaging procedures or both.<sup>129</sup>
- (5) "Office" includes:
  - (a) office or clinic space shared by a physician group, regardless of whether such physicians are a partnership, association, or corporation;
  - (b) offices or clinics maintained by medical practices such as health maintenance organizations or any other managed care provider;
  - (c) offices or clinics providing ambulatory surgery or health care services not otherwise subject to state regulation;
  - (d) emergency medical centers; and
  - (e) any other center, clinic, or office where physicians perform procedures.
- (6) "Physician" means a person licensed to practice medicine or osteopathy.
- (7) "Physicians' Office Disciplinary Panel" or the "Panel" means the panel defined by this Act under Chapter 8.
- (8) "Physicians' Office Procedure Committee" or the "Committee" means the committee defined by this Act under Chapter 6.

### Chapter 3. *Classification of Procedures.*

#### Section 1. *Class I Procedures.*

- (1) Class I procedures are noninvasive procedures that do not require a physician's skill. Class I procedures include procedures typically performed by nursing or ancillary staff. These procedures include but are not limited to:
  - (a) electrocardiograms;
  - (b) vital signs measurement;
  - (c) ear cleaning and irrigation;
  - (d) throat swabs;
  - (e) urinary catheter placement;
  - (f) intravenous catheter placement;
  - (g) glaucoma screening; and
  - (h) other procedures as defined by the Committee.

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128. Cf. MINN. R. 4675.2200 (1990).

129. Cf. VT. STAT. ANN. tit. 26, § 2801(4) (1989) ("Practice of nuclear medicine technology" means the act of giving a radioactive substance to a human being for diagnostic purposes, or the act of performing associated imaging procedures, or both.').

(2) Offices in which only Class I procedures are performed are not subject to the requirements of this Act.

Section 2. *Class II Procedures.*

(1) Class II procedures require a higher degree of physician skill than Class I procedures. Class II procedures include noninvasive procedures routinely performed by physicians. These procedures include but are not limited to:

- (a) X-rays;
- (b) Pap smears;
- (c) nuclear medicine services;
- (d) ultrasound procedures; and
- (e) other procedures as defined by the Committee.

(2) Class II procedures may be performed by qualified persons as defined by the State's licensure requirements.

Section 3. *Class III Procedures.*

(1) Class III procedures are invasive procedures requiring physician skill and training. These procedures include but are not limited to:

- (a) shunt or catheter placement with the exception of peripheral intravenous access;
- (b) pacemaker placement;
- (c) cardiac catheterization;
- (d) biopsy sampling;
- (e) thoracentesis;
- (f) paracentesis;
- (g) bronchoscopic procedures;
- (h) endoscopic procedures;
- (i) cystoscopic procedures;
- (j) hemodialysis;
- (k) fluoroscopic procedures;
- (l) radiation oncology; and
- (m) other procedures as defined by the Committee.

(2) Class III procedures shall be performed only by a physician. Hemodialysis, however, may be performed by a qualified registered nurse under the direct supervision of a physician trained in hemodialysis.

Chapter 4. *Registration and Renewal.*

Section 1. *Registration.*

(1) Offices conducting only Class I procedures shall not be required to register under this Act. All offices conducting Class II and Class III procedures shall register in accordance with this Chapter.

(2) The Committee shall register a physician's office if the managing physician:

- (i) submits an application that describes:

- (A) the procedures performed in the office;
  - (B) the methodologies used for the procedures;
  - (C) the identity and qualifications of persons assisting with such procedures;
  - (D) the name of the office if different from the name of the physician or physicians practicing at such office;
  - (E) the office address and a brief physical description of the office;
  - (F) the name, residential address, and professional license number of every practitioner participating in the office;
  - (G) the name and residential address of the person designated to assume responsibility for the central coordination and management of the office's activities;
  - (H) the annual expected frequency of the performance of each procedure based on the frequency of performance in the past year of procedures for which registration is sought; and
  - (I) the length of time the physician has been performing such procedures.<sup>130</sup>
- (ii) provides any other information required by the Committee to determine compliance with this Act;
  - (iii) agrees to provide the Committee with any change in the information submitted not later than three months after the change is put into effect;<sup>131</sup>
  - (iv) agrees to permit inspections by the Committee, its employees, or agents pursuant to Chapter 12 of this Act; and
  - (v) agrees to make records available and submit reports as required by the Committee or the Panel.<sup>132</sup>
- (3) In addition, all applications for registration shall include any information requested by the Committee confirming the adherence to any applicable state statutes and regulations for the operation of the office including plumbing, heating, lighting, ventilation, electric services, water, sewage, specimen handling, and similar conditions to ensure the health and safety of office personnel and the public.<sup>133</sup>

130. Cf. 42 U.S.C. § 263a(2)(A) (1988); N.Y. PUB. HEALTH LAW § 4704 (Consol. 1985) (registration of shared health facilities).

131. Cf. 42 U.S.C. § 263a(d)(1)(A)(iii) (1988).

132. Cf. *id.* § 263a(d)(1)(D).

133. Cf. ARIZ. REV. STAT. ANN. § 36-465(3) (Supp. 1990); ME. REV. STAT. ANN. tit. 22, § 2023(2) (West 1980 & Supp. 1990).

- (4) Registration issued under this section shall be valid for two years or any shorter period established by the Committee.

### Section 2. *Renewal.*

- (1) When an office renews its registration the managing physician shall report:
  - (a) the number and type of procedures performed;
  - (b) the percentage of each registered procedure resulting in complications and a description of the type of complications involved;
  - (c) the number of patients transferred to a hospital due to complications; and
  - (d) the number of patients returning for follow-up.

Section 3. A registration fee shall be assessed for each office registered. The fee shall be determined by the Physicians' Office Procedure Committee.

## Chapter 5. *Office Conditions Requirements.*

### Section 1. *Physical Requirements.*

- (1) Space, equipment, and supplies shall be adequate for the performance of procedures with optimal accuracy, precision, efficiency, timeliness, and safety.<sup>134</sup> Space and equipment needs shall be determined by the services contemplated and the estimated patient load. The office shall maintain space for administrative functions, public waiting, examination, and treatment rooms, and restrooms.<sup>135</sup>
- (2) A separate treatment room shall be maintained for Class III procedures.
- (3) Sanitary toweling and soap, including holders, shall be provided at all handwashing areas.<sup>136</sup>
- (4) Examination tables shall lock and adjust to their required positions.<sup>137</sup>
- (5) Side rails and safety steps shall be available when needed.<sup>138</sup>

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134. See JCAHO, *supra* note 76, at PA.2.

135. See IND. ADMIN. CODE tit. 410, r. 15-1-12(4) (1988).

136. Cf. 15-1-22(5)(d).

137. See JCAHO, *supra* note 76, at ER.6.8.7.

138. See *id.* at ER.6.8.7.2.

### Section 2. *Maintenance.*

- (1) Chemical substances used for maintenance, housekeeping, or control of insects or vermin shall be clearly labeled and stored separately from patient care supplies.<sup>139</sup>
- (2) Each office shall routinely clean articles and surfaces with an appropriate cleanser.<sup>140</sup> Each office shall be kept free of dust, rubbish, dirt, and hazards. To ensure cleanliness, each office shall:
  - (a) maintain floors in a clean condition with a nonslip finish;
  - (b) clean toilets at least daily; and
  - (c) clean equipment at least monthly and between patient uses.<sup>141</sup>

### Section 3. *Equipment.*

- (1) Only shockproof equipment shall be used.
- (2) All electrical equipment shall be grounded.
- (3) Temperatures shall be recorded daily for all temperature-controlled areas and instruments.<sup>142</sup>
- (4) Each instrument or other device shall be calibrated, tested, or inspected according to the manufacturer's recommendations.
- (5) Records showing equipment calibration, testing, or inspection shall be maintained and be available to the Committee. These records shall include any significant actions taken in response to revealed deficiencies.<sup>143</sup>
- (6) Equipment and supplies shall be suitable for the sizes of patients treated using the manufacturer's guidelines.<sup>144</sup>
- (7) Equipment maintenance records shall be retained for the life of each instrument used.<sup>145</sup>

### Section 4. *Safety.*

- (1) *X-rays.*
  - (a) Protective gloves and aprons shall be available in the office.
  - (b) A physician who supervises or performs X-ray procedures must be a licensed doctor of medicine or licensed doctor of osteopathy who:
    - (i) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology; or

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139. Cf. IND. ADMIN. CODE tit. 410, r. 15-1-22(9) (1988).

140. Cf. *id.* r. 16.2-2-6(g).

141. Cf. *id.* r. 16.2-2-6(g)(2).

142. See JCAHO, *supra* note 76, at PA.2.4.2.

143. See *id.* at PA.2.4.1.1.

144. See *id.* at HO.4.4.

145. See *id.* at PA.5.7.

- (ii) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes; or
  - (iii) specializes in radiology and is a recognized specialist in radiology.<sup>146</sup>
- (2) *Infection Control.*
- (a) Infectious waste shall be collected in containers with moisture-proof, heavy-duty, or double plastic liners. These containers shall be kept closed or sealed at all times.<sup>147</sup>
  - (b) Disposal containers for needles shall provide safety from puncture wounds.<sup>148</sup>
  - (c) A workroom for soiled materials shall be present in all offices where Class III procedures are performed. This workroom shall contain a clinical sink or equivalent flushing rim fixture, a sink equipped for handwashing, a work counter, a waste receptacle, and a linen receptacle.<sup>149</sup>
  - (d) Monthly inspections of all sterilizing equipment shall be carried out by a qualified person.<sup>150</sup> Bacteriological cultures shall be used to check sterilization processes of all types at least monthly.<sup>151</sup>
  - (e) Each office performing procedures requiring equipment sterilization shall maintain records of the results of bacteriological test of sterilizing equipment.<sup>152</sup>
- (3) *Oxygen.* Each office shall observe safety precautions when oxygen is stored or administered. Oxygen containers shall be suitably anchored to a floor, wall, or carrier to prevent tipping.<sup>153</sup>
- (4) *Other Safety & Hygiene Considerations.*
- (a) *Emergency Power.* In the event of power failure, the emergency power supply shall be sufficient to maintain emergency equipment. Battery power for emergency equipment is sufficient if available.<sup>154</sup>
  - (b) *Linen.*
    - (1) A clean linen storage area shall be provided in a clean closet or designated area within a clean workspace.<sup>155</sup>

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146. Cf. 42 C.F.R. § 405.1412 (1990).

147. See MINN. R. 4675.2400(1) (1990).

148. Cf. *id.* 4675.2400(2).

149. Cf. IND. ADMIN. CODE tit. 410, r. 15-1-10(6)(e)(2)(j) (1988).

150. Cf. *id.* r. 15-2-14(2).

151. Cf. *id.* r. 15-2-14(3).

152. Cf. *id.* r. 15-2-14(5)(b).

153. Cf. IND. ADMIN. CODE tit. 410, r. 16.2-2-6(n) (1988 & Supp. 1991).

154. Cf. JCAHO, *supra* note 76, at PA.2.3.3.

155. Cf. IND. ADMIN. CODE tit. 410, r. 15-1-10(6)(e)(2)(l) (1988).

(2) All linen shall be handled, processed, and transported in a way that guards against contamination of clean linen and transmission of infection.<sup>156</sup>

(3) All soiled linens shall be placed in impervious bags or containers that are properly closed at the site of collection.<sup>157</sup>

- (c) *Refuse*. Refuse and garbage shall be collected, transported, stored, and disposed of by methods which will decrease nuisances and hazards.<sup>158</sup> Insect- and rodent-proof refuse storage shall be provided.<sup>159</sup>

### Section 5. *Emergency Services*.

(1) A physician shall not perform Class III procedures within an office unless he or she is certified in Advanced Cardiac Life Support according to American Heart Association guidelines.<sup>160</sup>

(2) All offices performing Class III procedures shall maintain a cart for the storage of emergency equipment to be used in the event of cardiopulmonary arrest. The cart's contents shall include but are not limited to:

- (a) appropriately sized airways;
- (b) a bag-valve-mask resuscitator;
- (c) appropriately sized laryngoscopes and endotracheal tubes;
- (d) emergency resuscitation drugs recommended by the American Heart Association;<sup>161</sup>
- (e) a portable monitor with a defibrillator having synchronous capabilities. The defibrillator may be a separate unit if it is kept with the emergency equipment cart;
- (f) tracheobronchial and gastric suction source and equipment;
- (g) oxygen source and administration equipment; and
- (h) a vascular cut down set.<sup>162</sup>

(3) Emergency equipment, drugs, and supplies shall be checked daily and after each use to confirm that all items are immediately available and in usable condition.<sup>163</sup>

156. *Cf. id.* r. 15-1-19(4).

157. *Cf. id.* r. 15-1-19(4)(c).

158. *Cf. id.* r. 15-1-20(6).

159. *Cf. id.* r. 15-1-22(5)(s).

160. See AMERICAN HEART ASSOCIATION, TEXTBOOK OF ADVANCED CARDIAC LIFE SUPPORT (1989).

161. *See id.*

162. *See* JCAHO, *supra* note 76, at ER.6.8.2.1.

163. *See id.* at HO.4.5.

## Chapter 6. *Physicians' Office Procedure Committee.*

(1) *Committee members.* The Physicians' Office Procedure Committee shall be composed of nine members. One member shall be an engineer skilled in the proper use and maintenance of diagnostic and therapeutic medical equipment. One member shall be a nurse or ancillary medical professional. Four members shall represent consumers. Three members shall be practicing physicians. Committee members may be appointed by the Legislature or an administrative agency designated by the legislature.

(2) Each member of the Committee shall serve for three years except that:

(a) any member appointed to fill a vacancy occurring prior to the end of the term of which his or her predecessor was appointed shall be appointed for the remainder of such term;<sup>164</sup> and

(b) three members' terms shall expire each year so that three new members are appointed each year.

(3) The Committee shall select a director, assistant director, secretary, and treasurer from among its members.

(4) Six members shall constitute a quorum of the Committee.

(5) Committee members may receive compensation as determined by the Legislature.

(6) The Committee shall determine its own operating procedures for Committee business.

## Chapter 7. *Duties and Responsibilities of the Physicians' Office Procedure Committee.*

### Section 1. *Director.*

(1) The Director shall maintain a list of all offices meeting the requirements of this Act. The Director shall make this list available on request to the Panel, physicians, other health care providers, and the public.<sup>165</sup>

(2) The Director shall supervise the employment of professional, clerical, technical, investigative, and administrative personnel to carry out the work of the Committee.

### Section 2. *Secretary.*

(1) The Secretary shall:

(a) prepare any minutes, records, reports, registries, directories, books, and newsletters needed;

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164. See 1990 Neb. Adv. Legis. Serv. 551.

165. Cf. 42 U.S.C. § 263a(n) (1988); ARIZ. REV. STAT. ANN. § 36-465 (Supp. 1990).

- (b) record all Committee transactions and orders; and
- (c) publish the rules and regulations enacted by the Committee.

### Section 3. *Treasurer.*

- (1) The Treasurer shall:
  - (a) collect all monies due and payable for office registrations, office inspections, and fines imposed under Chapter 14, Section 1 of this Act;
  - (b) pay all bills for Committee expenditures; and
  - (c) prepare the annual budget.

### Section 4. *General Duties.*

- (1) The Committee shall have the authority to enact rules and regulations relative to the quality of diagnostic and therapeutic procedures performed by physicians in their offices. The Committee shall use the current standards adopted by the Joint Commission on Accreditation of Healthcare Organizations and the American Osteopathic Association in prescribing rules and regulations. These rules and regulations may relate to:
  - (a) defining Class II and Class III procedures;
  - (b) equipment maintenance; and
  - (c) continuing education requirements for physicians and office personnel.<sup>166</sup>
- (2) In carrying out its duties under this Chapter, the Committee may use the services of any state or local agency or nonprofit private organization and may pay for such services in advance.<sup>167</sup> The duties a state or local agency or nonprofit private agency or organization may perform include but are not limited to:
  - (a) conducting investigations;
  - (b) gathering information;
  - (c) monitoring continuing education compliance; and
  - (d) any other duties the Committee determines are necessary and appropriate for the enforcement of this Act.
- (3) The Committee shall ensure that all Class II and Class III offices are inspected annually.
- (4) In adopting or modifying regulations enacted pursuant to this Act, the Committee shall allow a reasonable time for compliance.

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166. Cf. ARIZ. REV. STAT. ANN. § 36-465 (Supp. 1990); GA. CODE ANN. § 31-22-6 (Michie 1991); NEV. REV. STAT. ANN. § 652.130 (Michie 1987).

167. Cf. 42 U.S.C. § 263a(o) (1988).

(5) Committee members shall be immune from civil liability for any action reasonably taken under this Act.

Section 5. *Prohibited Activities.*

- (1) The Committee shall not approve any office to perform an experimental procedure.
- (2) Committee members shall not be Panel members.
- (3) Committee members shall not have any financial or business arrangement with any Committee or Panel member which pertains to the business of physicians' office procedures.<sup>168</sup>

Chapter 8. *The Physicians' Office Disciplinary Panel.*

- (1) *Panel members.* The Physicians' Office Disciplinary Panel shall consist of five members. One member shall be an engineer skilled in the proper use and maintenance of diagnostic and therapeutic medical equipment. Two members shall represent consumers. Two members shall be health care providers. Panel members may be appointed by the legislature or an administrative agency designated by the legislature.
- (2) Each member of the Panel shall serve for three years except that:
  - (a) any member appointed to fill a vacancy occurring before the end of the term of which his or her predecessor was appointed shall be appointed for the remainder of such term; and
  - (b) members' office terms shall expire:
    - (i) one at the end of the first year;
    - (ii) two at the end of the second year; and
    - (iii) two at the end of the third year.<sup>169</sup>
- (3) Panel members shall not be Committee members.
- (4) Panel members shall not have any financial or business arrangement with any Committee or Panel member which pertains to the business of physicians' office procedures.<sup>170</sup>

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168. Cf. NEV. REV. STAT. ANN. § 652.170(5) (Michie 1987).

169. Cf. 1990 Neb. Adv. Legis. Serv. 551.

170. Cf. NEV. REV. STAT. ANN. § 652.170(5) (Michie 1987) ("No member of the advisory committee may have any financial or business arrangement with any other member which pertains to the business of laboratory analysis.").

Chapter 9. *Duties and Responsibilities of the Physicians' Office Disciplinary Panel.*

Section 1. *Panel Hearings.*

- (1) The Panel shall examine requests for hearings by the Committee.
- (2) The Panel shall not revoke, suspend, or limit any office registration without providing the physicians involved with an opportunity for a hearing. The Panel may, however, temporarily suspend or limit office registration for a period not in excess of sixty days upon written notice to the physicians' office following a Committee finding that the public health and safety is in imminent danger.<sup>171</sup> The Panel may also, in the name of the people of the State through the Attorney General, bring an action for an injunction to restrain such violation or to enjoin present and/or future performance of Class II or Class III procedures.<sup>172</sup>

Section 2. *Registration Revocation, Suspension, or Limitation by the Panel.*

- (1) A physicians' office registration may be revoked, suspended, limited, or denied if the Panel finds, after reasonable notice and opportunity for a hearing, that the office's physician(s) or employee(s):
  - (a) committed an act involving misrepresentation or fraud in providing information to the Committee or the Panel;<sup>173</sup>
  - (b) engaged or attempted to engage in any Class II or Class III procedure without registering the office pursuant to this Act;<sup>174</sup>
  - (c) engaged in any procedure resulting in an imminent threat to the public health;
  - (d) failed to comply with reasonable requests by the Committee or the Panel for information necessary to determine compliance with this Act or any rules or regulations enacted by the Committee thereunder;<sup>175</sup>

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171. Cf. N.Y. PUB. HEALTH LAW § 4712(b) (Consol. 1985) which provides: No registration shall be revoked, suspended, limited or annulled without a hearing. However, a registration may be temporarily suspended or limited without a hearing for a period not in excess of thirty days upon written notice to the shared health facility following a finding by the department that the public health or safety is in imminent danger.

172. Cf. 42 U.S.C. § 263a(j) (1988); 42 C.F.R. § 405.146 (1990); ARIZ. REV. STAT. ANN. § 36-478 (Supp. 1990); GA. CODE ANN. § 31-22-12 (Michie 1991).

173. Cf. 42 U.S.C. § 263a(i)(1)(A); GA. CODE ANN. § 31-22-2(d) (Michie 1991); N.Y. PUB. HEALTH LAW § 577(1)(a) (Consol. 1990).

174. See 42 U.S.C. § 263a(i)(1)(B); N.Y. PUB. HEALTH LAW § 577(1)(b).

175. Cf. 42 U.S.C. § 263a(1)(D)(ii).

- (e) refused a reasonable request of the Committee, the Panel, or any federal or state officer, employee, or agent duly designated by the Committee to inspect the office or pertinent records at any reasonable time;
- (f) violated or aided and abetted in the violation of any provisions of this Act or any rule or regulation enacted thereunder;<sup>176</sup>
- (g) failed to comply with a sanction or corrective plan imposed under this Act;<sup>177</sup>
- (h) consistently errs in the performance of a procedure for which the office is registered or in making reports based on a procedure;<sup>178</sup>
- (i) referred patients for procedures to the office of a practitioner who is not registered to perform such procedures;<sup>179</sup>
- (j) allowed an unregistered office to use his name, office name, or office address for the purpose of circumventing this Act or any rule or regulation enacted thereunder;<sup>180</sup> or
- (k) performed procedures within a Class for which the office is not registered.<sup>181</sup>

Section 3. In addition to or in lieu of revocation, suspension, limitation, or denial of the registration of an applicant or registrant, the Panel may impose any combination of the following intermediate sanctions:

- (1) a supervised correction plan;
- (2) civil money penalties in an amount of \$1,000 for each violation for each day of noncompliance with the requirements of this section;<sup>182</sup> or
- (3) inspection costs.<sup>183</sup>

Section 4. The Panel may also recommend to the Attorney General that a physician be charged with a misdemeanor if he or she:

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176. *Cf.* 42 U.S.C. § 263a(i)(1)(F); N.Y. PUB. HEALTH LAW § 577(1)(g) (Consol. 1990).

177. *Cf.* 42 U.S.C. § 236a(i)(1)(G).

178. *Cf.* GA. CODE ANN. § 31-22-2(d)(3) (Michie 1991); N.Y. PUB. HEALTH LAW § 577(1)(c) (Consol. 1990).

179. *Cf.* 42 U.S.C. § 263a(i)(4) (1988).

180. *Cf.* GA. CODE ANN. § 31-22-2(d)(7) (Michie 1991).

181. *Cf.* FLA. STAT. § 483.201 (West 1991); GA. CODE ANN. § 31-22-2(d) (Michie 1991); MASS. GEN. LAWS ANN. ch. 111D § 11 (West 1983); N.Y. PUB. HEALTH LAW § 577 (Consol. 1990).

182. *Cf.* N.Y. PUB. HEALTH LAW § 4704(3) (Consol. 1985).

183. *Cf.* 42 U.S.C. § 263a(h)(2)(C) (1988).

- (1) operates, maintains, or directs the use of medical equipment or performs or supervises procedures in an office that is not registered or in a registered office in which the physician is not recorded as a practitioner;<sup>184</sup> or
- (2) knowingly violates any provision of this Act or any regulation promulgated by the Committee pursuant to this Act.<sup>185</sup>

Section 5. Each day of a violation constitutes a separate violation.

Section 6. If a hearing is required or requested, the Panel shall notify the applicant or registrant of the date, time, and place of the hearing which shall be heard not more than ten days after notice is served or mailed. The notice shall fix the time and place for the hearing, which shall be no more than thirty days from the date of the mailing or delivery of the notice. The office shall file with the department within ten business days before the hearing, a written answer to the charges.<sup>186</sup>

Section 7. Notice of hearing may be delivered by a Panel member or by registered mail to the office address specified on the registration application.

Section 8. If the physician does not attend a required hearing or does not respond within thirty days after notice of a complaint is served or mailed, any denial, refusal, or revocation of registration by the Panel shall become final.

Section 9. Any physician who has sanctions imposed under this Chapter or has had his registration revoked, suspended, limited, or denied may, at any time within sixty days after the Panel's sanctions or determinations become final, file a petition with the state court in the jurisdiction where the office is located. The clerk of the court shall send a copy of the petition to the Secretary. The Secretary shall file in the court within ten days of receipt of the petition, the record on which the action of the Panel is based.<sup>187</sup>

Section 10. Upon a finding that office procedures were or are performed in violation of Section 2 of this Chapter, the Panel shall report to the

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184. *Cf.* ARIZ. REV. STAT. ANN. § 36-479 (Supp. 1990).

185. *See id.*; N.Y. PUB. HEALTH LAW § 578(1) (Consol. 1990).

186. *Cf.* N.Y. PUB. HEALTH LAW § 577(4); 35 PA. CONS. STAT. § 2162 (1977 & Supp. 1991).

187. *Cf.* 42 U.S.C. § 263a(k)(1) (1988).

state body responsible for physician licensure the violation and any disciplinary action taken.

Section 11. Panel members shall be immune from civil liability for any action reasonably taken under this Act.

## Chapter 10. *Personnel.*

### Section 1. *Qualifications and Staffing.*

- (1) Nursing and ancillary staff for each office shall be commensurate with the patient care requirements, staff expertise, available support services, and procedures performed.<sup>188</sup>
- (2) All personnel engaged in operating X-ray or nuclear medicine equipment shall be licensed or certified in accordance with all applicable state and local laws and regulations.<sup>189</sup>
- (3) Any physician participating in radiation oncology services shall be certified by the American Board of Radiology or shall demonstrate comparable qualifications.<sup>190</sup>

### Section 2. *Orientation and Continued Education.*

- (1) *X-rays.* All personnel operating X-ray equipment shall receive annual instruction on:
  - (a) protection from unnecessary exposure to radiation;
  - (b) equipment maintenance and use;
  - (c) appropriate documentation;
  - (d) technical problems which may arise and their solutions;
  - (e) protection against electrical hazards; and
  - (f) the hazards of excessive exposure to radiation.<sup>191</sup>
- (2) *Cardiopulmonary Resuscitation.* For all offices in which Class III procedures are performed, the physician, nursing, and ancillary staff shall be certified annually in Basic Cardiac Life Support according to American Heart Association guidelines.<sup>192</sup>

## Chapter 11. *Medical Records.*

- (1) Medical records shall include:
  - (a) patient identification data;

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188. See JCAHO, *supra* note 76, at NR.4.4.1.

189. See 42 C.F.R. § 405.1413 (1990); JCAHO, *supra* note 76, at NM.1.1.

190. See JCAHO, *supra* note 76, at RA.1.2.1.

191. Cf. 42 C.F.R. § 405.1413(b) (1990).

192. See JCAHO, *supra* note 76, at HO.2.1.2.

- (b) relevant patient history;
  - (c) the patient's chief complaint, physical findings, and disposition;
  - (d) a diagnosis, investigative diagnosis, or impression;
  - (e) a description of all diagnostic and therapeutic procedures performed at the office with results and observations related to such procedures including complications;
  - (f) the signature of the physician treating the patient;
  - (g) instructions given to the patient or his family and follow-up information;
  - (h) a copy of any information or reports that result from consultation with other practitioners; and
  - (i) patient allergies.<sup>193</sup>
- (2) Each office shall store inactive medical records in a manner that provides protection from vermin and unauthorized use.<sup>194</sup>
- (3) Each office shall maintain records for five years from the date of the patient's last visit.<sup>195</sup>
- (4) In the event an office registered under this statute closes, the physician managing the office's affairs shall inquire of the Committee how to dispose of its medical records.<sup>196</sup>

## Chapter 12. *Inspection of Offices Registered with the Physicians' Office Procedure Committee.*

### Section 1. *Office Inspection Requirements.*

- (1) The Committee, its employees, or its agents may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, offices registered or applying to register under this Act. In conducting such inspections the Committee, its employees, or its agents, shall have access to all premises, equipment, materials, records, and information needed to determine whether the office is being operated in accordance with this Act and any rules and regulations enacted thereunder. During the inspection, the Physicians' Office Procedure Committee, its employees, or its agents, may copy any material required to be submitted to the Committee.<sup>197</sup>
- (2) In lieu of or to supplement its own inspection, the Committee may use inspection results from other accrediting agencies.<sup>198</sup>

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193. See IND. ADMIN. CODE tit. 410, r. 15-2-8(1) (1988); JCAHO, *supra* note 76, at HO.5.2.

194. See IND. ADMIN. CODE tit. 410, r. 16.2-2-6(d) (1988 & Supp. 1991).

195. Cf. 42 C.F.R. § 405.1132(f) (1990).

196. Cf. IND. ADMIN. CODE tit. 410, r. 15-2-8(3)(b) (1988).

197. Cf. 42 U.S.C. § 263a(g)(1) (1988).

198. Cf. GA. CODE ANN. § 31-22-8 (Michie 1991).

(3) Each office cited by the Committee for failure to comply with the provisions of this Act shall document the remedial action taken. This documentation includes reporting the suspension or termination of procedures if necessary.

### Section 2. *Equipment Inspection Requirements.*

(1) X-ray equipment shall be inspected at least every twelve months by a radiation health specialist approved by an appropriate state or local agency.<sup>199</sup> The inspection shall include but is not limited to an evaluation of:

- (a) proper collimation and filtration;
- (b) the filtration and exposure rate where the beam enters the patient; and
- (c) storage and usage.<sup>200</sup>

Section 3. When an inspection of a physician's office reveals a minor or readily correctable defect and the Committee has cause to believe that the immediate interests of patients will be best served by affording the office the opportunity to correct such defects, the Committee shall register the office provisionally for a period of time no longer than six months. To maintain provisional registration, the registrant must agree to implement a plan acceptable to the Committee to remove these defects. The office may be registered after full compliance with the plan.<sup>201</sup>

Section 4. The Committee may upon its own initiative, or may, upon the verified complaint of any person setting forth facts which if proven would constitute grounds for registration revocation, suspension, or limitation pursuant to this Act, conduct an investigation of the office referred to in the complaint. If such investigation discloses grounds therefore, the Committee may request a Panel hearing of the matter.<sup>202</sup>

### Chapter 13. *Confidentiality.*

Section 1. Medical records shall remain confidential and shall be disclosed only with the written consent of the patient or in the event of a bona fide medical emergency.<sup>203</sup>

Section 2. All Committee records including inspection reports, but excluding the list of offices mandated under Chapter 7, Section 1(1), shall remain confidential.

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199. Cf. 42 C.F.R. § 405.1416 (1990).

200. Cf. IND. ADMIN. CODE tit. 410, r. 15-1-15(5) (1988).

201. Cf. ARIZ. REV. STAT. ANN. § 36-463.02(e) (Supp. 1990).

202. See *id.*

203. See 38 U.S.C. § 4132 (1988 & Supp. I 1989).

Chapter 14. *The Physicians' Office Procedure Revolving Fund.*

Section 1. The Physicians' Office Procedure Revolving Fund shall consist of monies from gifts, grants, donations, fees from workshops, conferences, and seminars, and fees collected pursuant to this Act.<sup>204</sup>

Section 2. Monies in the Revolving Fund shall be used to support the administration of this Act including sponsorship of workshops, conferences, and seminars.<sup>205</sup>

Section 3. Notwithstanding any other law, interest earned on monies in the Revolving Fund shall be credited to the Fund.<sup>206</sup>

Section 4. The Attorney General or the County Attorney may bring an action in the name of the State to enforce the collection of fees and penalties assessed pursuant to this Act.<sup>207</sup>

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204. *Cf.* ARIZ. REV. STAT. ANN. § 36-468 (Supp. 1990).

205. *See id.*

206. *See id.*

207. *See id.*