Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SURGERY IN OUTPATIENT SETTINGS: A FOUR-STATE STUDY

Richard P. Kusserow
INSPECTOR GENERAL

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OFFICE OF INSPECTOR GENERAL

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OEI-07-91-01470

EXECUTIVE SUMMARY

PURPOSE

To determine the types of surgical procedures which are commonly performed in outpatient settings in four States and the extent to which such outpatient settings are subject to licensure or accreditation.

BACKGROUND

An increasing number of surgical procedures performed in freestanding outpatient facilities has raised concerns about the appropriateness of the setting and the quality of care. Since many procedures are no longer performed in hospitals, consumers need to be confident that they will receive adequate quality of care in an outpatient setting.

This inspection is a companion to a related study conducted by the Office of Inspector General entitled "Surgery in Outpatient Settings: Forms of Oversight" (OEI-07-91-00690). In that report, we identified the forms of oversight in place in each State. Both studies were requested by the Subcommittee on Regulation, Business Opportunities and Energy of the House Committee on Small Business.

METHODOLOGY

We chose four States on a judgmental, non-random basis. The four States selected include California, Texas, Ohio, and Maryland. We then selected 160 facilities from the directories for those areas. We targeted non-Medicare certified facilities that perform risk-associated procedures. We also targeted facilities which advertised surgery or emergency services. We conducted 40 on-site visits consisting of interviews and a tour of the facilities (10 per State). We conducted telephone interviews with representatives from another 120 facilities (30 per State).

FINDINGS

Thirteen Percent of the Facilities We Surveyed Conduct Procedures Which We Classify as "High-Risk"

Thirteen percent of the facilities conduct procedures we classify as "high-risk": procedures employing general anesthesia or intravenous sedation.

Over Three-Fourths of the Surveyed Facilities Are Neither Licensed Nor Accredited; A Third of the Facilities Performing "High-Risk" Procedures Are Neither Licensed Nor Accredited

Of the 160 facilities in our sample, 131 are neither licensed nor accredited. Of the 21

facilities performing procedures we have classified as "high-risk," 7 (33 percent) are neither licensed nor accredited.

Medical Emergency Equipment And Procedures Are Not Uniformly Available

Over half of the sampled facilities have no written medical emergency procedures or could not produce them during an on-site visit. Eight percent of the sampled facilities have no life support/resuscitation equipment available.

Some Facilities Inaccurately Advertised Surgery or Emergency Services

Some facilities in our sample advertised surgery or emergency services. However, when reviewed, these services were seldom offered on-site.

RECOMMENDATION

States Should Examine their Licensure Rules to Ensure Quality of "High-Risk" Procedures Performed in Outpatient Settings

States nationwide should examine their rules for licensure and procedures for oversight and make any necessary changes to ensure the quality of surgery performed in outpatient settings, particularly in those facilities performing "high-risk" procedures.

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To determine the types of surgical procedures which are commonly performed in outpatient settings in four States and the extent to which such outpatient settings are subject to licensure or accreditation.

BACKGROUND

This inspection is a companion to a related study conducted by the Office of Inspector General entitled "Surgery in Outpatient Settings: Forms of Oversight" (OEI-07-91-00690). In that report, we identified the forms of oversight in place in each State. Both studies were requested by the Subcommittee on Regulation, Business Opportunities and Energy of the House Committee on Small Business.

The Shift Toward Outpatient Settings

Over the past ten years, there has been a visible shift in the health care marketplace. Many risk-associated procedures[1] traditionally conducted only in hospitals on an inpatient basis are now performed in freestanding facilities.[2] This trend is expected to continue.

Surgical volume was approximately 2 million in 1989 and is expected to grow to 3.2 million procedures by the end of 1992.[3] The Joint Commission on Accreditation of Health Care Organizations (JCAHO) estimates that by 1995, 65 percent of all surgical procedures will be performed outside the hospital. Several factors have contributed to this shift.

- Advances in technology, anesthesia, and surgical techniques have increased the number of procedures that can be safely performed on an outpatient basis.

- Outpatient procedures are usually less expensive and more convenient for the patient.

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[1] Risk-associated Procedures: medical procedures involving the prior and/or concurrent administration of general, spinal, regional or local anesthesia or of sedation and/or analgesia that is sufficient to compromise a patient's protective reflexes.

[2] Freestanding Facilities: medical facilities where physicians conduct risk-associated procedures on an outpatient basis.

[3] Health Care Competition Week. Vol. 7, No. 28, 1990.

- Medicare and some private insurance companies provide incentives for risk-associated procedures performed on an outpatient basis by authorizing payment of facility fees and other physician incentives for outpatient surgery.

Types of Freestanding Facilities

Freestanding facilities vary greatly. Due to increased technology and specialization, many types of facilities conduct a variety of risk-associated procedures. These facilities include, but are not limited to, physician's offices, ambulatory surgical centers, cancer treatment centers, emergency/minor emergency centers, abortion clinics, cosmetic/plastic surgery centers, pain treatment centers, and diagnostic imaging centers.

Forms of Oversight

The principal forms of oversight in place for outpatient facilities which perform surgery are licensure, certification, and accreditation. Other forms of oversight are provided by peer review organizations, insurance companies, and professional medical organizations. For a complete discussion of the forms of oversight in place in each State, see our companion report "Surgery in Outpatient Settings: Forms of Oversight" (OEI-07-91-00690).

METHODOLOGY

We selected four States on a judgmental, non-random basis. The four States selected include California, Texas, Ohio, and Maryland. We selected California as a State that has comparatively extensive requirements for regulation of freestanding facilities and Texas, Maryland, and Ohio as States where regulation is less extensive. We determined this from data collected for the inspection entitled "Surgery in Outpatient Settings: Forms of Oversight" (OEI-07-91-00690).

We selected the largest metropolitan area in each State to conduct on-site visits to 10 different facilities. We selected these facilities from the metropolitan areas' directories. We targeted non-Medicare certified facilities that perform risk-associated procedures. We also targeted facilities which advertised surgery or emergency services. Facility type was a consideration in selection of the sample as we sought facilities representing a variety of specialties. (For a list of sampled facilities by type, see Appendix A).

While visiting each facility, we interviewed either the office manager, physician, registered nurse (RN), or other person familiar with the specific operation of the facility. We asked questions addressing the types of procedures performed in the facility. We also inquired about the regulation of the facility, staffing of the facility, and medical emergency equipment and procedures. After completing the interview, we toured the facility to observe emergency equipment and procedures that the facility

had available. We also gathered information about the physical layout of the facility, advertising strategies, and general cleanliness.

To complete the sample, we selected an additional 30 facilities from each of the four States in the sample. We selected these facilities from the metropolitan areas' directories. Our goal was to target facilities that perform risk-associated procedures. We conducted telephone interviews with either the office manager, physician, or RN of these facilities. For consistency, we used identical interview guides for on-site visits and for telephone interviews.

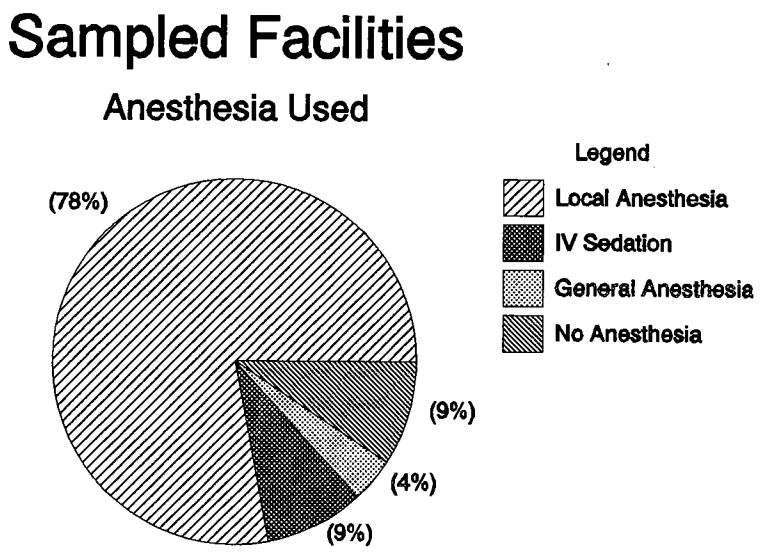
We conducted our review in accordance with the ***Interim Standards for Inspections*** issued by the President's Council on Integrity and Efficiency.

FINDINGS

Thirteen Percent of the Facilities We Surveyed Conduct Procedures Which We Classify as "High-Risk"

We asked the representative(s) from each facility about the procedures they perform in their facility and whether these procedures require the use of any form of anesthetic. For purposes of this study, anesthesia is an indication of the risk associated with a procedure. We classify "high-risk" as those procedures involving general anesthesia or intravenous (IV) sedation.

The following chart provides the percentage of the sampled facilities determined by the type of anesthetic.



Thirteen percent of the facilities conduct procedures that utilize IV sedation (9 percent) or general anesthesia (4 percent). Seventy-eight percent of the facilities use local anesthesia (low risk), and 9 percent use no anesthesia.

Single specialty and multi-specialty physician's offices have the largest variance in the types of procedures performed in the facility. Interviewees mentioned 22 different procedures they conduct in their freestanding facilities. Usually, we found that they utilize local anesthetia during these procedures.

In the remaining facilities the physician did not perform such a large variance of procedures. This is primarily due to the increased specialization of the other facility types. Table 1 on the following page presents the facility type, examples of the highest

risk procedures performed in any of the particular facilities, and the type of anesthesia used for that procedure.

Table 1

TYPE OF PROCEDURES PERFORMED IN VARIOUS FACILITIES

FACILITY TYPE	PROCEDURE	ANESTHETIC
Ambulatory Surgical Ctr.	Laparoscopy	General
Abortion Clinic	Abortion	General
Cosmetic Surgery Ctr.	Face Lift	General
Ophthalmologist	Cataract Surgery	IV Sedation/Local
Dermatologist	Dermabrasion	IV Sedation/Local
Pain Treatment Ctr.	Nerve Block	IV Sedation/Local
Physician's Office	Sigmoidoscopy	IV Sedation
Podiatrist Office	Toenail Removal	Local
Multi-specialty Office	Repair Lacerations	Local
Emergency Ctr.	Repair Lacerations	Local
Cancer Treatment Ctr.	Bone Marrow Biopsy	Local
Diagnostic Imaging Ctr.	Breast Biopsy	Local
Kidney Dialysis Ctr.	Needle Insertion	Local
Birthing Ctr.	Child Birth	None

Of the 21 facilities performing "high-risk" procedures, 7 of the facilities use general anesthesia. These facilities include ambulatory surgical centers, abortion clinics, and cosmetic and plastic surgery centers. Fourteen facilities use IV sedation.

The sampled facilities also varied in who administered anesthesia when it is necessary. This variance was due to the type of procedure and the type of anesthetic utilized. Of the seven sampled facilities that perform "high-risk" procedures utilizing general anesthesia, three use a Certified Registered Nurse Anesthetist (CRNA) and four use an anesthesiologist. Of the 14 sampled facilities that perform "high-risk" procedures utilizing IV sedation, five facilities use physicians, three use registered nurses, five use CRNA's, and one uses an anesthesiologist to administer the IV sedation.

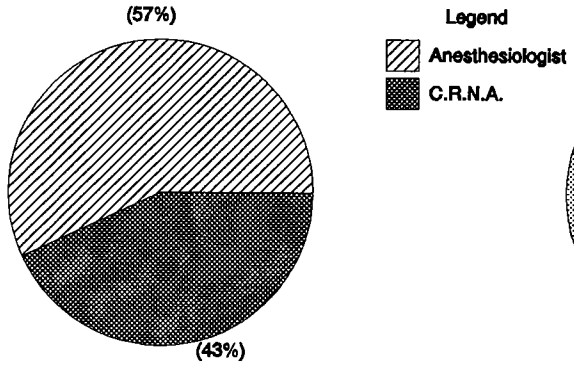
We found that the State Nursing Boards in the three States conducting procedures utilizing IV sedation administered by an RN were aware of this occurrence. We found that these States allowed an RN to administer IV sedation under a physician's order

and under the supervision of a physician. However, an RN performing this procedure presents a potential vulnerability in quality of care if the nurse has not received adequate training and if there is no emergency equipment on-site. Only one of the facilities utilizing an RN to administer IV sedation is licensed. None of the three facilities are accredited. Two of the three facilities had no emergency procedures, with one of the two stating they had procedures, yet unable to produce them on-site.

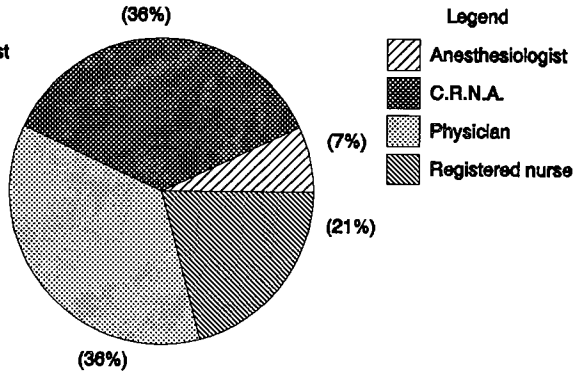
We found that the three most common procedures utilizing general anesthesia were abortions, face lifts, and breast augmentation procedures. We found that the three most common procedures utilizing IV sedation were cataract surgeries, abortions, and facial reconstruction procedures. The graphs below show the type of anesthesia used and who administers the anesthesia in those facilities performing "high-risk" procedures.

Anesthesia Used and Administered In
"High Risk" Facilities

General Anesthesia



IV Sedation



Over Three-Fourths of the Surveyed Facilities Are Neither Licensed Nor Accredited; A Third of the Facilities Performing "High-Risk" Procedures Are Neither Licensed Nor Accredited

Of the 160 facilities in our sample, 131 are neither licensed nor accredited. A large portion of these facilities are physician offices, which have typically been left unregulated by the States. Of the 21 facilities performing procedures we have classified as "high-risk," 7 (33 percent) are neither licensed nor accredited. These include an ambulatory surgical center, an abortion clinic, a plastic surgery center, a pain treatment center, and three physician offices.

For the purposes of this study, we considered only medical licenses as criteria for licensed medical facilities. We found that many facilities are licensed by a governmental entity (e.g., city, county) as a business. These licenses are no different for a medical facility than for a restaurant, hardware store, or barber shop. In our analysis, a business license was not considered licensure as a medical facility. Likewise, individual physician licensure should not be mistaken for facility licensure.

Twelve of 21 (57 percent) of the sampled facilities that conduct "high-risk" procedures requiring IV sedation or a general anesthetic are not licensed. These facilities include six plastic surgery centers, three physician offices, one abortion clinic, one ambulatory surgical center, and one pain treatment center.

Also, three-fourths (76 percent) of these 21 facilities are not accredited. These facilities are four abortion clinics, three physician offices, three ambulatory surgical centers, two plastic surgery centers, two ophthalmologists, one dermatologist, and one pain treatment center. All of the accredited facilities performing these "high-risk" procedures are plastic surgery centers.

Even when facilities are licensed, standards and monitoring vary. Of the licensed or accredited facilities, 59 percent of the licensed facilities do not have specific requirements for staff, equipment, or the physical facility. Sixty-five percent of the licensed facilities have not been inspected other than for their initial licensure. Only about one-third (35 percent) of the licensed facilities are inspected regularly.

Facilities which receive accreditation are generally reviewed at least every two or three years by an on-site reviewer. Accredited facilities must meet certain criteria in many areas such as emergency procedures, equipment standards, operational efficiency, and medical and educational standards of the staff to obtain and maintain accreditation status.

The Office of Inspector General companion report to this study entitled "Surgery in Outpatient Settings: Forms of Oversight" (OEI-07-91-00690) found that many facilities are not subject to licensure by the States and that physician's offices have little or no formal oversight. The report also found that the States are not consistent in their

regulation of freestanding medical facilities. These findings are substantiated by data from this study.

Medical Emergency Equipment And Procedures Are Not Uniformly Available

Medical emergency equipment and procedures vary greatly by facility. Over half of the sampled facilities (82 of 160) have no written medical emergency procedures or could not produce them during an on-site visit.

Eight percent (13 of 160) of the sampled facilities have no life support/resuscitation equipment available. One of the physician offices performing procedures requiring IV sedation did not have emergency equipment. Some of these facilities mentioned local medical emergency "911" services within minutes and access to a hospital across the street. Table 2 provides a summary of the facilities with no emergency equipment on-site.

Table 2

SUMMARY OF 13 FACILITIES WITH NO EMERGENCY EQUIPMENT

FACILITY TYPE	ANESTHETIC USED	OVERSIGHT
Physician's Office	Local	None
Physician's Office	Local	Accredited
Physician's Office	Local	None
Physician's Office	IV Sedation	None
Physician's Office	Local	None
Physician's Office	Local	None
Physician's Office	Local	None
Podiatrist Office	Local	None
Emergency Center	Local	None
Cosmetic Surgeon	Local	None
Cosmetic Surgeon	Local	None
Dermatologist	Local	None
Pain Treatment Ctr.	None	None

Our review entailed visiting 40 of the 160 medical facilities on-site. We conducted the remaining 120 interviews over the telephone. Trying to verify responses to the telephone interview question "whether a facility has written medical emergency

procedures," we asked several of the facilities which had procedures to forward them to us. Of those facilities stating that they had procedures, we received only one response.

Regarding preparedness for emergency response, 19 percent (31 of 160) of the medical facilities employ at least one physician who does not have admitting privileges at a local hospital. These physicians either prefer not to admit patients to hospitals or they have a network of physicians to whom they refer patients for admission. Also, a few of these physicians are retired, working part-time only.

Some Facilities Inaccurately Advertised Surgery or Emergency Services

We found that some facilities in our sample advertised surgery or emergency services. However, when we visited these facilities, these types of services were seldom offered on-site.

In conducting our study, we called providers which listed emergency and surgical services in the metropolitan areas' directories. However, when we spoke with the facility representatives, we found that most of the facilities were performing minor procedures with local anesthesia only. Most medical facilities are not performing "high-risk" medical procedures, yet some of the facilities advertise performing major surgical procedures.

The following examples are typical of what we found at some of the outpatient facilities. At one facility, a sign on the exterior of the physician office building advertised in-office surgery. During the interview, we learned that the physician no longer performed outpatient surgery in his office. The outdated advertisement remained posted, although the physician stopped performing in-office surgery years ago.

At a single specialty physician office facility which advertised "EMERGENCY CARE," personnel informed us that the medical emergency kit ("crash cart") was within immediate access. Upon a tour of the facility, staffers had to move several boxes of supplies from a back closet to retrieve the emergency kit. Also, at another facility, we asked to see the facility's medical emergency kit. The physician produced a small briefcase then opened it up and said, "Oh, that's not it. . . I think it is back there in another room." The physician did not produce the emergency kit.

RECOMMENDATION

States Should Examine their Licensure Rules to Ensure Quality of "High-Risk" Procedures Performed in Outpatient Settings

States nationwide should examine their rules for licensure and procedures for oversight and make any necessary changes to ensure the quality of surgery performed in outpatient settings, particularly in those facilities performing "high-risk" procedures.

APPENDIX A

SAMPLED FACILITIES BY TYPE

Single Specialty Physician's Office	66
Multi-Specialty Physician's Office	27
Cosmetic/Plastic Surgery Center	12
Emergency/Minor Emergency Center	11
Abortion Clinic	7
Podiatrist Office	7
Ophthalmologist	7
Dermatologist	6
Pain Treatment Center	5
Ambulatory Surgical Center	4
Cancer Treatment Center	3
Diagnostic Imaging Center	2
Kidney Dialysis Center	2
Birthing Center	1
TOTAL	160