

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SURGERY IN OUTPATIENT SETTINGS:
FORMS OF OVERSIGHT**



Richard P. Kusserow
INSPECTOR GENERAL

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Department of Health and Human Services

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OEI-07-91-00690

EXECUTIVE SUMMARY

PURPOSE

The purpose of this study is to determine the forms and extent of oversight for freestanding outpatient facilities in which surgery is performed.

BACKGROUND

An increasing number of surgical procedures that were once performed in an acute care setting are now being performed in outpatient facilities. This shift in setting is due in part to advances in medical technology and the lower cost of outpatient care. This shift has raised concerns about the appropriateness of the setting and the quality of care. The House of Representatives Small Business Subcommittee on Regulation, Business Opportunities, and Energy requested this study.

Surgery can be defined by the invasiveness of a procedure and/or the level of sedation/anesthesia required. The definition of surgery varies widely among the agencies, boards, and organizations involved in oversight.

The forms of oversight in place for outpatient facilities include licensure, certification, and accreditation. Licensure of facilities is performed by individual State health facility licensure agencies. Certification is carried out by the Health Care Financing Administration (HCFA). Certification is required for certain types of facilities to receive Medicare reimbursement. Accreditation is performed by private accreditation associations and is usually voluntary on the part of the facility. Other forms of oversight are provided by peer review organizations (PROs), insurance companies, and professional medical organizations.

METHODOLOGY

We contacted various regulatory bodies, as well as others that might play a role in the oversight of outpatient surgical facilities. We received data from most of these sources. Our analysis of the data focused on standards that promote quality of care in a health care setting. This information was compiled into tables for the appendices of the report.

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

A companion study, "Surgery in Outpatient Settings: A Four-State Study" (OEI 07-91-01470), is being released concurrently with this report. This inspection determined 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.

FINDINGS

MANY FACILITIES ARE NOT SUBJECT TO LICENSURE

- ▶ Ten States do not license ambulatory surgical centers (ASCs).
- ▶ Twenty-two States do not license birthing centers.
- ▶ Twenty-six States do not license abortion clinics.
- ▶ Forty-two States do not license emergency centers.

THE LICENSURE STANDARDS THAT EXIST VARY FROM STATE TO STATE

Licensure standards include legal limits on procedures, peer review, training for ancillary personnel, written transfer agreements, a minimum staffing requirement, and medical records. Other standards include infection control procedures, presence of emergency equipment and personnel trained in emergency procedures, anesthesia administration, and equipment maintenance. These standards vary greatly from State to State.

ACCREDITATION, CERTIFICATION, AND PEER REVIEW PROVIDE ANOTHER FORM OF OVERSIGHT

Accreditation associations apply a set of separate standards which are usually more stringent than the licensure agencies require. However, accreditation is usually voluntary on the part of the facility.

Certification requires that a facility meet certain specific requirements in order to display recognition that they meet the standards of the Medicare program. Once certified, a facility is eligible to receive reimbursement for care provided to Medicare beneficiaries. Only certain types of facilities are certified (such as ASCs) and not all of the facilities in each category are certified (i.e. not all ASCs are certified).

The Peer Review Organizations (PROs) conduct pre-procedure review for some types of procedures in outpatient settings such as ASCs and health maintenance organizations. We are currently conducting an inspection that addresses the role of PROs in an outpatient setting.

THERE IS LITTLE OR NO OVERSIGHT FOR PHYSICIANS' OFFICES

The State health facility licensure agencies do not license physicians' offices. State medical and podiatry boards regulate a physician's practice through control of the physician's license. The State medical and podiatry boards do not address setting when granting licenses to practitioners.

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INTRODUCTION

PURPOSE

The purpose of this study is to determine the forms and extent of oversight for freestanding outpatient facilities in which surgery is performed.

BACKGROUND

An increasing number of surgical procedures that were once performed in an acute care setting are now being performed in outpatient facilities. This shift in setting is due in part to advances in medical technology and the lower cost of outpatient care. This shift has raised concerns about the appropriateness of the setting and the quality of care. One concern is the lack of oversight for most types of outpatient surgical facilities. Another concern is that some surgical procedures may be inappropriate for an outpatient setting due to the high-risk nature of the procedure. Examples of high-risk procedures in outpatient facilities might include orthopedic procedures such as ankle fusions and triple arthrodesis, abortions, liposuction procedures, laparoscopy, hernia repair, radical mastectomies, some types of plastic surgery, and some types of eye surgery.

The House of Representatives Small Business Subcommittee on Regulation, Business Opportunities, and Energy requested this study.

No Uniform Definition of Surgery

Surgery is difficult to classify because several criteria can be used to define it. Surgery can be defined by the invasiveness of a procedure and/or the level of sedation/anesthesia required.

The Medicare Carrier Manual definition of surgery is very general and includes the terms incision, excision, repair, suture, destruction, introduction, fracture, manipulation, dislocation, amputation, and endoscopy in the definition.

The definition of surgery varies widely among the agencies, boards, and organizations involved in oversight. These definitions are contained in Appendix A.

Overview of Outpatient Facilities

Ambulatory surgical centers (ASCs) and outpatient hospital settings are capable of conducting "major" surgical procedures such as cardiac or vascular catheterization, trauma care, and hernia repair. According to SMG Marketing, a major marketing report firm, the number of procedures performed in ASCs increased more than 100 percent from approximately 1 million in 1986 to approximately 2.2 million in 1989. The most commonly performed procedures in ASCs are ophthalmological procedures;

gynecological surgery; ear, nose, and throat procedures; and orthopedic surgery. These make up 65.6 percent of all surgeries performed in ASCs.

Other outpatient settings, including physician's offices, are sites for relatively "minor" surgical procedures. Examples of minor surgery include suturing small wounds, performing skin biopsies, and drawing blood. The Part B Medicare Annual Data (BMAD) uses the Medicare Carrier Manual's definition of surgery that is listed on page one. According to BMAD, the number of surgeries performed in physicians' offices increased 39 percent from approximately 21.6 million in 1986 to approximately 30.0 million in 1989.

Selected medical procedures and the number of procedures performed in various medical settings based upon 1989 Part B Medicare Annual Data are contained in Appendix B.

Types of Facilities and Examples of Procedures

We have classified the types of outpatient surgery as minor procedures and major procedures. Minor procedures include cleaning and suturing small wounds, drawing blood, inserting IV's, performing electromyograms, etc. Major procedures include hernia repair, cardiac catheterization, trauma care, vascular catheterization, etc.

Table 1 on the following page gives types of outpatient facilities and examples of procedures normally performed in each.

Table 1

Types of Facilities and Examples of Procedures Performed		
<u>Facility</u>	<u>Minor Procedure</u>	<u>Major Procedure</u>
Ambulatory health care clinic	X	
Ambulatory surgical center		X
Birth center		X
Health maintenance organization (HMO)	X	
Urgent/immediate care center	X	
Cancer treatment center	X	
Cardiac catheterization lab		X
Emergency center		X
Home health care agency	X	
Independent clinical lab	X	
Abortion clinic		X
Diagnostic imaging center		X
Office surgery center	X	
Physician's office	X	

Forms of Oversight

The principal forms of oversight in place for outpatient facilities which perform surgery are licensure, certification, and accreditation. For our purposes, a license implies that a facility or person has met certain specific requirements and has been granted permission to provide service. Licensure, when it exists, is required rather than voluntary, and falls under the jurisdiction of State health facility licensure agencies. Certification of a facility involves meeting certain specific requirements in order to be reimbursed by the Medicare program. The HCFA certifies certain types of facilities. If a facility chooses not to seek certification, physicians can still be paid for professional services rendered there, but the facility will not receive a fee. Accreditation involves meeting standards set forth by an accreditation association. Accreditation is usually voluntary on the part of the facility, and occurs after licensure. Accreditation does not take the place of licensure or certification, but may act as a supplement or grounds on which to certify.

Other forms of oversight are provided by peer review organizations (PROs), insurance companies, and professional medical organizations.

The PROs review the quality of medical services provided to Medicare beneficiaries in certain settings such as ASCs. They play a role in the internal quality assurance of ASCs by reviewing samples of cases and procedures.

The current Scope of Work, as defined in the PROs' contract with HCFA, does not require a review of the services provided in a physician's office. However, HCFA does have contracts for two pilot projects currently in progress which address peer review of services provided in a physician's office. The Delmarva Foundation (Maryland PRO) is working on a pilot project with two PROs which will review the care that physicians provide in an office setting. This is a three year project that started September 1, 1990. The other project, The Wisconsin Ambulatory Review Project (WARP), involves seven PROs. This project will develop and assess a system for monitoring the quality and cost effectiveness of ambulatory medical care for office-based practices. The WARP began December 1, 1989 and was scheduled to last for two years. The contract for this has been extended through November of 1992.

Insurance companies provide a form of oversight through underwriting malpractice/liability insurance for individual physicians and/or facilities. We contacted a major insurance company that has general criteria for insuring physicians and facilities. The insurance company's coverage criteria included information about training, structure of the organization, staffing, services provided, licensing, practice restrictions, hospital privileges, jurisdiction of practice, risk management program (mainly for facilities), information on the physical plant, emergency procedures in place at day surgery centers, and claim information. There are specific criteria for determining insurability for surgical procedures. For physicians these criteria included training, specialty, and services performed. For facilities these criteria included staff (types of professionals and their expertise), equipment, training, and risk management in relation to the services provided.

Professional medical organizations may be a certifying body (for a specific branch of medicine) or they may be a membership body. The six professional medical organizations that we contacted have a set of ethical standards for members. Five of the organizations have educational guidelines for their members. Three of the professional organizations have an informal relationship with PROs and two of these organizations also have an informal relationship with State boards. None of the professional organizations perform a direct monitoring or oversight role. One organization indirectly provides oversight through its requirement for continuing medical education. Four of the organizations have received patient complaints and took action on them.

METHODOLOGY

We contacted every State health facility licensure agency and every State medical, osteopathic, and podiatry board. We contacted three accreditation associations: the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), and the Accreditation Association for Podiatric Surgical Facilities (AAPSF). We contacted five PROs: California Medical Review, Inc., the Florida Professional Foundation for Health Care, Louisiana Health Care Review, Rhode Island Health Care Review, Inc., and the Wisconsin Peer Review Organization. In addition, we contacted six professional medical organizations: the American Academy of Family Physicians, the American Board of Podiatric Surgery, the American Board of Surgery, the American College of Surgeons, the American Osteopathic Association, and the Association of American Physicians and Surgeons. The insurance company that we contacted was the St. Paul Fire and Marine Insurance Company, a major malpractice insurer.

We received data from most of the agencies, boards, and organizations. Our analysis focused on standards that promote quality of care in a health care setting. These included review of State health facility licensure requirements, review of State medical and podiatry board requirements for licensure of physicians and podiatrists, and review of accreditation association requirements for accreditation of outpatient facilities.

We contacted the primary health facility licensure agency in each State. Several States have different departments or offices within the agency or State government that provide licensure.

We analyzed narrative responses and the rules and regulations from the States. We conducted discussions with staff members of appropriate agencies, boards, and associations. We also analyzed the responses from the professional medical groups, PROs, and the insurance company.

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

A companion study, "Surgery in Outpatient Settings: A Four-State Study" (OEI-07-91-01470), is being released concurrently with this report. This second study determined 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.

FINDINGS

MANY FACILITIES ARE NOT SUBJECT TO LICENSURE

Ten of the States do not license ASCs. Twenty-two of the States do not license birthing centers. Twenty-six of the States do not license abortion clinics. Forty-two of the States do not license emergency centers (these facilities have the capability for emergency life support and stabilization). As reflected in Tables 1 and 2, all of the facilities listed above conduct major procedures.

Several of the facility categories may not exist in all States. Some States do not license certain facilities because there are so few of them. Classification of facilities also differs among the States; i.e. one State may categorize a facility as a birthing center while a neighboring State may categorize it as an ASC.

Table 2

Types of Freestanding Facilities and Number of States That License Each	
Facility	Number of States That License
Ambulatory surgical center *	41
Home health care service	35
Birthing center *	29
Abortion clinic *	25
Independent clinical lab	27
Health maintenance organization	21
Ambulatory health care clinic	11
Emergency center *	9
Cardiac catheterization lab *	10
Urgent/immediate care center	8
Cancer treatment center	7
Diagnostic imaging center *	9
Office surgery center	9
Physician's office	0
* Facilities that perform Major Procedures	

Additional information on State licensure is included in Appendix C.

THE LICENSURE STANDARDS THAT EXIST VARY FROM STATE TO STATE

There are a number of standards that promote quality of care in a health setting. These standards are utilized by several State health facility licensure agencies, medical boards, and podiatry boards.

A particular standard may not apply to all types of facilities. The following is a summary of the chief types of standards that exist.

1. Patient Complaints - The State health facility licensure agency requires the facility to have a system to receive patient complaints in:

31 of the 51 States.

2. Legal Limits - Guidelines for care (including surgical procedures) in an outpatient setting are set by:

46 of the 51 State health facility licensure agencies

26 of the 63 State medical boards

48 of the 50 State podiatry boards.

Licensure agencies, State boards, accreditation associations, and insurance companies usually let the facilities set their own guidelines for procedures which would be performed in the facility.

3. Peer Review - The State health facility licensure agency requires the facility to have some form of peer review as part of the internal quality assurance program in:

34 of the 51 States.

4. Training for Ancillary Personnel - The State health facility licensure agency requires training and/or certification of ancillary personnel (i.e. lab technicians or nurses aides) in:

41 of the 51 States.

5. Credentialing Process - The State health facility licensure agency requires each facility to have a separate credentialing process. Each facility must review the education, training, and background of their professional personnel in:

43 of the 51 States.

6. Infection Control Procedures - The State licensure authorities require that procedures to prevent the spread of infection are part of the daily operation of an outpatient surgical facility. Training in infection control procedures is often part of in-service training and/or continuing education. Infection control procedures are required by:

41 of the 51 State health facility licensure agencies

28 of the 63 State medical boards

26 of the 50 State podiatry boards.

The training and residency process for most physicians and podiatrists often includes infection control procedures. For this reason, most medical and podiatry boards do not cover this in the licensure process.

7. Medical Training Standards - The State licensure authorities have established requirements for the education, training, and background for physicians that perform surgery in an outpatient setting in:

45 of the 51 State health facility licensure agencies

32 of the 63 State medical boards

30 of the 50 State podiatry boards.

Licensure agencies, State boards, insurance companies, and accreditation associations often let the facilities set up their own screening process for physicians. The medical and podiatry boards do not address setting when granting a permanent unrestricted license which is the most common type of license.

8. Transfer Agreement - The State health facility licensure agency requires a written patient transfer agreement between the outpatient surgical facility and a hospital in:

43 of the 51 States.

9. Minimum Staff Requirement - The State health facility licensure agency requires the presence of an adequate number of specialized personnel in an outpatient surgical facility during hours of operation in:

44 of the 51 States.

10. Emergency Equipment and Trained Personnel - The State requires the presence of emergency equipment and personnel trained in emergency procedures to be on-site in an outpatient surgical facility. Some State medical and podiatry boards require applicants for licensure to demonstrate knowledge of emergency procedures such as cardiopulmonary resuscitation. Emergency equipment and trained personnel are required by:

44 of the 51 State health facility licensure agencies

24 of the 63 State medical boards

19 of the 50 State podiatry boards.

The training and residency process for most physicians and podiatrists usually includes a demonstration of knowledge of emergency procedures. For this reason, most medical and podiatry boards do not cover this in the licensure process.

11. Minimum Record-Keeping Standards - The State health facility licensure agency requires the outpatient surgical facility to have minimum record-keeping standards in:

47 of the 51 States.

12. Anesthesia Standards - The State health facility licensure agency requires that trained personnel, such as an anesthesiologist, or certified registered nurse anesthetist who is under the supervision of a qualified physician, administer anesthesia in:

46 of the 51 States.

13. Equipment Standards - The State health licensure agency requires regular inspection of calibrated equipment such as x-ray machines in:

44 of the 51 States.

Several States are now preparing legislation that will provide or increase oversight of these outpatient facilities. One State has indicated that it has the legislative authority to license facilities, but does not have adequate personnel or funding to carry out a licensure program.

Additional information on the licensure standards of the various State agencies and boards is included in Appendices D, E, and F.

ACCREDITATION, CERTIFICATION, AND PEER REVIEW PROVIDE ANOTHER FORM OF OVERSIGHT

Accreditation associations apply a set of separate standards which are usually more stringent than the licensure agencies require. However, accreditation is usually voluntary on the part of the facility.

The three accreditation associations that we contacted apply the thirteen standards that promote quality of care in a health setting that are listed in the previous finding.

Additional information on the accreditation associations and the standards that they apply is included in Appendix G.

Additional information on the accreditation associations' policies for unannounced or unscheduled visits and public release of information is included in Appendix H.

Certification requires that a facility meet certain specific requirements in order to be reimbursed by the Medicare program. Only certain types of facilities are certified (such as ASCs) and not all of the facilities in each category are certified (i.e. not all ASCs are certified).

The PROs perform pre-procedure review for some types of procedures in outpatient settings such as ASCs and HMOs. We are currently conducting an inspection that addresses the role of PROs in an outpatient setting.

THERE IS LITTLE OR NO OVERSIGHT FOR PHYSICIANS' OFFICES

The State health facility licensure agencies do not license physicians' offices. State medical and podiatry boards regulate a physician's practice through control of the physician's license. The facility in which the physician practices may impose additional restrictions upon the physician's practice. The State medical and podiatry boards do not address setting when granting licenses to a practitioner.

The HCFA has established a list of covered surgical procedures for ASCs. The HCFA reimburses ASCs based upon this list of covered procedures. There is no list of this type for physicians' offices.

The PROs have no current authorization to review the care provided in a physician's office. We found that PRO review of physicians' offices includes only the two previously described pilot projects currently in progress.

APPENDIX A

DEFINITIONS OF SURGERY

One of the Three accreditation associations that we contacted had a definition of surgery.

"Surgical and Anesthesia Services - those surgical or other invasive procedures for which patients receive general, spinal, or major regional anesthesia or sedation/analgesia either by intravenous, intramuscular, or inhalation methods that, in the manner used, may result in the loss of the patient's protective reflexes. Invasive procedures include, but are not limited to, percutaneous aspirations and biopsies, cardiac and vascular catheterizations, and endoscopies."

One insurance company's definition of surgery is:

"- No Surgery - no surgical procedures performed other than circumcisions, incision of boils and superficial abscesses or suturing of skin and superficial fascia. Includes closed fractures of the fingers and toes.
- Assisting in Surgery - assisting in surgery on physician's own patients, including closed bone fractures, except those of the finger and toes, and D&C's or vasectomies performed under local anesthesia.
- All Other Surgery - includes operations in or upon any body cavity, including, but not limited to the cranium, thorax, abdomen, or pelvis; any other operation which, because of the condition of the patient or the length or circumstances of the operation presents a distinct hazard to life. It also includes: removal of tumors, open bone fractures, amputations, abortions, caesarean sections, the removal of any gland or organ, plastic surgery, tonsillectomies, adenoidectomies, and any operations done using general anesthesia."

None of the professional organizations that we contacted had a definition of surgery.

All of the PROs that we contacted had a definition of surgery.

"Surgery - (a.) that discipline of health care delivery utilizing the knife, cautery, cryogenics, or chemicals, (b.) invasive procedures to remove, correct, or facilitate the cure of a disease, process, or injury, and (c.) that branch of medicine which treats diseases, injuries, and deformities by manual or operative methods."

"Surgery - all invasive procedures are considered surgery. Anything that can affect the diagnostic related groups (DRG) assignments."

"Surgery - any procedure that changes the Medicare reimbursement rate. Certain procedures done would affect the DRG's which would impact upon the Medicare reimbursement rate. Other procedures done would have no effect."

"Surgery - for outpatients, all surgery that has a CPT-4 code and is also on HCFA's list of covered surgical procedures."

"Surgery (outpatient) - anything that is on the HCFA list of covered procedures for ASCs. This may include procedures not normally considered to be surgery such as upper GI's, colonoscopy, and endoscopy. All cases are selected according to this list of procedures."

Seven of the 51 State health licensure agencies that we contacted had a definition for surgery.

"Surgery - treatment of human beings by a physician, by the use of one or more of the following procedures: cutting into any part of the body by surgical scalpel, electro-cautery, or some other means for diagnosis or removal of foreign bodies; reduction of fractures or dislocations of a bone, joint, or bony structure; repair of malformations or body defects resulting from injury, birth defects, or other causes that require cutting and manipulation or suture; instrumentation of the uterine cavity including the procedure commonly known as a D&C for diagnostic or therapeutic purposes; any instrumentation of or injection of any substance into the uterine cavity of a woman for the purpose of terminating a pregnancy; human sterilization procedures; or endoscopic procedures."

"Surgery - treatment of conditions by operative means, involving incision or repair of human tissues."

"Surgery - 'oscopy' procedures... are considered 'surgical' procedures within the context of the ASC provision. Also, surgical procedures are commonly thought of as those involving an incision of some type, whether done with a scalpel or (more recently) a laser, followed by removal or repair of an organ or other tissue."

"Surgery - while recognizing that surgery may include some nonoperative modalities, in the context of these regulations surgical service refers to the management of localized diseases and/or conditions by operative means which include peri-operative and operative treatment and the conditions outlined in Section 21.4 herein."

"Surgery - any manual or operative procedure performed upon the body of a living human being for the purpose of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defect, prolonging life or relieving suffering, and involving any of the following: incision, excision, or curettage of tissue or an organ; suture or other repair of tissue or an organ, including a closed as well as an open reduction of a fracture; extraction of tissue including the premature extraction of the products of conception from the uterus; or an endoscopic examination with use of a local or general anesthetic.

"Surgery - ...severing or penetrating of tissues of human beings."

"Surgery - pathological process for the surgical care shall be localized and not conducive to system disturbance."

Four of the 63 State medical and osteopathic boards that we contacted had a definition of surgery.

"Surgery - to sever the tissues of the body for the purpose of penetration for treatment, replacement, or removal of afflicted parts. The simple piercing of the skin by the insertion of a solid wire or needle (acupuncture) not intended to separate or sever tissue for the purpose of treating by acupuncture is not surgery as term is used in the Healing Arts Act."

"Surgery (osteopathic) - the use of any and all methods in the treatment of disease, injuries, deformities, and all other physical and mental conditions in and of human beings, including the use of osteopathic manipulative therapy."

"Surgery - the diagnosis or treatment of or operation or prescription for any human disease, pain, injury, deformity, or other physical or mental condition."

"Surgery - ... to penetrate, pierce, or sever the tissues of a human being..."

Six of the 50 State podiatry boards that we contacted had a definition for surgery.

"Surgery - "... to penetrate, pierce, or sever the tissues of a human being..."

"Surgery - use of any cutting instrument to treat a disease, ailment, or condition of the human foot as defined herein, except that a podiatrist shall not be authorized to amputate the human foot, or perform any surgery on the human body at or above the ankle joint, or administer anesthetics other than local anesthetics."

"Surgery - practice of medicine and surgery means the diagnosis or treatment of or operation or prescription for any human disease, pain, injury, deformity, or other physical or mental condition."

"Surgery - conditions that require operative procedures."

"Surgery - the surgical treatment of the foot, but shall not include the amputation of foot or leg, surgery of the leg, or use of any anesthetic other than local anesthetics, except that a podiatrist may administer narcotics and medications in the treatment of ailments of the human foot and leg in the same manner as a physician and surgeon."

"Surgery - use of any cutting instrument to treat a disease, ailment, or condition."

APPENDIX B

1989 PART B MEDICARE ANNUAL DATA SELECTED PROCEDURES AND NUMBER OF PROCEDURES PERFORMED IN EACH SETTING

Procedure	Hospital Inpatient	Hospital Outpatient	Ambulatory Surgical Center	Physician's Office
Incision and drainage	11,700	15,600	200	666,800
Skin biopsy	12,600	18,700	300	869,800
Excise benign lesion	16,700	93,000	2,900	880,200
Excise malignant lesion	4,200	37,700	1,600	302,200
Debride nails	27,500	13,700	100	2,141,300
Destruct lesion	20,500	36,900	1,100	4,505,000
Arthrocentesis	45,600	37,200	200	1,878,900
Total hip replacement *	60,000	1,100	0	1,300
Coronary artery bypass *	121,200	0	0	1,100
Endoscopy	434,400	309,700	8,300	86,700
Colonoscopy	251,200	464,900	14,400	121,900
Dilate urethra	3,200	4,600	0	209,000
Cataract removal	41,900	709,900	166,900	42,400

* The numbers that are less than 2,000 have a very high percentage of error.

APPENDIX C

TYPES OF FACILITIES AND THE NUMBER OF STATE HEALTH FACILITY
LICENSURE AGENCIES THAT LICENSE EACH

**TYPES OF FACILITIES AND THE NUMBER OF STATE HEALTH FACILITY
LICENSURE AGENCIES THAT LICENSE EACH**

TYPES OF FACILITIES	STATES												
	A L	A K	A Z	A R	C A	C O	C T	D E	D C	F L *	G A	H I	I D
Ambulatory Health Care Clinic			X		X		X						
Ambulatory Surgical Center	X	X	X	X	*	X	X	X	X	X	X	X	*
Birthing Center	X	X	X		*	X		X		X	X	X	
Health Maintenance Organization			*	X	*	*	X	X		X	X		
Urgent/Immediate Care Center			X				X						
Cancer Treatment Center			X										
Cardiac Catheterization Lab			X		X								
Emergency Center			X			X		X					
Home Health Care Agency		X	X	X	X		X	X		X	*	X	*
Independent Clinical Lab	X		X		*		X	X	X	X	X	X	*
Abortion Clinic	X		X	X	*		X		X	X	X		
Diagnostic Imaging Center													
Office Surgery Center					X				X				
Physician's Office													

X indicates the primary licensure agency in that State does license that type of facility

a blank indicates the State does not license that type of facility or that type of facility does not exist in the State

***** indicates there are conditions that relate to licensure of this type of facility in a given State and the reader should refer to the enclosed footnotes for greater detail

— indicates the licensure status of many or all of the facilities in a given State are unclear and the reader should refer to the enclosed footnotes for greater detail

**TYPES OF FACILITIES AND THE NUMBER OF STATE HEALTH FACILITY
LICENSURE AGENCIES THAT LICENSE EACH**

TYPES OF FACILITIES	STATES												
	I L	I N	I A	K S	K Y	L A	M E	M D	M A	M I	M N	M S	M O
Ambulatory Health Care Clinic					X				*				
Ambulatory Surgical Center	X	X	*	X	X	X	X	*	*	*	X	X	X
Birthing Center			X		X			X	X			X	*
Health Maintenance Organization	X				X		*	X	*		*		
Urgent/Immediate Care Center					X			*	*				
Cancer Treatment Center					X				*				
Cardiac Catheterization Lab					X			*					
Emergency Center					X			*	*				
Home Health Care Agency	*	X		X	X		X	X			*	X	*
Independent Clinical Lab	X			*	X		*	X	X	X			
Abortion Clinic	*			*	X				*			X	X
Diagnostic Imaging Center					X		*	*	*		*		
Office Surgery Center	*				X								
Physician's Office													

X indicates the primary licensure agency in that State does license that type of facility

a blank indicates the State does not license that type of facility or that type of facility does not exist in the State

***** indicates there are conditions that relate to licensure of this type of facility in a given State and the reader should refer to the enclosed footnotes for greater detail

— indicates the licensure status of many or all of the facilities in a given State are unclear and the reader should refer to the enclosed footnotes for greater detail

**TYPES OF FACILITIES AND THE NUMBER OF STATE HEALTH FACILITY
LICENSURE AGENCIES THAT LICENSE EACH**

TYPES OF FACILITIES	STATES												
	M T	N E *	N V	N H *	N J	N M	N Y	N C	N D	O H	O K	O R *	P A
Ambulatory Health Care Clinic		X		X	X	X	X		-				
Ambulatory Surgical Center	X	X	X	X	X	X	X	X	*	*	X	X	X
Birthing Center		X		X	X	X	X	*	-		*	X	
Health Maintenance Organization		X			X		X		-	*			
Urgent/Immediate Care Center		X		X					-				
Cancer Treatment Center	X	X		X		X			-				
Cardiac Catheterization Lab	X	X		X	X	X	*		-				
Emergency Center		X		X					-				
Home Health Care Agency	X	X	X	X	*	X	*	X	X			X	
Independent Clinical Lab	X		X	X	X		*		-		*	X	
Abortion Clinic		X			X	X	X	X	-				
Diagnostic Imaging Center	X	X			X				-				
Office Surgery Center	*	X		X				*	-				
Physician's Office													

X indicates the primary licensure agency in that State does license that type of facility

a blank indicates the State does not license that type of facility or that type of facility does not exist in the State

***** indicates there are conditions that relate to licensure of this type of facility in a given State and the reader should refer to the enclosed footnotes for greater detail

- indicates the licensure status of many or all of the facilities in a given State are unclear and the reader should refer to the enclosed footnotes for greater detail

**TYPES OF FACILITIES AND THE NUMBER OF STATE HEALTH FACILITY
LICENSURE AGENCIES THAT LICENSE EACH**

TYPES OF FACILITIES	STATES												
	R I	S C	S D	T N	T X	U T	V T	V A	W A	W V	W I	W Y	
Ambulatory Health Care Clinic	X						-		*				-
Ambulatory Surgical Center	X	X	X	X	X	X	*	X	*	*	*	*	
Birthing Center	X	*		X	X	X	-		X	X			X
Health Maintenance Organization	*	*				*	-		*	*			-
Urgent/Immediate Care Center	X						-		*				-
Cancer Treatment Center							-		*				-
Cardiac Catheterization Lab							-		*				-
Emergency Center	X						-		*				-
Home Health Care Agency	X	X		X	X	X	-	X	X		X		-
Independent Clinical Lab	X						-		X		X	*	
Abortion Clinic	X	*		X	X	X	-		X				-
Diagnostic Imaging Center	X						-		*				-
Office Surgery Center	X						-		*				-
Physician's Office													

X indicates the primary licensure agency in that State does license that type of facility

a blank indicates the State does not license that type of facility or that type of facility does not exist in the State

***** indicates there are conditions that relate to licensure of this type of facility in a given State and the reader should refer to the enclosed footnotes for greater detail

— indicates the licensure status of many or all of the facilities in a given State are unclear and the reader should refer to the enclosed footnotes for greater detail

**FOOTNOTES FOR TYPES OF FACILITIES AND THE NUMBER OF STATE
HEALTH FACILITY LICENSURE AGENCIES THAT LICENSE EACH**

- * Arizona - The Department of Insurance licenses HMOs.
- * California - Most, if not all, of the ASCs in the State are certified while fewer than 50% of them are licensed. Licensure and certification standards are the same for ASCs. Licensure of Birthing Centers and Abortion Clinics may be provided as a service under a primary care clinic license (i.e. a primary care clinic is non-profit and the patients served are Medi-Cal eligible). The State of California Department of Corporations licenses HMOs. The Department of Health Service's Laboratory Field Services program licenses Independent Clinical Labs.
- * Colorado - The Colorado Division of Insurance must grant a certificate of authority to HMOs in order to operate legally in the State. The Health Facilities Division has a role in regulation as the designee of the Executive Director of the Colorado Department of Health.
- * Florida - The State is currently revising their licensure statutes.
- * Georgia - The Health Care Section of the Georgia Department of Human Resources licenses only the home health care services that hold themselves out to the public as Home Health Care Agencies (when care is being provided by private nursing services).
- * Idaho - The State licenses Home Health Care Agencies if they are for-profit organizations. The State Department of Health and Welfare conducts Medicare certification surveys for Ambulatory Surgical Centers and Independent Clinical Labs.
- * Illinois - Abortion Clinics and Office Surgery Centers may be licensed if they meet rules set out for ASCs. Home Health Agencies are licensed by the Illinois Department of Public Health.
- * Iowa - The Department of Inspections and Appeals has a task force looking at the issue of licensure for ASCs. This would apply only to those ASCs where the recovery period is over 24 hours. The State Health Facilities Division conducts Medicare certification surveys for Ambulatory Surgical Centers.
- * Kansas - The State regulates labs through Medicare certification and CLIA. Licensing is done only for laboratories testing for HIV, controlled substances, and pre-natal syphilis. The Department of Health and Environment, Division of Health may license an Abortion Clinic as an ASC under certain conditions. The State does not have separate licensing statutes pertaining to Abortion Clinics.

* Maine - The Bureau of Insurance is responsible for licensure of HMOs. The Health and Environmental Testing Laboratory is responsible for licensure of Independent Clinical Labs. The Division of Health Engineering, Bureau of Health is responsible for licensure of Diagnostic Imaging Centers.

* Maryland - The Department of Health and Mental Hygiene licenses Urgent/Immediate Care Centers if they use the term "urgent" or "emergency" in their advertising. Cardiac Catheterization Labs are licensed only if equipment acquisitions costs were over \$600,000. Emergency Centers are licensed only if they use the term "emergency" or "urgent" in their advertising. Diagnostic Imaging Centers are licensed only if equipment acquisition costs were over \$600,000. The State conducts Medicare certification surveys for Ambulatory Surgical Centers.

* Massachusetts - The Department of Public Health, Division of Health Care Quality licenses Ambulatory Health Care Clinics, ASCs, HMOs, Urgent/Immediate Care Centers, Cancer Treatment Centers, Emergency Centers, Diagnostic Imaging Centers, and Abortion Clinics if they meet the statutory definition of a "clinic."

* Michigan - The Department of Public Health has a licensure program for freestanding outpatient surgical facilities, which includes some pregnancy termination activities.

* Minnesota - The Department of Health, Health Maintenance Organization Unit licenses HMOs. The Health Resources Division of the Department of Health are in the process of promulgating licensure rules for Home Health Care Agencies. The Radiation Control Section, Environmental Health Division, in the Department of Health licenses Diagnostic Imaging Centers.

* Missouri - The State has licensing laws that are applicable to ASCs, Abortion Clinics, and Home Health Care Agencies but the Department of Health is responsible for licensure of only ASCs and Abortion Clinics. The ASC licensing law encompasses Birthing Centers but at present time they are not being licensed.

* Montana - The Department of Health and Environmental Sciences licenses Office Surgery Centers if they are multi-specialty group practices.

* Nebraska - The State is preparing to revise outpatient health care clinic standards for facilities such as ASCs.

* New Hampshire - State statutes are currently under revision and will change dramatically in the next year. Currently all outpatient facilities are under the same set of standards.

* New Jersey - The State Department of Health licenses only Medicare-certified Home Health Care Agencies. If a physician acquires equipment which is subject to a health planning/certificate of need requirement, licensure of the equipment is required. (New statutory requirement 7/91)

* New York - The Bureau of Hospital Services, State Department of Health licenses Cardiac Catheterization Labs. The Bureau of Home Health Care Services, State Department of Health licenses Home Health Care Agencies. The Wadsworth Center for Laboratories, State Department of Health licenses Independent Clinical Labs.

* North Carolina - The Division of Facility Services, Department of Human Resources licenses Office Surgery Centers if they meet the definition of ASCs. There are two Birthing Centers in the State that are licensed as ASCs.

-- North Dakota - The State Department of Health is responsible for licensure of outpatient facilities (to exclude physicians' offices). Of these outpatient facilities that are licensed, Home Health Care Agencies are the only one that are mentioned by name. Present licensure rules do not include any program standards. Outpatient facilities for purpose of licensure have not been further defined at this point in terms of specific services or types of programs.

* North Dakota - Freestanding outpatient facilities that are not part of a private practice can be licensed. These licensed facilities have facility standards but no program standards. The State Department of Health conducts Medicare certification surveys for Ambulatory Surgical Centers.

* Ohio - All HMOs are licensed by the Department of Insurance after being certified by the Department of Health. The State Department of Health conducts Medicare certification surveys for Ambulatory Surgical Centers.

* Oklahoma - Legislation on licensure of Birthing Centers is pending. Laboratories that test for the presence of HIV are licensed (there are less than 20 of these in the State).

* Oregon - The State has Type I and Type II facilities in the State. The standards are the same for both except for physical plant standards.

* Rhode Island - The Department of Business Regulation licenses HMOs.

* South Carolina - The Department of Insurance licenses HMOs. Birthing Centers are licensed by the State for deliveries by midwives. The State licenses Abortion Clinics that perform second trimester abortions.

* Utah - The authority has been given to license HMOs but there is no program in place.

-- Vermont - There are very few outpatient facilities in Vermont other than Medicare/Medicaid certified providers which are affiliated with hospitals. Any other outpatient facilities that exist provide very limited services.

* Vermont - The State Agency of Human Services conducts Medicare certification surveys for Ambulatory Surgical Centers.

* Washington - The Home Health and Rehabilitation Survey Section of the State Department of Health licenses Home Health Care Agencies. The Laboratory Quality Assurance Division of the State Department of Health licenses medical test sites. The Radiation Protection Division of the State Department of Health licenses radiation equipment for Diagnostic Imaging Centers and all other facilities with x-ray equipment. The Department of Health, Licensing Cluster includes both facility and professional licensing programs. Facilities with x-ray, nuclear, medical test sites (lab), and pharmacy operations are subject to these licensure requirements. The State Department of Health conducts Medicare certification surveys for Ambulatory Surgical Centers.

* West Virginia - The Insurance Commission licenses HMOs. The Office of Health Facility Licensure and Certification conducts Medicare certification surveys for Ambulatory Surgical Centers.

* Wisconsin - The State Division of Health conducts Medicare certification surveys for Ambulatory Surgical Centers, Home Health Care Agencies, and Independent Clinical Labs.

-- Wyoming - In 1989 the WY Legislature passed a comprehensive Health Facility licensure bill but did not appropriate staff or funds to implement the law. The Department of Health has licensure authority which has not been implemented for Ambulatory Health Care Clinics, ASCs, Birthing Centers, Urgent/Immediate Care Centers, Emergency Centers, Home Health Care Agencies, and Diagnostic Imaging Centers. They are not responsible for licensing the remainder of the facilities.

* Wyoming - The State Public Health Laboratory licenses laboratories. The State Department of Health conducts Medicare certification surveys for Ambulatory Surgical Centers.

APPENDIX D

STATE HEALTH FACILITY LICENSURE AGENCIES STANDARDS FOR LICENSURE

HEALTH FACILITY LICENSURE AGENCIES STANDARDS FOR LICENSURE

STANDARDS FOR LICENSURE	STATES												
	A L	A K	A Z	A R	C A	C O	C T	D E	D C	F L	G A	H I	I D
Legal limits	3	3	2	2	3	2	2	2	2	2	2	3	1
Medical standards	3	3	3	1	3	2	3	2	3	2	3	2	1
Emergency equipment and trained personnel	3	3	3	3	2	2	3	3	3	2	3	2	1
Infection control procedures	3	3	3	3	2	2	3	3	2	3	2	3	1
Patient complaints	1	3	1	1	2	1	3	3	1	2	2	2	1
Minimum staffing requirements	3	3	2	3	3	3	3	2	2	3	3	3	1
Peer review	2	3	2	1	3	1	3	2	1	3	2	2	1
Transfer agreements	2	2	2	2	3	3	3	3	3	3	3	2	1
Equipment standards	2	3	2	2	2	2	3	2	2	3	2	2	1
Anesthesia administered by qualified personnel	3	2	2	2	2	2	3	3	3	3	3	2	1
Record-keeping standards	3	3	3	3	3	3	3	3	3	3	3	3	1
Training/certification for ancillary personnel	1	3	1	2	2	1	2	2	2	3	2	2	1
Require facility to have a credentialing process	3	3	2	2	2	1	3	2	1	2	2	2	1
Licensure renewal	1	1	1	1	1	1	2	1	1	2	1	2	1

The licensure standards listed above relate to outpatient facilities where surgery is performed.

We have included only one set of licensure standards for each State. For 41 of the States, we used Ambulatory Surgical Center licensure standards. For Idaho and North Dakota, we used Home Health Care Agency standards. For Iowa, Washington, West Virginia, and Wyoming, we used Birthing Center standards. For Maryland and Ohio, we used HMO standards. No standards apply for Vermont or Wisconsin.

Explanation of rankings (1, 2, or 3) is on pages D-7, D-8, and D-9.

HEALTH FACILITY LICENSURE AGENCIES STANDARDS FOR LICENSURE

STANDARDS FOR LICENSURE	STATES												
	I L	I N	I A	K S	K Y	L A	M E	M D	M A	M I	M N	M S	M O
Legal limits	3	3	3	2	3	2	3	3	3	2	2	3	2
Medical standards	3	3	2	2	3	2	2	3	3	3	2	3	2
Emergency equipment and trained personnel	3	3	3	2	3	2	3	3	2	2	2	3	3
Infection control procedures	2	3	3	2	3	2	3	1	2	1	2	3	3
Patient complaints	3	3	2	1	1	2	2	3	3	1	2	2	3
Minimum staffing requirements	3	3	2	3	3	3	3	3	3	3	3	3	3
Peer review	1	3	1	2	3	3	2	3	2	2	2	3	3
Transfer agreements	3	2	2	1	3	2	3	3	2	2	2	2	2
Equipment standards	2	2	2	3	2	2	3	3	2	2	2	2	3
Anesthesia administered by qualified personnel	2	3	2	2	3	3	2	3	3	2	3	2	3
Record-keeping standards	3	3	3	3	3	3	3	3	3	3	3	3	3
Training/certification for ancillary personnel	2	3	2	2	2	3	3	3	2	2	3	3	2
Require facility to have a credentialing process	2	3	2	3	2	3	3	3	2	2	2	3	3
Licensure renewal	1	1	1	1	1	1	1	3	2	1	1	1	1

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HEALTH FACILITY LICENSURE AGENCIES STANDARDS FOR LICENSURE

STANDARDS FOR LICENSURE	STATES												
	M T	N E	N V	N H	N J	N M	N Y	N C	N D	O H	O K	O R	P A
Legal limits	1	2	2	2	3	2	3	2	1	3	2	2	2
Medical standards	2	2	2	2	3	2	3	3	1	2	2	2	3
Emergency equipment and trained personnel	1	2	3	2	3	3	3	3	1	1	3	2	3
Infection control procedures	1	2	3	2	3	2	3	3	1	1	1	3	3
Patient complaints	1	2	1	3	3	3	3	1	1	3	1	2	2
Minimum staffing requirements	1	2	3	3	3	3	3	2	1	1	1	2	2
Peer review	1	2	1	1	2	2	3	2	1	1	2	3	3
Transfer agreements	1	2	2	1	2	2	3	2	1	1	2	2	3
Equipment standards	1	3	2	2	2	2	2	3	2	1	2	2	2
Anesthesia administered by qualified personnel	1	2	2	2	3	2	2	3	1	2	2	3	2
Record-keeping standards	3	2	3	3	2	3	3	3	1	2	2	3	2
Training/certification for ancillary personnel	1	2	2	2	3	3	2	3	1	1	1	3	3
Require facility to have a credentialing process	1	2	2	2	3	3	3	3	1	2	2	3	3
Licensure renewal	1	1	1	1	1	1	2	1	1	1	1	1	1

The licensure standards listed above relate to outpatient facilities where surgery is performed.

We have included only one set of licensure standards for each State. For 41 of the States, we used Ambulatory Surgical Center licensure standards. For Idaho and North Dakota, we used Home Health Care Agency standards. For Iowa, Washington, West Virginia, and Wyoming, we used Birthing Center standards. For Maryland and Ohio, we used HMO standards. No standards apply for Vermont or Wisconsin.

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HEALTH FACILITY LICENSURE AGENCIES STANDARDS FOR LICENSURE

STANDARDS FOR LICENSURE	STATES												
	R I	S C	S D	T N	T X	U T	V T	V A	W A	W V	W I	W Y	
Legal limits	3	3	3	2	3	2	1	3	3	2	1	2	
Medical standards	3	3	3	2	3	2	1	3	2	2	1	1	
Emergency equipment and trained personnel	3	3	2	3	3	2	1	2	3	1	1	3	
Infection control procedures	3	3	3	1	2	2	1	2	2	3	1	3	
Patient complaints	2	2	2	2	3	1	1	1	1	2	1	1	
Minimum staffing requirements	2	3	3	3	3	2	1	2	2	2	1	3	
Peer review	2	2	3	1	1	2	1	1	2	1	1	2	
Transfer agreements	2	2	2	3	3	3	1	2	3	3	1	3	
Equipment standards	2	2	2	2	2	2	1	1	2	2	1	1	
Anesthesia administered by qualified personnel	2	2	3	2	3	3	1	2	2	2	1	2	
Record-keeping standards	3	3	2	3	3	3	1	3	3	3	1	3	
Training/certification for ancillary personnel	2	3	3	2	3	3	1	2	2	3	1	3	
Require facility to have a credentialing process	3	2	3	3	3	2	1	3	3	1	1	2	
Licensure renewal	1	1	1	1	1	1	1	1	1	1	1	1	

The licensure standards listed above relate to outpatient facilities where surgery is performed.

We have included only one set of licensure standards for each State. For 41 of the States, we used Ambulatory Surgical Center licensure standards. For Idaho and North Dakota, we used Home Health Care Agency standards. For Iowa, Washington, West Virginia, and Wyoming, we used Birthing Center standards. For Maryland and Ohio, we used HMO standards. No standards apply for Vermont or Wisconsin.

Explanation of rankings (1, 2, or 3) is on pages D-7, D-8, and D-9.

HEALTH FACILITY LICENSURE AGENCIES STANDARDS FOR LICENSURE

Legal limits

- 1 - No standards apply or the information received was incomplete.
- 2 - Guidelines for patient care, such as type of anesthesia allowed or length of stay, are listed as requirements for licensure.
- 3 - In addition to the guidelines listed above, the governing body of each licensed facility is required to establish a list of procedures that can be legally performed in that setting.

Medical standards

- 1 - No standards apply or the information received was incomplete.
- 2 - The health facility licensure agency requires that surgical procedures be performed by physicians who are licensed in that State.
- 3 - The health facility licensure agency requires that surgical procedures be performed by physicians who are licensed in that State and requires that physicians be granted privileges to perform those procedures by the facility.

Emergency equipment and trained personnel

- 1 - No standards apply or the information received was incomplete.
- 2 - Licensure standards address the presence of emergency equipment or the presence of personnel trained in emergency procedures.
- 3 - Licensure standards address the presence of emergency equipment and presence of personnel trained in emergency procedures in great detail.

Infection control procedures

- 1 - No standards apply or the information received was incomplete.
- 2 - Licensure standards for infection control procedures exist but are not explained in great detail.
- 3 - Licensure standards for infection control procedures are explicit and may include designated committees that provide oversight in this area.

Patient complaints

- 1 - No standards apply or the information received was incomplete.
- 2 - The health facility licensure agency requires the facility to have a process in place to receive patient complaints but does not go into great detail.
- 3 - The health facility licensure agency requires the facility to have a specific process in place to receive patient complaints.

Minimum staffing requirements

- 1 - No standards apply or the information received was incomplete.
- 2 - The health facility licensure agency requires the facility to have established a minimum staff requirement for qualified personnel to be onsite during the hours of operation.
- 3 - The health facility licensure agency requires the facility to have established a minimum staff requirement for qualified personnel and a physician or a registered nurse to be onsite during the hours of operation.

Peer review

- 1 - No standards apply or the information received was incomplete.
- 2 - Licensure standards require the facility to have some form of internal peer review.
- 3 - Licensure standards require the facility to have some form of internal peer review within specified time frames.

Transfer agreements

- 1 - No standards apply or the information received was incomplete.
- 2 - The health facility licensure agency requires that the facility have a written patient transfer agreement with a hospital that is located nearby.
- 3 - The health facility licensure agency requires that the facility have a written patient transfer agreement with a hospital that is located nearby; or it requires the physicians from that facility to have admitting/staff privileges at a local hospital.

Equipment standards

- 1 - No standards apply or the information received was incomplete.
- 2 - Licensure standards require that all equipment be inspected, maintained, and calibrated.
- 3 - Licensure standards require that all equipment be inspected, maintained, and calibrated within specified time frames.

Anesthesia administered by qualified personnel

- 1 - No standards apply or the information received was incomplete.
- 2 - Licensure standards require that anesthesia be administered by qualified personnel.
- 3 - Licensure standards require that anesthesia be administered by qualified personnel with specific provisions in place for the administration of a general anesthetic.

Record-keeping standards

- 1 - No standards apply or the information received was incomplete.
- 2 - Licensure standards require the facility to have patient records which contain personal and medical information for each patient.
- 3 - Licensure standards require the facility to have patient records which contain personal and medical information and a post-operative report for each patient.

Training/certification for ancillary personnel

- 1 - No standards apply or the information received was incomplete.
- 2 - The health facility licensure agency requires that the ancillary personnel employed in the facility are qualified for their position through previous training or certification.
- 3 - The health facility licensure agency requires that the ancillary personnel employed in the facility are qualified for their position through previous training or certification. These employees must also be CPR certified and take part in continuing education courses.

Require facility to have a credentialing process

- 1 - No standards apply or the information received was incomplete.
- 2 - The health facility licensure agency requires the facility to have a credentialing process in place to review the credentials of potential professional staff but does not specify whose role this is or the credentialing process.
- 3 - The health facility licensure agency requires the facility to have a credentialing process in place to review the credentials of potential professional staff. The accrediting body specifies whose role this is and lists the criteria used in the credentialing process.

Licensure renewal

- 1 = Annual renewal
2 = Biennial renewal
* = Renewal periods vary depending on the type of facility that is being licensed

APPENDIX E

STATE MEDICAL AND OSTEOPATHIC BOARDS STANDARDS FOR LICENSURE

**STATE MEDICAL AND OSTEOPATHIC BOARDS
STANDARDS FOR LICENSURE**

STANDARDS FOR LICENSURE	A L	A K	A Z	A <u>Z</u>	A R	C A	C <u>A</u>	C O	C T	D E	D C	F L	F <u>L</u>
Minimum standards for licensure	3	3	3	3	3	3	3	3	3	2	3	3	3
Legal limits	1	1	1	2	1	1	3	1	1	1	1	1	2
Medical standards	2	2	2	2	1	1	2	1	1	1	1	1	2
Emergency procedures	1	2	2	2	2	1	2	2	1	1	1	1	1
Infection control procedures	1	2	2	2	2	1	1	2	1	1	1	1	3
Patient complaints	3	3	3	2	2	2	3	3	2	2	2	2	3
Licensure renewal	1	2	1	2	1	2	1	2	1	2	2	2	2

STATE = Medical board

STATE = Osteopathic board

Explanation of rankings (1, 2, or 3) is on pages E-8 and E-9.

A blank indicates the State has not responded or there are no standards that apply.

**STATE MEDICAL AND OSTEOPATHIC BOARDS
STANDARDS FOR LICENSURE**

STANDARDS FOR LICENSURE	G A	H I	H I	I D	I L	I N	I A	K S	K Y	L A	M E	M E	M D
Minimum standards for licensure	3	3	3	3	3	3	3	3	1	3	3	3	3
Legal limits	3	2	2	3	1	1	2	2	2	1	1	2	1
Medical standards	2	2	1	2	2	1	2	1	2	1	2	2	1
Emergency procedures	2	1	1	2	2	1	2	2	2	1	1	2	1
Infection control procedures	3	1	1	2	2	1	2	2	2	1	1	2	1
Patient complaints	3	3	3	3	3	3	3	3	3	3	2	2	3
Licensure renewal	2	2	2	1	3	2	2	1	1	1	2	2	2

STATE = Medical board

STATE = Osteopathic board

Explanation of rankings (1, 2, or 3) is on pages E-8 and E-9.

A blank indicates the State has not responded or there are no standards that apply.

**STATE MEDICAL AND OSTEOPATHIC BOARDS
STANDARDS FOR LICENSURE**

STANDARDS FOR LICENSURE	M A	M I	M N	M S	M O	M T	N E	N V	N V	N H	N J	N M	N M
Minimum standards for licensure	3	3	3	3	3	3	3	3	2	3	3	3	3
Legal limits	2	1	1	1	2	1	2	2	1	1	1	1	1
Medical standards	2	2	1	1	2	2	1	3	1	1	2	1	1
Emergency procedures	2	1	1	1	1	2	2	1	1	1	1	1	1
Infection control procedures	2	1	1	1	2	3	2	2	1	1	1	1	1
Patient complaints	3	3	2	3	3	2	3	3	2	2	2	3	3
Licensure renewal	2	3	1	1	1	1	2	2	1	1	2	3	1

STATE = Medical board

STATE = Osteopathic board

Explanation of rankings (1, 2, or 3) is on pages E-8 and E-9.

A blank indicates the State has not responded or there are no standards that apply.

**STATE MEDICAL AND OSTEOPATHIC BOARDS
STANDARDS FOR LICENSURE**

STANDARDS FOR LICENSURE	N Y	N C	N D	O H	O K	O <u>K</u>	O R	P A	P <u>A</u>	R I	S C	S D	T N
Minimum standards for licensure	3	3	3	3	3	3	3	3	3	3	3	3	3
Legal limits	1	2	1	2	1	1	1	2	2	1	3	2	2
Medical standards	1	2	2	1	2	3	1	1	2	2	2	3	1
Emergency procedures	1	2	1	1	1	1	1	1	1	1	2	2	2
Infection control procedures	1	2	1	1	1	1	1	1	1	1	2	2	2
Patient complaints	3	3	3	3	3	3	3	3	3	2	3	3	3
Licensure renewal	2	2	1	2	1	1	2	2	2	1	1	1	1

STATE = Medical board

STATE = Osteopathic board

Explanation of rankings (1, 2, or 3) is on pages E-8 and E-9.

A blank indicates the State has not responded or there are no standards that apply.

**STATE MEDICAL AND OSTEOPATHIC BOARDS
STANDARDS FOR LICENSURE**

STANDARDS FOR LICENSURE	T N *	T X	U T	V T	V A	W A	W A	W V	W V	W I	W Y		
Minimum standards for licensure		3	3	3	3	3	3	3	3	3	3		
Legal limits		2	2	2	2	2	1	1	1	1	1		
Medical standards		2	1	2	1	2	1	2	1	2	1		
Emergency procedures		2	1	2	1	2	1	1	1	1	2		
Infection control procedures		2	1	2	1	2	3	1	1	2	2		
Patient complaints		3	3	3	3	3	3	2	2	3	2		
Licensure renewal		1	2	2	2	1	1	2	2	2	1		

STATE = Medical board

STATE = Osteopathic board

Explanation of rankings (1, 2, or 3) is on pages E-8 and E-9.

A blank indicates the State has not responded or there are no standards that apply.

* The Tennessee Osteopathic Board of Medicine did not respond.

STATE MEDICAL AND OSTEOPATHIC BOARDS STANDARDS FOR LICENSURE

Minimum standards for licensure

- 1 - No standards apply or the information received was incomplete.
- 2 - Candidates for licensure must be graduates of an approved or accredited medical or osteopathic school, must have passed National Boards (or equivalent), and must have passed State licensure exam.
- 3 - Candidates for licensure must be graduates of an approved or accredited medical or osteopathic school, must have passed National Boards (or equivalent), must have passed State licensure exam, and must have completed at least one year of postgraduate training (internship, residency, or equivalent).

Legal limits

- 1 - No standards apply or the information received was incomplete.
- 2 - Licensed practitioners are required to adhere to at least minimal "standards of care" that have been established.
- 3 - Licensed practitioners are prohibited from performing certain specific procedures that do not adhere to minimal "standards of care."

Medical standards

- 1 - No standards apply or the information received was incomplete.
- 2 - Education and medical standards (including continuing medical education) is referenced in the State's rules and regulations.
- 3 - Specific subjects and courses of study that are required for licensure are listed in the State's rules and regulations.

Emergency procedures

- 1 - No standards apply or the information received was incomplete.
- 2 - Knowledge of emergency procedures (such as CPR) is considered to be part of the education, training, or examination process. The Board considers it to be an indirect requirement for licensure.
- 3 - Knowledge of emergency procedures is a direct requirement for licensure.

Infection control procedures

- 1 - No standards apply or the information received was incomplete.
- 2 - Knowledge of infection control procedures is considered to be part of the education, training, or examination process. The Board considers it to be an indirect requirement for licensure.
- 3 - Knowledge of infection control procedures is a direct requirement for licensure.

Patient complaints

- 1 - No standards apply or the information received was incomplete.
- 2 - Members of the Board receive and investigate patient complaints.
- 3 - There is a specific unit or office within the Board that is designed solely to receive and investigate patient complaints.

Licensure renewal

- 1 - Licenses are renewed annually.
- 2 - Licenses are renewed biennially.
- 3 - Licenses are renewed triennially.

APPENDIX F

STATE PODIATRY BOARDS STANDARDS FOR LICENSURE

STATE PODIATRY BOARDS STANDARDS FOR LICENSURE

STANDARDS FOR LICENSURE	A L	A K	A Z	A R	C A	C O	C T	D E *	D C	F L	G A	H I	I D
Minimum standards for licensure	3	2	3	2	3	2	2	3	2	3	3	3	3
Legal limits	2	2	3	2	3	2	3	3	3	2	3	3	3
Medical standards	2	2	2	2	2	1	1	2	1	3	2	2	1
Emergency procedures	2	2	2	2	2	2	1	1	1	1	1	1	1
Infection control procedures	2	2	2	2	1	2	1	2	1	3	1	1	1
Patient complaints	3	3	2	3	3	3	3	3	2	3	2	3	2
Licensure renewal	1	2	1	1	2	1	1	2	2	2	2	2	1

STATE = Podiatry board

Explanation of rankings (1, 2, or 3) is on pages F-7 and F-8.

A blank indicates the State has not responded or there are no standards that apply.

* The State of Delaware has indicated that their rules and regulations have been revised and will go into effect at the end of February of this year. The licensure standards listed above for Delaware represent the rules and regulations that were in place prior to this revision.

STATE PODIATRY BOARDS STANDARDS FOR LICENSURE

STANDARDS FOR LICENSURE	I L	I N	I A	K S	K Y	L A	M E	M D	M A	M I	M N	M S	M O
Minimum standards for licensure	3	2	2	3	2	2	2	3	3	3	3	3	2
Legal limits	3	3	3	3	2	3	1	3	2	3	3	3	2
Medical standards	3	1	2	3	2	1	2	2	2	2	2	1	2
Emergency procedures	2	1	2	2	1	1	1	2	2	1	1	1	1
Infection control procedures	2	1	2	2	2	1	1	2	2	1	2	1	1
Patient complaints	3	3	2	3	3	3	2	3	2	3	2	3	2
Licensure renewal	2	2	2	1	1	1	2	2	1	3	2	1	1

STATE = Podiatry board

Explanation of rankings (1, 2, or 3) is on pages F-7 and F-8.

A blank indicates the State has not responded or there are no standards that apply.

STATE PODIATRY BOARDS STANDARDS FOR LICENSURE

STANDARDS FOR LICENSURE	M T	N E	N H	N J	N M	N Y	N C	N D	O H	O K	O R	P A	R I
Minimum standards for licensure	3	2	2	3	2	2	3	3	3	3	1	2	3
Legal limits	3	3	3	2	3	3	3	2	2	2	1	2	2
Medical standards	1	2	1	2	1	2	2	2	1	2	1	1	2
Emergency procedures	1	1	2	1	1	1	2	2	1	1	1	1	1
Infection control procedures	2	1	2	1	1	2	1	2	1	1	1	1	2
Patient complaints	2	3	2	2	2	3	1	2	3	3	1	3	2
Licensure renewal	1	2	1	2	1	3	1	1	2	1	2	2	2

STATE = Podiatry board

Explanation of rankings (1, 2, or 3) is on pages F-7 and F-8.

A blank indicates the State has not responded or there are no standards that apply.

STATE PODIATRY BOARDS STANDARDS FOR LICENSURE

STANDARDS FOR LICENSURE	S C	S D	T N	T X	U T	V T	V A	W A	W V	W I	W Y		
Minimum standards for licensure	2	2	3	2	2	2	3	2	3	2	2		
Legal limits	3	3	3	3	3	3	3	3	3	2	3		
Medical standards	1	2	1	2	2	2	1	1	1	1	1		
Emergency procedures	3	2	1	2	2	2	1	1	1	1	1		
Infection control procedures	3	2	1	2	2	2	1	3	1	2	1		
Patient complaints	3	2	1	2	3	3	3	3	2	3	2		
Licensure renewal	1	1	1	1	2	2	2	1	2	2	1		

STATE = Podiatry board

Explanation of rankings (1, 2, or 3) is on pages F-7 and F-8.

A blank indicates the State has not responded or there are no standards that apply.

STATE PODIATRY BOARDS STANDARDS FOR LICENSURE

Minimum standards for licensure

- 1 - No standards apply or the information received was incomplete.
- 2 - Candidates for licensure must be graduates of an approved or accredited podiatry school, must have passed National Boards (or equivalent), and must have passed State licensure exam.
- 3 - Candidates for licensure must be graduates of an approved or accredited podiatry school, must have passed National Boards (or equivalent), must have passed State licensure exam, and must have completed at least one year of postgraduate training (internship, preceptorship, or equivalent).

Legal limits

- 1 - No standards apply or the information received was incomplete.
- 2 - Licensed practitioners are required to adhere to written guidelines for the parts of the human foot that a podiatrist can treat.
- 3 - Licensed practitioners are restricted from performing amputations and/or are prohibited from administering anesthetics other than local anesthetic.

Medical standards

- 1 - No standards apply or the information received was incomplete.
- 2 - Education and medical standards (including continuing medical education) is referenced in the State's rules and regulations.
- 3 - Specific subjects and courses of study that are required for licensure are listed in the State's rules and regulations.

Emergency procedures

- 1 - No standards apply or the information received was incomplete.
- 2 - Knowledge of emergency procedures (such as CPR) is considered to be part of the education, training, or examination process. The Board considers it to be an indirect requirement for licensure.
- 3 - Knowledge of emergency procedures is a direct requirement for licensure.

Infection control procedures

- 1 - No standards apply or the information received was incomplete.
- 2 - Knowledge of infection control procedures is considered to be part of the education, training, or examination process. The Board considers it to be an indirect requirement for licensure.
- 3 - Knowledge of infection control procedures is a direct requirement for licensure.

Patient complaints

- 1 - No standards apply or the information received was incomplete.
- 2 - Members of the Board receive and investigate patient complaints.
- 3 - There is a specific unit or office within the Board that is designed solely to receive and investigate patient complaints.

Licensure renewal

- 1 - Licenses are renewed annually.
- 2 - Licenses are renewed biennially.
- 3 - Licenses are renewed triennially.

APPENDIX G

ACCREDITATION ASSOCIATION STANDARDS

STANDARDS	AAHC	AAPSF	JCAHO
Legal limits	2	2	2
Medical standards	3	3	3
Emergency equipment and trained personnel	3	3	3
Infection control procedures	3	2	3
Patient complaints	2	2	3
Minimum staffing requirements	3	2	3
Peer review	2	2	3
Transfer agreements	3	2	3
Equipment standards	3	2	3
Anesthesia administered by qualified personnel	3	3	3
Record-keeping standards	3	3	3
Training/certification for ancillary personnel	3	3	3
Require facility to have a credentialing process	3	3	3
Accreditation renewal	*	*	*

AAHC - Accreditation Association for Ambulatory Health Care

AAPSF - Accreditation Association for Podiatric Surgical Facilities

JCAHO - Joint Commission on the Accreditation of Healthcare Organizations

Legal limits

- 1 - No standards apply or the information received was incomplete.
- 2 - Procedures that can be performed are established by the facility or the physician's practice and are examined as part of the accreditation process.
- 3 - The accreditation association establishes their own list of procedures that can be performed in each setting.

Medical standards

- 1 - No standards apply or the information received was incomplete.
- 2 - The accreditation association requires that surgical procedures be performed by physicians who are licensed in that State.
- 3 - The accreditation association requires that surgical procedures be performed by physicians who are licensed in that State and physicians must have been granted privileges to perform those procedures by the facility.

Emergency equipment and trained personnel

- 1 - No standards apply or the information received was incomplete.
- 2 - Accreditation standards address the presence of emergency equipment or the presence of personnel trained in emergency procedures.
- 3 - Accreditation standards address the presence of emergency equipment and presence of personnel trained in emergency procedures in great detail.

Infection control procedures

- 1 - No standards apply or the information received was incomplete.
- 2 - Accreditation standards for infection control procedures exist but are not explained in great detail.
- 3 - Accreditation standards for infection control procedures are explicit.

Patient complaints

- 1 - No standards apply or the information received was incomplete.
- 2 - The accreditation association requires the facility to have a process in place to receive patient complaints but does not go into great detail.
- 3 - The accreditation association requires the facility to have a specific process in place to receive patient complaints.

Minimum staffing requirements

- 1 - No standards apply or the information received was incomplete.
- 2 - The accreditation association requires the facility to have established a minimum staff requirement for qualified personnel to be onsite during the hours of operation.
- 3 - The accreditation association requires the facility to have established a minimum staff requirement for qualified personnel and a physician or an anesthesiologist to be onsite during the hours of operation.

Peer review

- 1 - No standards apply or the information received was incomplete.
- 2 - Accreditation standards require the facility to have some form of internal peer review for quality assurance.
- 3 - Accreditation standards require the facility to have some form of internal peer review with specific time frames mentioned.

Transfer agreements

- 1 - No standards apply or the information received was incomplete.
- 2 - The accreditation association requires that the facility have a written patient transfer agreement with a hospital that is located nearby.
- 3 - The accreditation association requires that the facility have a written patient transfer agreement with a hospital that is located nearby or it requires the physicians from that facility to have admitting/staff privileges at a local hospital.

Equipment standards

- 1 - No standards apply or the information received was incomplete.
- 2 - Accreditation standards require that all equipment be inspected, maintained, and calibrated.
- 3 - Accreditation standards require that all equipment be inspected, maintained, and calibrated within specified time frames.

Anesthesia administered by qualified personnel

- 1 - No standards apply or the information received was incomplete.
- 2 - Accreditation standards require that anesthesia be administered by qualified personnel.
- 3 - Accreditation standards require that anesthesia be administered by qualified personnel with specific provisions in place for the administration of a general anesthetic.

Record-keeping standards

- 1 - No standards apply or the information received was incomplete.
- 2 - Accreditation standards require the facility to have patient records which contain personal and medical information for each patient.
- 3 - Accreditation standards require the facility to have patient records which contain personal and medical information and a post-operative report for each patient.

Training/certification for ancillary personnel

- 1 - No standards apply or the information received was incomplete.
- 2 - The accreditation association requires that the ancillary personnel employed in the facility are qualified for their position through previous training or certification.
- 3 - The accreditation association requires that the ancillary personnel employed in the facility are qualified for their position through previous training or certification, that these employees are CPR certified, and that these employees take part in continuing education courses.

Require facility to have a credentialing process

- 1 - No standards apply or the information received was incomplete.
- 2 - The accreditation association requires the facility to have a credentialing process in place to review the credentials of potential professional staff but does not specify whose role this is or the criteria involved in the credentialing process.
- 3 - The accreditation association requires the facility to have a credentialing process in place to review the credentials of potential professional staff. The accrediting body specifies whose role this is and lists the criteria used in the credentialing process.

Accreditation renewal

* AAAHHC - An organization can be accredited for three years if it is in substantial compliance with the standards. An organization can be accredited for one year if it is in substantial compliance with the standards but compliance does not appear to be well-established or the organization's commitment to one or more of the standards appears to be short-lived. Accreditation can be deferred for six months for those facilities that have the commitment and the capability to correct identified deficiencies so that they are in substantial compliance with the standards. Accreditation can also be denied to those facilities that are not in substantial compliance with the standards.

* AAPSF - An organization can be accredited for three years if it is in substantial compliance with the standards. An organization can be accredited for less than three years if it is in substantial compliance with the standards but compliance does not appear to be well-established or the organization's commitment to one or more of the standards appears to be short-lived. Accreditation can be deferred for six months for those facilities that have the commitment and the capability to correct identified deficiencies so that they are in substantial compliance with the standards. Accreditation can also be denied to those facilities that are not in substantial compliance with the standards.

* JCAHO - An organization can be accredited for three years if it is in substantial compliance with the standards. This award may be accompanied by specific citations or Type I recommendations. Organizations with Type I recommendations must demonstrate compliance with specified time frames or risk the loss of accreditation. Organizations not in substantial compliance with standards may become conditionally accredited or not accredited. Conditionally accredited organizations must submit a Plan of Correction and are subject to a follow-up survey in six months.

APPENDIX H

ADDITIONAL ACCREDITATION ASSOCIATION STANDARDS

Unannounced or unscheduled visits

Accreditation Association for Ambulatory Health Care (AAAHC)

"An accredited organization may be re-surveyed with or without advance notice at any time at the discretion of the AAAHC. No fee shall be charged the organization when such a resurvey is initiated at the discretion of the AAAHC. If an accredited organization is surveyed by the AAAHC and is judged not to be in substantial compliance with the standards, its accreditation will be revoked."

Accreditation Association for Podiatric Surgical Facilities (AAPSF)

The AAPSF conducts two types of visits. Scheduled visits are always performed for initial accreditation and renewal of accreditation. Unscheduled visits are a means of following up on facilities that had questionable deficiencies with the survey. These facilities are notified of the time period in which another visit will be made but the exact date and time of the visit are not given.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

The JCAHO conducts three types of visits. Scheduled visits are always performed for the initial full survey, renewal full survey, and for focused visits (a survey to see that Type 1 recommendations have been resolved). Unannounced visits involve a survey team arriving for an inspection without giving prior notification to the facility. This type of visit is for the more severe cases (the level of severity is based upon the perceived threat to patient safety). Unscheduled visits are for the less severe cases. These involve giving the facility 24 to 48 hours notice prior to the visit. The latter two types of visits usually take place as a result of information received indicating non-compliance, patient complaints, or media issues.

Public release of information

Accreditation Association for Ambulatory Health Care (AAAHC)

"...the AAAHC will not release any information obtained through the survey without the organization's written authorization." Survey findings are released to the organization only. The general public may call the AAAHC office to request information on the accreditation status of facilities. The AAAHC does not provide press releases or written directories.

Accreditation Association for Podiatric Surgical Facilities (AAPSF)

"Except as required by law, the AAPSF will not release any information obtained through the survey of an organization without the facility's written authorization. Consequently, the contents of the survey report, the survey team findings, and the accreditation decision are provided only to the participating facility and are disseminated solely at its discretion." There is no directory or media release of information.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

The JCAHO does not publish survey findings or accreditation status. A facility's accreditation status and accreditation history are available upon request by the public. Survey findings go to the Health Care Financing Administration and to State agencies if required by law (if the State requires accreditation for licensure).