Chapter 4
Ambulatory Surgery Services

Maryland Ambulatory Surgery Services: Definition and Overview

The growth in ambulatory surgery and the rise of non-hospital settings for surgical services that this growth has enabled over the last twenty years are truly remarkable. The shift from inpatient to outpatient, or ambulatory, surgery and the outright growth of new ambulatory surgery procedures has been driven by changes in technology, patient preferences, cost control efforts, regulatory policies and competition. Ambulatory, or outpatient surgery, is defined in the Maryland State Health Plan (COMAR 10.24.11.02F) as:

> Surgery performed requiring a period of post-operative observation but not requiring overnight hospitalization. This includes procedures involving the actual use of any cutting instrument, less-invasive procedures involving microscopic or endoscopic surgery or the use of laser for the removal or repair of an organ or other tissue. When not performed in an operating room, minor procedures routinely performed in physicians' offices and clinic settings are specifically excluded.

Maryland's health planning statute includes an ambulatory surgical facility in the definition of a health care facility in the context of the Certificate of Need program. Generally, a CON is required to build, develop or establish a new health care facility. The statute defines an ambulatory surgical facility, for CON purposes,[1] as follows:

(1) "Ambulatory surgical facility" means any center, service, office, facility or office of one or more health care practitioners or a group practice, as defined in 19-301 of the Health Occupations Article, that:

(i) Has two or more operating rooms;

(ii) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and

(iii) Seeks reimbursement from payers as an ambulatory surgical facility.

(2) For purposes of this subtitle, the office of one or more health care practitioners or a group practice with two operating rooms may be exempt from the certificate of need requirements under this subtitle if the Commission finds, in its sole discretion, that:

(i) A second operating room is necessary to promote the efficiency, safety, and quality of the surgical services offered; and

(ii) The office meets the criteria for exemption from the certificate of need requirements as an ambulatory surgical facility in accordance with regulations adopted by the Commission.

[1] Maryland's licensure law defines an ambulatory surgical facility differently, for licensure purposes.

Alternative Settings for Ambulatory Surgery

As stated in the Maryland State Health Plan: Ambulatory Surgical Services, COMAR 10.24.11 ("SHP"), ambulatory surgery may be performed in any of the following settings:

- hospital operating rooms in which both inpatient and outpatient surgery is performed;
- hospital-based discrete ambulatory surgical facilities or centers located either within the main hospital building or in a distinct facility on the hospital campus, in which operating rooms are dedicated exclusively for outpatient surgery;
- health maintenance organizations;[2]
- freestanding ambulatory surgical facilities or centers that operate primarily for the purpose of providing surgical services to patients not requiring hospitalization;
- physicians' offices that include surgical suites and may be Medicare certified as freestanding "ambulatory surgical centers" [ASCs]; and
- physicians' offices and clinic settings that do no include surgical suites.

The following Table 4-1 shows the capacity and utilization for each licensed setting in CY 2000.

[2] Kensington ASC is the only known FASF used exclusively by HMO patients. It is a Medicare-certified ASC and licensed as a FASF and is included as a FASF in Table 4-1.

Table 4-1
Facilities, Rooms, and Utilization of Ambulatory Surgery Settings
Maryland, CY 2000

	Facilities	Operating Rooms (ORs)	Procedure Rooms (PRs)	Cases
Acute General Hospital	47	258*	82*	522,379
Inpatient Surgery	--	--	--	153,601
Outpatient Surgery	--	--	--	368,778
Hospital-Based Ambulatory Surgical Facility (On-Campus, Unregulated)	3	14	7	15,103
Freestanding Ambulatory Surgical Facility (FASF) (More than one OR)	57	155	61	107,469
Physician's Office With Surgical Suite (One OR)	136	136	104	74,275
Physician's Office Without Surgical Suite (PR only)	59	0	101	105,240

Source: Maryland Ambulatory Surgery Facility Survey, Maryland Health Care Commission, preliminary data for 2000
* Based on MHCC survey of hospitals, with 30 of 47 hospitals reporting.

The term "operating room" used in the CON statute and the SHP is not defined, but is distinguished in practice from a "procedure room". "Operating room" connotes rooms situated within a sterile corridor that can be appropriately used for "open" or major surgical procedures usually involving general anesthesia. "Procedure rooms" typically refer to rooms which are appropriate only for minor surgical procedures, such as gastrointestinal endoscopy or other closed endoscopic procedures or many types of laser procedures, which do not require a sterile operating environment to be safely provided.

Over half of the ambulatory surgery reported by licensed surgical facilities in Maryland occurs in the general acute care hospital setting. In 2000, 54.9 percent of the total ambulatory surgical visits reported by health care facilities of all kinds in Maryland occurred in the state's 47 general acute care hospitals. Most of the ambulatory surgery provided in hospitals is provided through general mixed-use surgical facilities, utilized for the provision of both inpatient and outpatient surgery and procedures. A few hospitals operate surgical facilities on their campus that are dedicated to outpatient surgery.

An important and rapidly growing setting for ambulatory surgery in Maryland is the freestanding ambulatory surgical facility (FASF) which, for purposes of this paper, will include all licensed non-hospital ambulatory surgical facilities, including those facilities which are also used as physician offices. In 1990, a little less than 10 percent of the state's total ambulatory surgical visits occurred in FASFs. By 2000, this setting accounted for over 45 percent of total ambulatory surgery visits.

Number and Distribution of Ambulatory Surgery Providers in Maryland

Surgical capacity has increased significantly in the last six years, as shown in the following two tables. The number of surgical facilities in Maryland has more than doubled since 1994, and has increased over five fold since 1984, with all of this increase occurring in the freestanding ambulatory surgical facility sector. The operating room inventory identified by hospitals (excluding dedicated c-section rooms and delivery rooms) increased 34 percent between 1994 and 2000. The number of operating rooms reported by FASFs increased 142 percent over that same period, and the reported FASF procedure room inventory increased 150 percent. Over this same period the state's population increased approximately 6.2 percent.

Table 4-2
Trends in Number of Surgical Facilities
(General Hospital and Non-Hospital)
Maryland, 1984 – 2000

	1984	1994	2000
Hospitals with surgical facilities	54	51	47
Freestanding ambulatory surgical facilities	7	86	255[3]
Total surgical facilities	61	137	302

Sources: Maryland Health Resources Planning Commission; Maryland Health Care Commission

Table 4-3
Trends in Operating and Procedure Room Inventories
Hospitals and Freestanding Ambulatory Surgical Facilities
Maryland, 1994 – 2000

	1994		2000	
	Operating Rooms	Procedure Rooms	Operating Rooms	Procedure Rooms
Hospitals with surgical facilities	470	210	629	NA
General purpose	381		469	
Special purpose	89		105	
Other	0		55	
Freestanding ambulatory surgical facilities	126	109	305	273
All surgical facilities	596	319	934	NA

Source: Maryland Health Resources Planning Commission; Maryland Health Care Commission, preliminary data for 2000

Note: The 1994 hospital figures do not include dedicated c-section rooms, delivery rooms, or procedure rooms. The 2000 hospital figures may include such rooms.

[3] As of July 9, 2001, there were 292 licensed ambulatory surgical facilities.

As shown in Table 4-4, Maryland has a higher concentration of Medicare-certified ambulatory surgery centers, by a wide margin, than any other state in the country. With 1.86 percent of the nation's population in 2000, Maryland accounted for 9.15 percent of the total certified ASCs in the U.S. It can be hypothesized that Maryland probably has more ASCs per capita than any other state because of its unique blend of market forces and regulatory policies. Maryland is characterized by high hospital prices for outpatient surgery due to hospital rate regulation incentives favoring inpatient efficiencies, and a long-standing CON policy exempting physician office-based surgical facilities from CON regulation but maintaining CON regulation over larger health care facilities, or FASFs.[4]

[4] Until 1995, a physician's office in Maryland could establish an ambulatory surgical facility with up to four operating rooms without CON authorization so long as those rooms were utilized only by the physician or physician group based at the office in which the operating rooms were located and as long as only one surgical specialty was provided in the surgical facilities. After 1995, the threshold size of an FASF for purposes of CON requirements was reduced to one operating room, the requirement limiting CON-exempt FASFs to a single specialty was dropped, and facilities limited to the provision of closed endoscopic procedures were determined to be non-surgical and, thus, exempt from CON regulation on that basis. This exemption from CON regulation does not prevent these latter facilities from being certified by Medicare as ambulatory surgical centers or licensed by Maryland as FASFs. Therefore, a surgical facility with only one operating room is not an "ambulatory surgical facility" for purposes of defining the "health care facilities" subject to CON regulation. This report will use the term "freestanding ambulatory surgical facility" in reference to the universe of licensed freestanding ambulatory surgical facilities in Maryland, including those that were exempt from CON regulation with respect to their establishment.

Table 4-4
Medicare-certified ASCs and Number per Population by State and United States (including Puerto Rico, District of Columbia)
Top Five and Bottom Five States

TOP FIVE	No. of ASCs 2001	2000 Population	ASCs per 100,000 Population
Maryland	**293**	**5,296,486**	**5.53**
Washington	157	5,894,121	2.66
North Dakota	17	642,200	2.65
Wyoming	13	493,782	2.63
Idaho	34	1,293,953	2.63
BOTTOM FIVE			
Iowa	12	2,926,324	0.41
Michigan	33	9,938,444	0.33
Virginia	20	7,078,515	0.28
New York	51	18,976,457	0.27
Vermont	1	608,827	0.16
U.S.	**3,202**	**285,230,516**	**1.12**

Source: Health Care Financing Administration; U.S. Census of Population, 2000

The establishment of single-operating room FASFs has occurred primarily since changes in Maryland's regulatory policy in 1995. Single-operating room FASFs comprised 53 percent of the total FASFs in Maryland in 2000 (based on preliminary data from the state's survey of FASFs), and the average number of operating rooms per FASF in the state was only 1.2. Almost a quarter of the state's ambulatory surgical facilities do not report the presence of any operating rooms, but only procedure rooms. If we combine the number of FASFs with one operating room and the number with one procedure room, these one room surgical facilities comprise 65 percent of the state's total freestanding ambulatory surgical facilities. The average inventory of both operating rooms and procedure rooms in a Maryland FASF is 2.3.

Table 4-5
Freestanding Ambulatory Surgical Facilities
Maryland, 2000 Inventory and 1997- 2000 Cases

	Facilities	Operating Rooms	Procedure Rooms	Cases			
				1997	1998	1999	2000
Single Specialty/Single OR	113	113	79	26,232	35,686	51,850	52,707
Single Specialty/Multiple Ors	23	50	25	19,242	21,926	29,297	24,912
Single Specialty/No Ors	49	0	81	40,094	56,985	69,414	86,840
Multi-Specialty/Single OR	23	23	25	10,971	15,932	23,239	21,838
Multi-Specialty/Multiple Ors	36	119	43	57,847	69,907	79,362	97,660
Multi-Specialty/No Ors	11	0	20	11,865	18,636	22,511	18,400
Total	255	305	273	166,251	219,072	275,673	302,357

Source: Maryland Ambulatory Surgery Facility Survey, Maryland Health Care Commission, preliminary data for 2000

Prior to 1995 the state's regulatory policies also restricted the operation of FASFs which were exempt from CON regulation to a single surgical specialty. Since 1995, CON-exempt facilities can be utilized to provide more than one surgical specialty. However, as can be noted in Table 4-5, the majority of FASFs (73 percent) still identify themselves as single specialty facilities. Of the FASFs which report the presence of only one operating room, 83 percent identify themselves as single specialty.

Tables 4-6 and 4-7 profile Maryland's FASFs by reported specialization in 2000. Table 4-6 shows that podiatry facilities are the most common type of single specialty center and that four specialties, podiatry, urology, gastroenterology, and plastic surgery account for 74 percent of all licensed single specialty FASFs and a similar proportion of the total operating and procedure rooms in such facilities. This table also indicates that gastroenterology (gastrointestinal endoscopies) is the largest surgical specialty, accounting for 45 percent of all cases reported by single specialty FASFs and almost twice the volume of the next largest specialty, urology.

Hospitals and hospital systems own and operate freestanding ambulatory surgical facilities. [Table 4-8.] Their control is concentrated in the larger multi-specialty centers. While accounting for less than 9 percent of total freestanding facilities, ambulatory surgical centers affiliated with hospitals or hospital systems accounted for nearly 16 percent of total FASF operating rooms and over 21 percent of FASF surgical cases in 2000. Table 4-8 provides detail of capacity and utilization information for hospital and non-hospital affiliated surgery centers. The chart in Appendix 4-1 lists the hospitals that have an ownership interest in a FASF, and the names of those facilities.

Table 4-6
Freestanding Ambulatory Surgical Facilities Reporting a Single Specialty,
2000 Inventory and 1997-2000 Utilization

Specialty	Facilities	Operating Rooms	Procedure Rooms	Reported Cases 1997	1998	1999	2000
Podiatry	56	63	31	6,682	5,272	6,918	5,990
Urology	28	22	33	16,652	24,837	32,495	37,084
Gastroenterology	25	0	49	36,868	49,744	60,042	72,719
Plastic surgery	26	27	27	6,697	7,445	8,546	7,291
Ophthalmology	13	18	13	13,697	15,348	18,026	17,052
Obstetrics/gynec.	7	7	4	2,689	3,564	3,993	4,197
Oral surgery	6	14	1	319	760	7,073	2,782
General surgery	5	4	3	277	674	585	937
Orthopaedic surgery	3	1	2	16	495	267	1,820
Pain management	4	2	5	388	2,900	9,889	7,221
Repro.endocrinology	2	3	3	760	1,756	523	1,075
Breast biopsy	1	0	1	-	112	210	94
Dermatology	1	1	1	-	-	34	30
Facial plastic surgery	1	1	1	-	-	-	502
Infertility/gynec.	1	0	3	-	-	-	52
Internal medicine	1	0	2	-	-	-	300
Otolaryngology	1	1	3	374	288	454	70
Rheumatology	1	1	2	229	202	265	322
Interventional Rad.	1	0	1				634
TOTAL	183	165	185	85,568	113,397	149,320	161,321

Source: Maryland Health Care Commission, preliminary inventory data for 2000

Table 4-7
Freestanding Ambulatory Surgical Facilities Reporting Two or More Specialties,
and Frequency of Reported Specialties, 2000

Specialty	N=70 Facilities Reporting Specialty	Proportion of Total Facilities Reporting Specialty
Plastic surgery	41	58.6%
General surgery	37	52.9%
Pain management	34	48.6%
Gastroenterology	28	40.0%
Podiatry	28	40.0%
Orthopaedic surgery	26	37.1%
Urology	25	35.7%
Obstetrics/gynecology	23	32.9%
Otolaryngology	26	37.1%
Ophthalmology	21	30.0%
Colon and rectal surgery	19	27.1%
Oral surgery	17	24.3%
Vascular surgery	11	15.7%
Dermatology	8	11.4%
Neurology	6	8.6%
Six other specialties	1	1.4%

Source: Maryland Health Care Commission, preliminary data

Table 4-8
Freestanding Ambulatory Surgical Facilities
Inventory and Utilization by Hospital and Non-Hospital Affiliation
Maryland, CY 2000

Facility Type	Number of Facilities	ORs	Proced. Rms.	Cases	% of Total Facilities	% of ORs	% of Proced. Rms.	% of Cases
Single Specialty/ Single OR								
Non-Hospital	112	112	79	51,780	99.1%	99.1%	100.0%	98.2%
Hospital	1	1	0	927	0.9%	0.9%	0.0%	1.8%
Single Specialty/ Multiple Ors								
Non-Hospital	22	48	24	22,294	95.7%	96.0%	96.0%	89.5%
Hospital	1	2	1	2,618	4.3%	4.0%	4.0%	10.5%
Non-Hospital	21	21	24	21,720	91.3%	91.3%	96.0%	99.5%
Hospital	2	2	1	118	8.7%	8.7%	4.0%	0.5%
Multi-Specialty/ Multiple Ors								
Non-Hospital	25	75	24	54,206	69.4%	63.0%	55.8%	55.5%
Hospital	11	44	19	43,454	30.6%	37.0%	44.2%	44.5%
Single Specialty/ No Ors								
Non-Hospital	43	0	68	71,572	87.8%	-	84.0%	82.4%
Hospital	6	0	13	15,268	12.2%	-	16.0%	17.6%
Multi-Specialty/ No Ors								
Non-Hospital	10	0	18	15,874	90.9%	-	90.0%	86.3%
Hospital	1	0	2	2,526	9.1%	-	10.0%	13.7%
All Freestanding ASCs								
Non-Hospital	233	256	237	237,446	91.4%	83.9%	86.8%	78.5%
Hospital	22	49	36	64,911	8.6%	16.1%	13.2%	21.5%

Source: Maryland Health Care Commission; preliminary data

Trends in the Utilization of Ambulatory Surgery

In the last decade, Maryland has seen a substantial increase in its use of surgery, with the number of reported surgical cases per thousand population increasing 33.7 percent [Table 4-9] between 1995 and 2000, after declining 6.2 percent between 1991 and 1995. The growth in the use of surgery is seen in the increased use of outpatient surgical procedures. Inpatient surgical case volume declined 50 percent between 1991 and 1998, but has begun to increase since that time, suggesting that most, if not all, of the potential substitution of outpatient surgery for inpatient procedures has taken place for the present and that population growth and aging will now tend to increase the use of inpatient surgical services.

Table 4-9
Trends in Surgical Case Volume
Maryland, 1991 – 2000

I. Cases by Type (Inpatient/Outpatient) and Setting							
	1991	1995	1996	1997	1998	1999	2000
Hospital Inpatient	293,085	165,726	162,103	154,861	145,454	149,303	153,601
Hospital Outpatient	320,092	344,270	343,611	347,493	353,221	356,950	368,778
FASF	44,119	106,718	140,448	177,634	222,972	275,673	302,357
Total	657,296	616,714	646,162	679,988	721,647	781,926	824,736
II. Proportion of Total Cases by Type and Setting							
Hospital Inpatient	44.6%	26.9%	25.1%	22.8%	20.2%	19.1%	18.6%
Hospital Outpatient	48.7%	55.8%	53.2%	51.1%	48.9%	45.7%	44.7%
FASF	6.7%	17.3%	21.7%	26.1%	30.9%	35.3%	36.7%

III. Percentage Change in Case Volume						
	1990-95	1995-96	1996-97	1997-98	1998-99	1999-2000
Hospital Inpatient	-43%	-2%	-4%	-6%	+3%	+3%
Hospital Outpatient	+8%	-0%	+1%	+2%	+1%	+3%
FASF	+142%	+32%	+26%	+26%	+24%	+10%
Total	-6%	+5%	+5%	+6%	+8%	+5%

Source: Maryland Health Resources Planning Commission and Maryland Health Care Commission

Table 4-10
Surgical Use Rates
(Surgery Visits or Cases per 1,000 Population)
Maryland and the United States, 1990 – 2000

	1990	1995	1996	1997	1998	1999	2000
Inpatient Surgery							
Maryland	67.1	62.1	60.7	58.7	58.2	58.5	59.4
U.S.	NA	73.6	73.1	71.9	73.5	73.8	NA
Hospital-Based Ambulatory Surgery							
Maryland	49.9	66.6	65.6	62.7	63.5	63.2	65.8
U.S.	NA	62.8	66.4	NA	NA	NA	NA
FASF-Based Ambulatory Surgery							
Maryland	6.0	21.2	27.6	34.5	42.9	52.6	56.9
U.S.	NA	12.3	12.6	NA	NA	NA	NA
All Surgery							
Maryland	123.0	149.9	153.9	155.9	164.6	174.3	182.1
U.S.	NA	148.7	152.1	NA	NA	NA	NA

Sources: National Survey of Ambulatory Surgery, 1995 and1996; National Hospital Discharge Survey, 1995 and 1996; Maryland Health Resources Planning Commission and Maryland Health Care Commission Surveys of FASFs, 1990, 1995-2000; Maryland Health Care Cost Review Commission Hospital Discharge Abstract, 1990, 1995-2000;

Note: U.S. rates for inpatient surgery for 1997-1999 estimated by MHCC based on NSAS use rate estimates of 1994-1996

The inpatient surgical use rate in Maryland, which is estimated to be lower than the national rate, has declined since 1990 [Table 4-10] and has been relatively stable since 1995. Use of ambulatory surgery has increased far in excess of population growth in the hospital setting and, at an even faster pace, in the FASF setting. Use of the FASF setting was already substantially higher for Maryland than for the nation as a whole in 1995 and 1996 (approximately twice as high, for the combined two years), the most recent years for which national estimates of ambulatory surgical use have been developed by the National Center for Health Statistics. From 1996 to 2000, consistent with the growth in capacity, the use rate of freestanding ambulatory surgical facilities in Maryland has more than doubled.

The Maryland pattern is not inconsistent with a recent review of surgical care use on a national level which found that "the major trend in surgery … has been a decline in the rate of inpatient operations, but growth in ambulatory surgery that outweighed this inpatient decline.[5] Two major factors have been suggested to explain this pattern … advances in surgical techniques have made surgery easier on patients and thus increased the demand for care … second, health care policies created economic incentives that stimulated not just a shift to ambulatory settings, but explosive growth in ambulatory surgery."

This high use rate of ambulatory surgery facilities relative to the nation as a whole is consistent with the comparison of the supply of ambulatory surgical facilities in Maryland and other states. However, it is highly likely that the actual use of outpatient surgery outside of the hospital setting in Maryland, as compared with other states, is overstated by these statistics. Many single physicians and physician groups have established small Medicare-certified ambulatory surgical centers in their offices and many of these facilities are only utilized to provide closed endoscopic procedures or relatively minor procedures which are surgical in nature primarily with respect to the procedural coding used by Medicare and other payors for purposes of reimbursing these facilities. As previously noted, 24 percent of the Medicare-certified ASCs in Maryland do not even report the presence of a sterile operating room. As described in section IV, some of the high use of outpatient surgery in Maryland is related to the fact that more freestanding surgical capacity is licensed, and therefore counted in an inventory, than in most other states.

The efficiency of hospital operating room use, viewed in terms of surgical cases per room, appears to have declined precipitously between 1994 and 2000, from approximately 1,245 cases per room per year to 910 cases per room, as operating room capacity increased and surgical case volume declined.[6] [Table 4-11.] In the freestanding

[5] "*Changing Patterns of Surgical Care in the United States, 1980-1995*," Health Care Financing Review, Vol. 21, No.1, Fall, 1999, USDHHS, HCFA.

[6] Commission staff is currently surveying hospitals to better understand problems with comparing the hospital operating and procedure room inventories over time due to changes in reporting formats, which is why the previous sentence uses the word "appears." It currently appears likely that the final tally of hospital operating rooms will be lower than the reported figure in Table 4-11. Efficiency of room use is more accurately measured by operating minutes of use rather than cases per room, and increasing average procedure times may provide a different perspective. Commission staff is also

setting, efficiency of operating/procedure room use has, using the same measure, increased between 1994 and 2000 from approximately 280 cases per room per year to 523 cases, though the average number of cases is still only 57 percent of the average hospital room caseload. This increase in room efficiency is due to growth in volume at single specialty FASFs exceeding growth in supply. At multi-specialty FASFs, growth in room supply outstripped growth in volume over the same period and the average number of cases per room per year dropped 37 percent from 960 cases per room to 602.

attempting to establish usable information on this indicator.

Table 4-11
Operating and Procedure Room Use
Maryland Hospitals and Freestanding Ambulatory Surgical Facilities, 1994-2000

Facility Type	Operating/ Procedure Rooms	Cases	Cases per Operating/ Procedure Room
A. HOSPITAL			
1994 general purpose and special purpose ORs	470	585,200*	1,245.1
2000 general purpose and special purpose ORs	574	522,379	910.1
B. FREESTANDING AMBULATORY SURGICAL FAC.			
1994 operating and procedure rooms	235	65,300*	277.9
2000 operating and procedure rooms	578	302,357	523.1
Single Specialty FASF			
1994 operating and procedure rooms	182	14,400*	79.1
2000 operating and procedure rooms	348	163,959	471.1
Multi-Specialty FASF			
1994 operating and procedure rooms	53	50,900*	960.4
2000 operating and procedure rooms	230	138,398	601.7

Source: Maryland Health Resources Planning Commission and Maryland Health Care Commission, preliminary FASF inventory data for 2000
*Estimated

While utilization of operating and procedure room capacity at Maryland's single specialty FASFs has risen in recent years, there is substantial variation among these facilities by specialty. Facilities specializing in gastrointestinal endoscopy, a procedure that does not require a sterile operating room environment, experienced utilization of their rooms in 2000 that was nearly three times higher than the overall FASF average per room utilization and was over four times higher than the average per room use of single specialty FASFs. Facilities dedicated to pain management, urologic procedures, orthopaedic surgery, and ophthalmologic procedures are also utilized at above-average levels. At the other end of the spectrum, single specialty FASFs dedicated to podiatry, which constitute over a third of all single specialty FASFs reported an average of approximately 1.2 cases per week per room in 2000.

Finally, Table 4-12 shows a comparison of payer source between hospital outpatient departments and freestanding facilities. As expected, the freestanding facilities do less Medicare patients, less Medicaid patients and more privately insured patients. Maybe somewhat surprisingly, the proportion of cases attributable to self pay and charity cases is almost identical.

Table 4-12
Percent of Total Ambulatory Surgery Cases,
by Payer Source Category and Facility Type, CY 2000

	Hospital	FASF
Medicare	28.3%	25.5%
Medicaid	4.7%	0.6%
HMO, BC/BS, Commercial	60.8%	67.8%
Self Pay, Charity	6.3%	6.1%

Sources: Maryland Hospital Discharge Abstract; MHCC Survey of Freestanding Ambulatory Surgical Facilities, preliminary data.

Reimbursement Issues

Maryland's unique regulatory environment for hospital charges has influenced the development of freestanding ambulatory surgery centers. Because hospitals cannot negotiate individually with payers hospitals could not respond to the cost control efforts of managed care.[7] As a result, some managed care companies have directly or indirectly, through utilization management or pre-authorization policies, steered patients to the lower cost freestanding centers. Providers responded by building more freestanding centers in Maryland, on a per capita basis, than in any other state. Maryland's CON rules, rather than limiting this growth, have ensured that this growth is primarily in the small, physician-office-based locations. In addition, many surgeons as well as patients prefer freestanding centers over hospital based ambulatory surgery, contributing to their popularity over the use of hospital capacity for ambulatory procedures.

Maryland's hospital rate setting has also shaped the way Maryland hospitals have responded to the state and national shift towards outpatient surgery. Historically, under Maryland's rate setting rules, all acute general hospitals charged inpatients and ambulatory surgery patients based on the number of minutes that the patient was in the operating room and on the basis of ancillary charges, including charges for drugs, medical/surgical supplies, and radiology and laboratory services. In addition to these charges, hospitals may also charge outpatient surgery patients an administrative charge designated as a "same day surgery" charge.[8]

Beginning in 1997, the HSCRC allowed hospitals to enter into an alternative method of charging for ambulatory surgery called "Procedure-Based Ambulatory Surgery Pricing". Under this methodology, all of the charges associated with ambulatory surgery patients are combined (or "bundled') into a single rate center which includes operating room, drug, medical supply, laboratory and other charges. This procedure-based, bundled rate is based on the eight Medicare ambulatory surgery payment groups. By establishing these overall procedure-based ambulatory surgery prices, Maryland's

[7] Some would argue that hospitals could have lowered their charges for ambulatory surgery to all payers, and thus remained in compliance with HSCRC regulations, but chose not to do so for financial reasons.

[8] The same day surgery charge covers administrative paperwork (similar to the 'admission' rate for all inpatients) and recovery room time. It may also be applied to major diagnostic procedures.

hospitals hoped to be competitive with the lower charges of freestanding ASCs.

Since 1997, 27 Maryland hospitals received approval to establish procedure-based ambulatory surgery rates. However, in the last few months, 17 hospitals have dropped this alternative rate in favor of returning to the unit rate approach, charging patients individually for operating room time, medical supplies, drugs, laboratory and other charges. The HSCRC recently reported that hospital outpatient revenue, particularly the revenue associated with ambulatory surgery, has been increasing at a rapid rate. In the 12 months ending June 30, 2001, outpatient revenue increased 16.45 percent over the same period ending June 30, 2000, while inpatient revenue increased only 7.56 percent.[9] The average ambulatory surgery charge per case has risen from about $1,280 in the first quarter of 2000 to $1,510 in the first quarter of 2001, about a 15 percent increase in one year.

The HSCRC's initial assessment is that the increase associated with outpatient surgery is primarily due to two factors: the effects of unit rate changes (primarily in the 'operating room' cost center) on conversion from the procedure-based pricing scheme, and increases in the costs of medical-surgical supplies and drugs.[10] In the five quarters beginning January 1, 2000 through March 31, 2001, outpatient revenue for medical-surgical supplies rose 53 percent but only 13 percent for inpatient supply revenue. In the same period, outpatient revenue for drugs rose 35 percent, while inpatient revenue for drugs rose only 10 percent. Revenue from drugs has also shown a long-term rapid increase: 18 percent in 1998, 20 percent in 1999, 25 percent in 2000 and 35 percent in the first quarter of 2001. Increases in outpatient surgery volume played an insignificant role in the rapid increases in outpatient revenue. In the same five quarters, the number of ambulatory surgery cases reported to the HSCRC increased only 2.4 percent (91,600 to 93,800). To address these increases the HSCRC is considering a recommendation to develop a prospective payment system for ambulatory surgery based on the ambulatory payment categories, or APCs, used by Medicare.

State Quality of Care Initiatives

The MHCC may play a role in the public dissemination of information about ambulatory surgery. The 1999 Maryland General Assembly charged the Commission with developing and implementing a system to comparatively evaluate the quality of care outcomes and performance measurements of hospitals and ambulatory surgical facilities on an objective basis. The purpose of a comparable performance measurement system, or "report card", is to improve the quality of care provided by hospitals and ASCs. Although not yet developed, these tools would likely contain comparable information about ambulatory surgery in hospital and freestanding settings.

The authority for overseeing the activities of health care facilities is divided among several State agencies in Maryland. The Maryland Health Care Commission is required by law to coordinate its planning and regulatory activities with other agencies. The agencies have used various means to accomplish that coordination, including participation in joint meetings, collaboration in developing policies and regulations, membership on advisory committees, and

[9] *Monitoring Maryland Performance: HSCRC Monthly Charge Per Case Summary*. September 5, 2001.

[10] Presentations, Health Services Cost Review Commission meeting of September 5, 2001, Robert Murray, Executive Director and Graham Atkinson, PhD.

sharing data and information needed to perform mandated functions. The following discussion describes the roles of the three state agencies with regulatory responsibilities over ambulatory surgery services in hospitals or in freestanding ambulatory surgical facilities or centers.

Government Oversight of Ambulatory Surgery Services in Maryland.

Office of Health Care Quality. State law requires all hospitals in Maryland to be licensed by the Department of Health and Mental Hygiene. The Office of Health Care Quality (OHCQ) is the State's licensure authority. Like most states, Maryland uses a deeming process for hospitals to qualify for a license. Hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are deemed to have met the standards for State licensure.

Maryland licensure regulations (COMAR 10.10.05.01) define a "freestanding ambulatory surgical facility" as "a facility, service, office facility, or other entity that: (i) operates primarily for the purpose of providing surgical services to patients requiring a period of postoperative observation but not requiring overnight hospitalization; and (ii) seeks reimbursement from payors as a freestanding ambulatory surgical facility." The regulations specifically exclude from the definition of FASF, "the office of one or more health care practitioners seeking only professional reimbursement for the provision of medical services unless the office operates under a contract or other agreement with a payer as a freestanding ambulatory surgical facility, regardless of whether it is paid a technical or facility fee, or the office is designated to receive ambulatory surgical referrals, in accordance with utilization review or other policies adopted by a payer." Also excluded are:

- " a facility or service owned or operated by a hospital and regulated under …" hospital licensure law;
- "the office of a health care practitioner" or "a group of health care practitioners … with not more than one operating room if the office does not receive a technical or facility fee, and the operating room is used exclusively by the health care practitioner" or "the group practice … for patients of the health care practitioner" or "the group practice," and;
- "an office owned or operated by one or more" licensed "dentists … for the sole purpose of practicing dentistry."

Beginning in August, 1999, freestanding ambulatory surgical facilities were subject to licensure by the Department. To qualify for a license, an ASC must have a CON from the Maryland Health Care Commission or a determination letter stating that the facility is exempt from the CON requirement, and undergo an on-site inspection by OHCQ. A condition of FASF licensure is that the facility obtain Medicare certification as an "ambulatory surgery center."

As implied by the definitions cited above, ambulatory surgery can also be provided in the unlicensed and non-certified physician office setting. Since laser eye surgery and cosmetic plastic surgery are not covered by third party reimbursement, surgery centers limited to these types of procedures may not be licensed. The number of such office sites which provide surgical services and the volume of non-licensed and non-certified office-based surgery is not known.

Health Services Cost Review Commission. Maryland's Health Services Cost Review Commission (HSCRC) approves rates for all hospital services provided "at the hospital" based on the costs of those services, including outpatient or ambulatory surgery. The HSCRC does not have jurisdiction over freestanding ambulatory surgery centers, regardless of whether they are owned wholly or in part by the hospital. Hospitals are required to charge all payers the same rates. In addition, rates cannot vary by payer without HSCRC approval.[11] Negotiating for discounts with payers is not allowed.

In order to meet market demands, some hospitals have relocated some proportion of their ambulatory surgery cases to a separate location on the hospital campus. Even though a service or an ambulatory surgery building may be on the hospital campus, for purposes of the HSCRC's rate setting authority it may or may not be "at the hospital". The HSCRC uses an uncodified list of criteria to make the distinction on a case by case basis. On-campus locations in separate buildings that are determined to be "at the hospital" must have rates approved by the HSCRC. The rates and charges for ambulatory surgery services that are *not* provided "at the hospital", however, are not governed by the HSCRC. In these cases, hospitals are free to negotiate charges with individual payers, and payments are generally less than in the regulated settings. Three hospitals have established separate on-campus locations for hospital-based outpatient surgery that are not under the HSCRC's rate setting rules: Carroll County General, Howard County General and Upper Chesapeake Medical Center.

Maryland Health Care Commission. The planning and regulatory policies governing ambulatory surgical facilities in Maryland have evolved over two decades. [See Appendix 4-2.] Currently, a CON is required in Maryland to establish a health care facility, which includes an ambulatory surgical facility, defined, for purposes of CON, as a facility with two or more operating rooms.

Maryland's Certificate of Need program regulates some categories of surgical facility projects. The establishment of a new hospital or a new "ambulatory surgical facility" requires CON approval. Additionally, the relocation of a hospital or related institution or a FASF to another site, unless the relocation is the result of a partial or complete replacement of an existing health care facility, and the relocation is to another part of the site or immediately adjacent to the site of the existing health care facility, requires CON authorization. A capital expenditure which builds or expands a hospital's ambulatory surgical capacity in any setting owned or controlled by the hospital requires CON authorization. Finally, most types of expenditure by or on behalf of a hospital or related institution or a FASF in excess of the "threshold for capital expenditures," currently set at $1,450,000, require CON approval. All the activities covered by MHCC statute and regulations regarding ambulatory surgery are listed in Figure 4-1.

The State Health Plan chapter on ambulatory surgical services provides policies and review standards for Certificate of Need reviews for new ambulatory surgery

[11] Medicare and Medicaid are allowed a 6% discount from approved rates. In addition, some payers qualify for discounts from approved rates for meeting the requirements of the SAAC (substantial, available and affordable coverage) program, or for early payments.

facilities and expansions to existing facilities that require CON review. The Plan chapter defines ambulatory surgery, but does not define ambulatory surgical capacity or the distinction between an operating room and a procedure room. There is no need projection methodology in the Plan chapter, which means that applicants are responsible for demonstrating the needs of the population to be served, and how the proposal will meet those needs. The Plan also establishes optimal utilization of surgical capacity, based on assumptions about the average number of minutes per case for ambulatory cases and the number of hours available for use. This SHP chapter has been used 11 times since 1990 for the approval of new freestanding ASCs and twice for relocations of existing facilities. In addition, five of the approved CONs for new ASCs were relinquished or returned to the Commission, in 2000 and 2001, without development. Two applications were denied. Fifteen (15) applications were withdrawn by applicants before a Commission decision.

FIGURE 4-1
ACTIVITIES COVERED BY MHCC STATUTE AND REGULATIONS REGARDING AMBULATORY SURGERY

- To build, develop or establish a health care facility, which includes an ambulatory surgery facility, defined as a center, service or office or facility that has two or more operating rooms, operates primarily for the purpose of providing surgical services, and seeks reimbursement from payers as an ambulatory surgical facility requires a CON.
- To build or expand ambulatory surgical capacity in any setting owned or controlled by a hospital requires a CON.
- To relocate a health care facility to another site, under certain circumstances requires a CON.
- To expand ambulatory surgical capacity in an ambulatory surgical facility requires a CON.
- To undertake a capital expenditure in excess of the current threshold of $1,450,000 for construction related to ambulatory surgical capacity requires a CON.
- To build surgical capacity for surgical services in a physician's office that does not meet the definition of a health care facility requires a determination that the capacity does not meet the definition of a health care facility for CON coverage (a 'determination of coverage').
- To change the facts or circumstances upon which a determination of coverage was based requires another determination of coverage.
- To change the type or scope of any health care service offered by a health care facility requires a CON.
- Acquisition of a freestanding ambulatory surgical facility by a hospital does not require a CON, but requires notification to the Commission.
- Health Maintenance Organizations must obtain a CON before it establishes an ambulatory surgical facility, but not before purchasing an existing facility.
- The law also requires data reporting through an annual survey of ambulatory surgery providers.

Maryland Certificate of Need Regulation Compared to Other States

Thirty-seven states and the District of Columbia have CON programs. Of those, 29 regulate, to some extent, the supply and distribution of ambulatory surgery facilities through their CON programs.

Commission staff recently began a detailed survey of CON and other regulation of ambulatory surgery facilities in all fifty states and the District of Columbia. The survey is an attempt to establish, for the first time, a baseline of detailed information on the scope of FASF and licensure regulation and the information available on FASF inventories, operating room inventories, and utilization in other states. Some of the early data from this survey is shown in Table 4-13. It compares recent FASF inventory and utilization statistics for Maryland and eight other states, grouping the states based on the scope of their CON programs in regulating the supply of FASFs. Mississippi is grouped with Maryland as a state with limited CON regulation of FASF supply. Mississippi exempts single specialty FASFs developed within physician offices from CON regulation.

In general, both "limited CON" states have higher ratios of FASFs per population, more single-room FASFs, fewer average rooms per FASF, fewer cases per room per year, and higher proportions of single specialty FASFs than states with more extensive CON regulation of FASF supply or states without CON regulation of FASF supply.

Table 4-13
Selected FASF Inventory and Utilization Statistics
Maryland and Eight Other States

Regulatory Scope	State	Reported Number of Freestanding Ambulatory Surgical Centers Or Facilities	FASFs per 1,000 population	Percentage of FASFs that are Single Room	Operating and Procedure Rooms per FASF	Surgical Cases per Room 2000	Percentage of FASFs that are Single Specialty
Limited CON	Maryland	293	5.53	65%	2.3	523	68.1%
	Mississippi	68	2.39	66%[1]	1.7	954[2]	82.4%
Standard CON	Kentucky	39	0.96	14%	3.6	952	33.3%
	North Carolina	52	0.65	12%	3.5	883	51.9%
	Rhode Island	7	0.67	29%	2.3	1,015	71.4%
	South Carolina	51	1.27	6%	3.1	533	19.6%
	Virginia	19	0.27	11%	3.9	1,603[3]	15.8%
No CON	Florida	267	1.67	21%	2.8	1,151	NA
	Indiana	96	1.58	10%	3.4	1,022	43.8%

Sources: MHCC Survey of State CON Programs; MHCC Ambulatory Surgical Facility Survey, North Carolina 2001 State Medical Facilities Plan
[1] Estimated (as per Mississippi CON staff); [2] 1999 cases for the state's 12 multi-specialty FASFs only [3] 1999

Most states with CON programs have used CON to control development of FASFs to varying degrees of rigor. These states exert more comprehensive regulatory control over FASF development than Maryland, not exempting small providers from CON requirements and, in most cases, not authorizing large numbers of small physician-office style FASFs. However, whether authorizing larger numbers of FASFs or sharply limiting FASF development, such states have tended to produce a smaller number of larger freestanding facilities than Maryland.

Other states, which have never regulated or have not regulated the supply of FASFs since the early to mid-1980s, have fewer ASCs than Maryland because the development of single-operating room FASFs has not been encouraged by the type of market and regulatory forces at work in Maryland. In these states that have had no regulatory barriers to market entry, economies of scale have dictated that facilities with multiple operating rooms are the preferred model for development and, as larger FASFs are developed, the market feasibility and competitiveness of single operating room operations would tend to diminish in these states.

Many of the states which regulate the supply of surgical facilities, no matter how many operating rooms proposed, have laws and regulations that require any freestanding

surgical facility to obtain CON authorization as a prerequisite to licensure and Medicare certification. These states may also allow many of the small office-based facilities which are typically licensed and certified in Maryland to operate without a license, but have regulatory policies that preclude such facilities from obtaining the CON approval that would allow them to obtain licensure, certification, and, most importantly, the facility reimbursement obtainable with licensed and certified status.

For example, Virginia, with a total population in excess of 7 million, has approximately 20 licensed freestanding ambulatory surgical facilities. These are the only freestanding surgical facilities in Virginia eligible for Medicare certification. Comparing the utilization statistics from this pool of facilities with those of the nearly 300 licensed FASFs in Maryland (all of which are Medicare-certified ASCs), with its population of only 5.3 million, would suggest that Maryland's population uses outpatient surgery at a much higher rate. However, some Virginia practitioners such as gastroenterologists, podiatrists, urologists and others routinely provide the same operative procedures in their Virginia offices that are provided by these same practitioners in Maryland, but these procedures are not reported to the state or counted in any state data base. Virginia does not attempt to regulate this office-based surgery through its licensure program, relying on a combination of historical tradition and regulation to define a posture in which it allows physicians and others to provide these services as an adjunct to their office practice, so long as they are willing to fully rely on professional fees or payment arrangements they can negotiate with private payers as compensation. Similarly, Virginia does not attempt to regulate plastic surgery, a specialty which relies almost exclusively on out-of-pocket payments, through facility licensure and, in this case, allows the line between physician office and dedicated surgical facility to blur considerably. When such facilities have sought CONs in Virginia in order to obtain the license needed to obtain Medicare certification, they have historically been rebuffed on the basis that sufficient operating room capacity is already in existence and that the higher utilization levels typically obtainable in the general hospital surgical facility setting and the broader access provided by hospitals to all classes of patients favors limiting the widespread development of FASFs.

Intuitively, Maryland could be expected to have higher comparable population use rates of outpatient surgery than Virginia and most other states, adjusted for the differences related to regulatory policy, because of the greater supply of Medicare-certified ASCs allowed to develop in Maryland. However, official statistics overstate this difference. The primary difference between a state like Virginia and Maryland is that many more providers have the ability to obtain higher levels of reimbursement from Medicare and, to some extent, from other payers, because of their status as certified ambulatory surgical centers.

Alternative Regulatory Strategies: An Examination of Certificate of Need Policy Options

Almost all states with Certificate of Need regulation programs regulate, to a greater or lesser extent, the supply and distribution of surgical facilities. The provision of surgery and related invasive procedures is a major component of acute medicine in the hospital

and outpatient setting, and a population's use of surgical facilities and services is a significant determinant of the overall medical care expenses that population must bear.

Three broad CON policy options were discussed by the Commission in the process of conducting this study. The first approach, in both Options 1 and 2, suggests continuation of the current scope of CON regulation, or continuation with some adjustment of the current regulatory regime. Options 3 and 4 suggest expanded CON regulation with two variations on this theme. Option 5 calls for elimination of CON regulation of ambulatory surgical facilities and services. Additionally, a set of possible actions not directly linked to a particular CON policy position are outlined in Options 6 through 8.

Option 1 - Continue Current Scope of CON Regulation: Full Continuation of All Current CON Policies with Respect to Ambulatory Surgery

This option would continue the requirement for a Certificate of Need for the establishment of a FASF with two or more operating rooms, the expansion of FASFs, the expansion of outpatient operating room capacity at general hospitals, and the relocation of hospitals and FASFs.

This option will require no statutory or regulatory changes and will continue a policy that has been in place for six years. Thus, it provides continuity in policy for the regulated industry and eliminates the potential for any unanticipated consequences of policy change. Based on recent trends, it can be expected to produce:

- a growing number of single operating room FASFs within the physician(s) office setting, most of which will be single specialty or limited specialty facilities, although growth will probably be somewhat slower than that seen in the 1990s; a smaller increase in larger, multi-specialty FASFs;

- continued growth in Medicare ASCs that have only procedure rooms and provide closed endoscopic procedures and other invasive procedures that do not require a sterile operating room.

This option could be viewed as continuing to promote a pattern of FASF development with a high proportion of one operating room facilities and single specialty facilities with a low average number of cases per operating room, and higher levels of Medicare reimbursement. It will continue the pattern of skewing the mix of surgical cases provided by general hospitals to inpatient cases, Medicaid patients, and indigent and uninsured patients, potentially resulting in higher cost per surgical unit of service in the hospital setting and lower levels of profitability than would otherwise be the case.

Option 2 - Slightly Modify Current Scope of CON Regulation: General Continuation of Current CON Provisions with Respect to Ambulatory Surgery with Two Adjustments of Current Policy – Elimination of the Two Operating Room Exemption and Elimination of all Regulation of Operating Room Additions by Hospitals Except Those

Above the Capital Expenditure Threshold

This option would continue the requirement for a Certificate of Need to establish a FASF with two or more operating rooms, to expand a FASF, and to relocate a hospital or FASF. It would eliminate the requirement that hospitals must obtain a CON to add operating rooms used for outpatient surgery, and it would eliminate the exception of exempting the establishment of a two operating room FASF from CON requirements, if the Commission finds that a second operating room is necessary to promote the efficiency, safety, and quality of the surgical services offered and all other exemption criteria are met.

Based on the six year history of the current CON policies with respect to ambulatory surgical facilities, these changes would not appear likely to result in any noticeable change in CON activity levels or decision making. The exception for allowing CON exemption of FASFs with two operating rooms has never been used. Eliminating it will create a clear line of demarcation between regulated and unregulated FASFs.

Eliminating the restriction on hospital operating room expansion when the new operating room will be used to provide outpatient surgery arguably eliminates a policy that may create an incentive for development of inefficient surgical facilities, by exempting development of dedicated inpatient operating rooms from CON regulation. More importantly, it seems likely that this policy has been ignored in practice. Since 1995, only two hospitals have requested CON authorization to add operating rooms in which outpatient surgery will be performed. The first of these two projects was approved in June, 2001 and the other is currently under review. However, significant increases in hospital operating room capacity have been reported in the last six years, with all of the increase occuring in dedicated outpatient or mixed use rooms. The number of reported dedicated inpatient operating rooms in Maryland hospitals declined from 66 in 1994 to 13 in 2000. The inpatient surgical caseload has declined over 7 percent statewide since 1995. The policy is clearly difficult to enforce, and does not create the "level playing field" intended, since the bulk of FASF operating room development since 1995 has remained unregulated under the single operating room/physician office exemption.

As with Option 1, this policy would continue to allow the trend in Maryland for high levels of physician office FASF development, high levels of Medicare reimbursement for office-based outpatient procedures, and migration of outpatient procedures from the general hospital setting, increasing the average cost and acuity of surgical services offered in that setting.

Option 3 - Expand CON Regulation to Cover All Surgical Facility and Service Projects: Full CON Regulatory Coverage of All Operating Rooms and Procedure Rooms Utilized for Surgical or Other Invasive Procedures Using the Public Need for Operating Room or Procedure Room Capacity as the Standard for Needs Assessment

Under this option, establishment of any type of surgical facility, no matter the setting in which establishment was proposed or the number or type of operating or procedure rooms being developed, or the expansion of

operating room or procedure room capacity by an existing surgical facility, of any type, would require CON authorization. Facility relocations would continue to be regulated. The standard of need would be operating room and procedure room capacity and utilization of this capacity would drive the identification of net need or surplus for additional room capacity in the geographic areas appropriate for surgical capacity needs assessment.

This approach to CON regulation would be similar to that of many other state CON programs. It is the most consistent approach that can be employed if a state is going to regulate the supply of surgical facilities capacity in any way, since it applies a consistent regulatory standard across the full spectrum of providers wishing to obtain status as licensed ambulatory surgical facilities or surgical hospitals and certification as Medicare-participating ambulatory surgical centers, with the reimbursement advantages that status bestows.

It would allow Maryland, over time, to shape what would arguably be a more efficient pattern of FASF development, i.e., a smaller number of larger facilities, most of which provide multiple surgical specialties, than would be likely to develop under current policies. This would especially be the case if this option also included liberal CON policies with respect to consolidation of single operating room FASFs. For example, the expansion of the regulatory scope of CON entailed by Option 3 could be coupled with a policy that exempts from CON requirements the establishment of FASFs involving the consolidation of two or more single operating room FASFs and no net increase in the number of operating rooms licensed in the state. Additionally, Option 3 would allow the state, again over time, to shape a more uniformly accessible pattern of FASF development by using the comprehensive scope of CON regulation to limit development opportunities to providers with community service missions or liberal accessibility policies. Access policies could be applied and enforced through CON regulation.

This option would, in all likelihood, drastically reduce opportunities for market entry of new facilities and any expansion of most facilities. Thus, it could be expected to face substantial opposition from many physicians and others interested in pursuing development of freestanding ambulatory surgical facilities. Given the history preceding such a change in the regulatory environment, it could be argued that this option would, at least to some extent and in the short to medium term, freeze in place and insulate from competition the current landscape of surgical facilities. Since Maryland has allowed the ambulatory surgical services market to develop with only limited regulatory oversight, one could hold that removing what dynamism for change currently exists in this market is an inferior option to further freeing up development choices (See Option 5) and allowing the market to allocate resources without the regulatory constraints currently in place.

Option 4 - Expand CON Regulation to Cover All Operating Room Projects: Full CON Regulatory Coverage of All Operating Rooms Utilized for Surgical or Other Invasive Procedures Using the Public Need for Operating Room Capacity as the Standard for Needs Assessment

This option would require CON approval to establish any type of surgical facility providing a sterile operating room environment, to expand operating room capacity at a FASF or hospital, or relocate a FASF or hospital. Unlike Option 3, establishment of facilities limited to non-open surgical procedures which only build and operate non-sterile room capacity ("procedure rooms") or the expansion of procedure room capacity by FASFs or hospitals would not be regulated, just as it is not regulated now. The standard of need would be operating room capacity and utilization of this capacity would drive the identification of net need or surplus for additional operating room capacity in the geographic areas appropriate for operating room capacity needs assessment.

This option would apply a consistent regulatory policy across the full spectrum of providers wishing to provide the most expensive category of surgical services and the category of surgical services for which quality and accessibility concerns are greatest. In contrast to Option 3, it would apply an expanded regulatory policy that is more consistent with the notion of not regulating physician office practice. Providing open surgical procedures in a sterile operating room is, arguably, not routine physician office care. Providing closed endoscopic procedures or other types of minor surgical procedures in a non-sterile procedure room is much more consistent with conventional notions of routine physician office care. Option 4 would allow continuation of unregulated development of a major proportion of the ambulatory surgical facility development historically unregulated in Maryland. (In 2000, 24 percent of the state's licensed FASFs reported no operating room availability.) This would tend to provide some balance to the expansion of CON regulation of surgical facilities and services entailed by this option.

As with Option 3, but on a more limited basis, this option would probably allow the state, over time, to shape a pattern of FASF development characterized by a smaller number of larger facilities, most of which provide multiple surgical specialties, when compared with current CON policies. And, as with Option 3, this "reshaping" of the surgical facilities inventory could be assisted by liberal CON policies with respect to consolidation of single-operating room FASFs. Option 4 would also share some of the same advantages as Option 3 with respect to promoting a more equitable sharing of the uncompensated care burden between general hospitals and freestanding ambulatory surgical facilities.

Substantial opposition could be anticipated to this expansion of the scope of CON regulation, given that it would eliminate the long-established policy of allowing physicians to build limited operating room capacity within their offices.

Option 5 - Eliminate CON Regulation of Any Surgical Facility or Service Projects: Eliminate CON Regulation of All Ambulatory Surgical Facilities and Services Development

This option would eliminate any requirement to obtain a CON to establish a freestanding ambulatory surgical facility, to expand operating room capacity at an existing FASF or hospital, or relocate such facilities. Additional development of ambulatory surgical capacity would be likely, and with the removal of the incentive

to develop small, single operating room facilities, market incentives might allow development of larger multi-specialty facilities. The Maryland Health Care Commission would continue to collect and analyze survey information on all ambulatory surgery providers.

There is evidence suggesting that this option, like the regulatory Options 3 and 4, would probably, over time, lead to a more efficient pattern of FASF development by reducing the current incentives for development of single-operating room facilities. Full deregulation could be viewed as an incremental deregulatory step for Maryland given that, in many respects, the state has largely deregulated this sector by providing a significant exemption for development of small-scale, physician office-based surgical facilities. This option would potentially change the competitive balance between hospitals and physicians in development of freestanding ambulatory surgical facilities by allowing unregulated development of the larger multi-specialty facilities which make the most economic sense for hospitals to pursue.

On the other hand, this option continues Maryland's high levels (and may even promote higher levels) of Medicare facility fee reimbursement (and perhaps other third party payments) for physician office-based outpatient procedures. It may promote a competitive environment which results in unnecessary duplication of surgical facilities (even if fewer and larger facilities tend to be developed) and, thus, higher than necessary capital costs and less efficient operational levels. Without other changes in law and regulation, this option will enable hospitals to more easily shift growing outpatient surgery activity to a non-rate regulated setting, thereby weakening whatever advantages of cost control and equity that the Maryland rate setting program can provide by more comprehensively regulating the charges of hospitals.

Option 6 - Expanded Data Reporting Requirements for Freestanding Ambulatory Surgical Facilities

This option would expand the Maryland Health Care Commission's Survey of Freestanding Ambulatory Surgery Facilities to include information on the cost of the surgical services provided by FASFs, actual operating and procedure room times used in the provision of surgical procedures, and information on quality indicators needed for performance evaluation and "report card" development, such as post-surgical infection rates, sedation complications, and rate of transfer of patients to hospitals from FASFs.

Implementing this option would allow the Commission to gauge the impact of historic CON policies on the actual cost of surgical services delivery in the state and better understand the likely impact of alternative policy options. Comparative information on the direct and indirect cost of surgical service delivery in FASFs and general hospitals is essential if an understanding is to be gained concerning the relationship between cost, volume, and varying levels of operating/procedure room use in various facility settings. Only crude indicators of cost efficiency are available now in analyzing FASF operations.

This option would also provide the Commission with information necessary to adequately fulfill the legislative mandate for developing and implementing a system to comparatively evaluate the quality of care

outcomes and performance measurements of ambulatory surgical facilities on an objective basis.

This option would involve an incremental increase in the costs borne by FASFs in complying with the data collection and reporting requirements of state government. It would also incrementally increase the Commission's cost of operations, as a result of greater levels of data collection, storage, and analysis.

Option 7 - Expand the Scope of Ambulatory Surgical Facility Licensure: Require Licensure of All Freestanding Ambulatory Surgical Facilities Whether or Not They Seek Reimbursement from Payers as Freestanding Ambulatory Surgical Facilities

This option would require facilities that provide surgical services, such as laser eye surgery for vision correction and cosmetic surgery, for which there is no third party payor coverage, to obtain a license as freestanding ambulatory surgical facilities. It would expand the benefits of facility licensure in terms of quality assurance and public safety to all facilities in which medical operative procedures are performed, regardless of how such facilities are paid. It will also aid in assuring that FASF licensure will stay ahead of changes in technology or surgical techniques which might create new categories of surgical facility in the future. However, Option 7 would increase public sector regulatory costs by expanding the universe of facilities requiring licensure.

On the other hand, this option would impose regulatory costs on surgical facilities for which the cost/benefit ratio of regulatory oversight is unclear. Under current law, it is likely that the facilities brought under licensure requirements would, in most cases, need to undertake capital expenditures to bring their facilities in line with the physical facility requirements for Medicare ASC certification (a certification which would provide them with no payment advantages) and such expenditures may have little or no benefit in terms of quality of care or patient safety. The presumed advantages of this option could be realized if FASF licensure was tiered to allow for different classes of license for different types of facility. For example, certain facilities might be allowed to obtain licensure without Medicare certification by meeting specific requirements determined to be appropriate to the level and type of surgical care they provide.

Option 8 - Define the Terms "Operating Room" and "Procedure Room" in Both Facility Licensure and Certificate of Need Regulation to a Degree of Specificity that Will Allow for Accurate and Consistent Measurement of Facility and Service Capacity

This option would provide clarity which is currently lacking with respect to a key capacity measure needed for effective policy development under current or proposed CON policies, if Maryland continues to exercise some level of regulatory control over the supply of surgical facilities and operating rooms in the state. It would provide the state agencies with a tool for assuring that only appropriate operative spaces are developed in Maryland hospitals and FASFs and that facilities are appropriate to the types of surgical procedures being performed.

This option may increase the cost of facility licensure by the Department of Health and Mental Hygiene required to count, evaluate room characteristics, and classify rooms in hospitals and FASFs as part of the licensure survey process.

Summary

The alternative policy options for changes to CON regulation for ambulatory surgical facilities and services and facilities address issues identified in the previous sections of this chapter. Table 4-14 summarizes these policy options.

Commission Recommendations

Recommendation 4.0

On an interim basis, the Commission should make no changes should be made in ambulatory surgical facilities CON policy. However, a research agenda should be developed to clarify the likely impact of policy alternatives. (See Recommendation 4-4).

Recommendation 4.1

Revisions to the MHCC Ambulatory Surgical Facility Survey should be initiated for the 2001 survey cycle, with appropriate consultation and coordination with the affected providers, to address data deficiencies.

Recommendation 4.2

In cooperation with the Department of Health and Mental Hygiene's (the Department) Office of Health Care Quality (OHCQ), research should be undertaken to define the universe of facilities in Maryland which serve as settings for invasive procedures but are not required to obtain licensure under current law and regulation. A white paper outlining the costs and benefits of expanding the scope of freestanding ambulatory surgical facility (FASF) licensure, based on this research, should be developed and distributed for review and comment. MHCC and OHCQ should consider the research and comments and formulate recommendations to the Department concerning the appropriate scope of FASF licensure.

Recommendation 4.3

A process should be initiated to develop a consensus among MHCC, OHCQ, and the regulated industry on definitions of "operating room" and "procedure room" to be employed in both CON regulation and licensure.

Recommendation 4.4

Research should be conducted to clarify the appropriate direction of CON policy reform with respect to ambulatory surgical facilities. Three areas of research focus are recommended:

- **A detailed comparative analysis of the ambulatory surgical services delivery system and the regulatory policies that have shaped those systems in a group of selected states;**

- **An in-depth analysis of the charge and cost structure of a sample of Maryland FASFs identifying the relationship between costs and charges and characteristics such as range of specialties, type of specialties, volume of procedures,**

and competitiveness within market service areas;

- **A review and analysis of the implications for quality of care of Maryland policies promoting the establishment and operation of low volume, physician-office based surgical facilities.**

The reader should consider the issues and options presented in this report in a broad context. Maryland's CON policies appear to have had the effect of channeling freestanding ambulatory surgical services in the direction of many small and specialized centers. The effect of these policies on surgical use rates or system-wide health care costs is unclear, and comparisons of Maryland's unique landscape of FASFs with experience in other states or at the national level is difficult. There are some indications that the efficiency of operating room use in hospitals, in terms of average cases per room, has fallen and that Maryland's CON policies may have produced lower case volumes per room in the FASF sector compared to that seen in most other states.

The case for regulating the supply and distribution of outpatient surgical facilities has usually rested on two major concerns and these concerns are reflected in the historic record of Maryland's consideration of CON policy in this area. The first concern is with appropriate use of surgical facilities and services and, in particular, overuse. Will continued development of ambulatory surgical facilities result in excessive use of surgical services? The second concern is with the intersection of hospital expenses for and equitable access to surgical services and how these factors are affected by varying levels of proliferation of outpatient surgical facilities, many of which will tend to have non-hospital sponsorship. Will continued development of ambulatory surgical facilities result in less efficient use of hospital and outpatient surgical center capacity, increasing the unit cost of producing surgical services? Furthermore, will the shift of surgical caseload away from the hospital setting resulting from development of outpatient surgical facilities lead to a costly and unprofitable mix of surgical patients relying on the hospital for these services while the outpatient centers dominate the provision of care to the insured population? What will be the impact of such a market segmentation on hospital financial stability and hospitals' ability to provide unprofitable but needed services and uncompensated or poorly compensated care?

On the other hand, to what extent can development of freestanding ambulatory surgical facilities be beneficial in lowering the cost of providing outpatient surgical services, by moving provision of these services out of the costly hospital setting? Do hospitals adjust their physical facilities and variable cost elements to better compete for ambulatory surgical business, or do they focus more effectively on other categories of service? There has also been strong historic support in Maryland for allowing physicians and other practitioners to engage in the provision of surgery in their private offices, at least on a limited scale, without regulatory barriers to market entry and there is undoubtedly support by consumers for the option of obtaining outpatient surgery in settings that are more personal in ambiance, more specialized in their focus on particular patient needs, and more convenient to access than most general hospitals.

Table 4-14
Summary of Regulatory Options:
Ambulatory Surgery Services

Options	Level of Government Oversight	Description	Administrative Tool
Option 1 Continue current scope of CON regulation	No Change in Government Oversight	▪ Establishment of 2+ OR FASFs regulated by CON ▪ Expansion of FASFs (ORs) regulated by CON ▪ Addition of outpatient ORs by hospitals regulated by CON	Commission Decision (CON / Exemption)
Option 2 Slightly modify current scope of CON regulation	Reduced Government Oversight (net)	▪ Establishment of 2+ OR FASFs regulated by CON ▪ Expansion of FASFs (ORs) regulated by CON ▪ Addition of outpatient ORs by hospitals not regulated by CON (if under capital spending threshold) ▪ No exemption from CON for 2+ OR FASFs	Commission Decision (CON / Exemption)
Option 3 Expand CON regulation to cover all surgical facility and service projects	Increased Government Oversight	▪ Establishment of any FASF regulated by CON ▪ Expansion of FASF or hospital (ORs or PRs) regulated by CON ▪ No exemptions based on size of FASF	Commission Decision (CON)
Option 4 Expand CON regulation to cover all operating room projects	Increased Government Oversight	▪ Establishment of any FASF with ORs regulated by CON ▪ Expansion of FASF or hospital (ORs only) regulated by CON ▪ No exemptions based on size of FASF – procedure room only FASFs exempt	Commission Decision (CON)
Option 5 Eliminate CON regulation of any surgical facility or service projects	Reduced Government Oversight	▪ No CON regulation of establishment of FASFs ▪ No CON regulation of additional ORs or PRs by hospitals or FASFs	None
Option 6 Expand FASF data reporting	Increased Government Oversight	▪ Collection of data from FASFs on costs, quality Indicators, and OR and PR minutes	• FASF report cards • Commission policy analysis
Option 7 Expand scope of FASF licensure	Increased Government Oversight	▪ License all surgical facilities without regard to payment sources	Licensure issuance and ongoing surveys
Option 8 Define “operating room” and “procedure room” for licensure and CON	Increased Government Oversight	▪ Establish consistent terminology in licensure and CON regulation	▪ Licensure issuance and ongoing surveys ▪ Commission policy analysis

APPENDIX 4-1

Freestanding Ambulatory Surgery Centers With Hospital or Health System Affiliation, September 2001

Appendix 4-1

Freestanding Ambulatory Surgery Centers
With Hospital or Health System Affiliation, September 2001

Name of Freestanding ASC	Hospital/System Affiliation	Location
Calvert Memorial Hospital of Calvert County	Calvert Memorial Hospital	Hospital Campus
Children's Ambulatory Surgery Center	Children's National Medical Center	Rockville
Civista Surgery Center	Civista Medical Center	Waldorf
Dimensions Healthcare System	Dimensions Healthcare System	Bowie
Metropolitan Ambulatory Urologic Institute	Doctors Community Hospital	Greenbelt
Frederick Surgical Center	Frederick Memorial Hospital	Frederick
Maryland Kidney Stone Center	Greater Baltimore Medical Center	Baltimore County
Howard Endoscopy Center	Howard County General	Hospital Campus
Johns Hopkins Endoscopy at Greenspring Station	Johns Hopkins Hospital	Lutherville
Ophthalmology Associates at Greenspring Station	Johns Hopkins Hospital and Lifebridge	Lutherville
SurgiCenter of Baltimore	Lifebridge Health	Owings Mills
Surgery Center of Chevy Chase	MedStar Health	Chevy Chase
MedStar SurgiCenter at Pasadena (formerly Helix Health)	MedStar Health	Pasadena
Digestive Health Center	Memorial Hospital of Easton	Easton
Maryland Endoscopy Center	Mercy Medical Center	Towson
Metropolitan Ambulatory Care	Mercy Medical Center	Baltimore
Surgery Center of Maryland	Montgomery General and Holy Cross hospitals	Rockville
Peninsula Regional Medical Center (opening January 2002)	Peninsula Regional Medical Center	Salisbury
Endoscopy Center at Belvedere	Sinai Hospital	Sinai Campus
Eye Surgery Center of Ophthalmology Associates	Sinai Hospital	Lutherville
Waldorf Surgical Center	Southern Maryland Hospital Center	Waldorf
HealthSouth St. Agnes Surgery Center	St. Agnes Hospital	Ellicott City
Suburban Breast Center (opens Jan 2002)	Suburban Hospital	Bethesda
Suburban Endoscopy Center	Suburban Hospital	Bethesda
Greater Chesapeake Surgery Center	Union Memorial Hospital	Towson
HealthSouth Central Maryland Surgery Center	University of Maryland Medical Systems	Joh Avenue, Baltimore
Robinwood Surgery Center	Washington County Hospital	Hagerstown

APPENDIX 4-2

History of Commission Statute Governing Definition and CON Regulation of Ambulatory Surgical Facilities in Maryland

1982 - 1999

History of Commission Statute Governing Definition and CON Regulation of Ambulatory Surgical Facilities in Maryland

1982

Statute creating the MHRPC includes, among definitions of what constitutes a "health care facility" subject to Certificate of Need review, an "ambulatory surgical facility" that

- "provides surgical treatment to individuals who do not need overnight hospitalization;
- "is not part of a hospital; and
- "is not part of the office of 1 or more private physicians or dentists or part of any office of physicians or dentists who are organized as a professional association."
  (Ch. 108, Acts 1982)

[by inference, if it ***is*** part of the office of private practitioners or a PA, it is not considered a health care facility for the purposes of CON review]

1986

Statute was enacted "to include certain ambulatory surgical facilities under Certificate of Need requirements" by defining what did ***not*** constitute a "health care facility" requiring CON review and approval (and so further refining the statutory definition of an ambulatory surgical facility that ***did*** require a CON); according to this new provision, a CON was not required by:

- The office of one or more private physicians, podiatrists, or dentists,
- Regardless of whether that office is eligible to receive or receives reimbursement from third party payers as an ambulatory surgical facility or center (i.e., a "facility fee");
- "If the office provides services only within a single medical or surgical subspecialty as determined by the Health Resources Planning Commission;
- If the office is used only for the physician's patients or patients of the group; and,
- If the office includes not more than four surgical suites."

The new statute also explicitly included ophthalmology as one of the medical specialties; subsequently the former MHRPC adopted in regulation a list of ten specialties, including those of ophthalmology, podiatric surgery, and oral surgery specified in statute, with the addition of colon and rectal surgery, dermatology, gynecology, otolaryngology, plastic surgery, urological surgery, and vascular surgery.

Grandfathering language provided that the new law did not apply to any person who had, by February 12, 1986, either (i) received Medicare certification as an ambulatory surgical facility or center, or (ii) received a determination from the former HRPC that no CON was needed to establish ambulatory surgical capacity and had obligated by that date not less than $100,000 in reliance on the determination.

1992 – 1993

A December 1992 determination that no CON was needed to establish a proposed center for gastrointestinal endoscopy – coupled with a directive issued in March 1993 by CIGNA directing physicians to perform its members' endoscopies in non-hospital settings – brought calls from the Maryland Hospital Association and Commission members for staff to re-examine policies related to CON coverage of endoscopy, and whether endoscopy was primarily diagnostic, or should be considered primarily surgical.

MHRPC's Consensus Development Group deliberated the question, and issued its finding through a report issued in January 1994 that "a diagnostic gastrointestinal endoscopy center, because it does not operate primarily for the purpose of providing surgical services, is not an ambulatory surgery center *for the purposes of CON coverage* based on current Maryland law."

1994

Continuing concern of hospitals about the number of determinations of non-coverage for endoscopy centers and other single specialty FASFs (all with the potential for being 4 ORs) leads to introduction of legislation that would impose a moratorium on issuing new determinations.

At the end of the 1994 session, the General Assembly instead inserted language in the Joint Chairman's Report expressing the "intent of the budget committees that no dollars be expended by [the former HRPC]" to process requests for letters finding CON not required (or for hospital capital expenditures to build more hospital-based outpatient capacity) until the legislature reviews a study "of the proliferation of ambulatory care capacity or by May 1, 1995, whichever comes first." MHRPC undertakes the legislatively-mandated study of the growth in ambulatory surgical capacity and its own procedures and coverage rules.

In December 1994, MHRPC issues *Ambulatory Surgical Services: Policy and Regulatory Issues*, which recommends removing any distinction between single- and multi-specialty use, requiring CON for 2 or more ORs, and also for one OR if it accepted a facility fee. Report strongly recommended licensing FASFs, and removing CON "exemption for hospital capital expenditures intended to increase OR capacity."

1995

As part of the Health Care Reform Act of 1995 (SB 639), much of what MHRPC recommended is enacted into law:

- ASF now defined as 2 or more ORs, regardless of specialty;
- FASFs may be used by physicians other than those a single group practice;
- single OR in physician office excluded from CON review (regardless of facility fee status);
- any increase in outpatient surgical capacity in "any setting owned or controlled by a hospital" now required CON;

- Grandfathering language excluded from new provision "existing and operating" ASFs, as well as any determination of non-coverage by CON issued before February 13, 1995, and on which at least $25,000 had been obligated toward implementation, or those with Medicare certification before June 1995.

SB 639 also establishes requirement that all ambulatory surgery ORs (that accept a facility fee or other third party reimbursement) obtain a license from DHMH

MHRPC issues Program Policy Notice on June 13, 1995 in which it delineates changes in statutory definition of ASF and applicability of grandfathering language, and notes that existing and operating single specialty FASFs may notify the Commission that they will, *prospectively*, permit practitioners of other specialties to use their facility. The Notice articulated rationale for these policies: "to encourage the most efficient use of existing capacity."

MHRPC issues survey of all entities with determination letters, advising of new law, need to get grandfathering determination, and requiring information on status of implementation (limiting to what had been built by July date of survey).

1996

MHRPC supports an MHA proposal to amend SB 639's provisions to clarify that if a hospital acquires an existing FASF, which has either previously received CON approval, or been found not to require a CON to establish, then additional CON approval is not required.

1997

MHRPC's policies regarding the multi-specialty use of previously single-specialty FASFs is challenged by a group of four hospitals; HRPC eventually upheld by decision of Maryland Court of Appeals.

1998

MHRPC issues new provisions in a reorganized section of CON regulation governing FASFs, which require a periodic showing of "good faith effort" to implement any outstanding approved but unbuilt ASFs, and limit to two years the effective duration of a determination permitting a single OR to be established without CON review to two years.

November 1998, HRPC issues first comprehensive inventory of ambulatory surgery in Maryland
[subsequent editions published May and December 2000, following the October 1999 creation of the Maryland Health Care Commission]

1999

August 1999, DHMH licensing regulations take effect for ambulatory surgical facilities as well as other kinds of facilities defined as "ambulatory care facilities" under licensing law.