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Health Policy Review

Ambulatory Surgery Centers and Interventional Techniques: A Look at Long-Term Survival

Laxmaiah Manchikanti, MD[1], Allan T. Parr, MD[2], Vijay Singh, MD[3], and Bert Fellows, MA[1]

From [1]Pain Management Center of Paducah, Paducah, KY; [2]Premier Pain Center, Covington, LA; and [3]Pain Diagnostics Associates Niagara, WI.

Dr. Manchikanti is Medical Director of the Pain Management Center of Paducah, Paducah, KY and Associate Clinical Professor, Anesthesiology and Perioperative Medicine, University of Louisville, Louisville, KY. Dr. Parr is Medical Director of Premier Pain Center, Covington, LA. Dr. Singh is Medical Director, Pain Diagnostics Associates, Niagara, WI. Bert Fellows is Director Emeritus of Psychological Services at the Pain Management Center of Paducah, Paducah, KY.

Address Correspondence:
Laxmaiah Manchikanti, MD
2831 Lone Oak Road
Paducah, KY 42003
E-mail: drlm@thepainmd.com

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With health care expenditures skyrocketing, coupled with pervasive quality deficits, pressures to provide better and more proficient care continue to shape the landscape of the U.S. health care system. Payers, both federal and private, have laid out several initiatives designed to curtail costs, including value-based reimbursement programs, cost-shifting expenses to the consumer, reducing reimbursements for physicians, steering health care to more efficient settings, and finally affordable health care reform.

Consequently, one of the major aspects in the expansion of health care for improving quality and reducing costs is surgical services. Nearly 57 million outpatient procedures are performed annually in the United States, 14 million of which occur in elderly patients. Increasing use of these minor, yet common, procedures contributes to rising health care expenditures. Once exclusive within hospitals, more and more outpatient procedures are being performed in freestanding ambulatory surgery centers (ASCs), physician offices, visits to which have increased over 300% during the past decade. Concurrent with this growing demand, the number of ASCs has more than doubled since the 1990s, with more than 5,000 facilities currently in operation nationwide. Further, total surgical center ASC payments have increased from $1.2 billion in 1999 to $3.2 billion in 2009, a 167% increase. On the same lines, growth and expenditures for hospital outpatient department (HOPD) services and office procedures also have been evident at similar levels.

Recent surveys have illustrated on overall annual growth per capita in Medicare allowed ASC services of pain management of 23%, with 27% growth seen in ASCs and 16% of the growth seen in HOPD. Further, the proportion of interventional pain management which was 4% of Medicare ASC spending in 2000 has increased to 10% in 2007. Thus, interventional pain management as an evolving specialty is one of the most commonly performed procedures in ASC settings apart from HOPDs and well-equipped offices.

In June 1998, the Health Care Financing Administration (HCFA) proposed an ASC rule in which at least 60% of interventional procedures were eliminated from ASCs, and the remaining 40% faced substantial cuts in payments. Following the publication of this rule, based on public comments and demand, Congress intervened and delayed implementation of the rule for several years. The Centers for Medicare and Medicaid Services (CMS) published its proposed outpatient prospective system for ASCs in 2006, setting ASC payments at 62% of HOPD payments. Following multiple changes, the rule was incorporated with a 4-year transition formula which ended in 2010, with full effect occurring in 2011 with ASCs reimbursed at 57% of HOPD payments.

Thus, the landscape of interventional pain management in ambulatory surgery centers has been constantly changing with declining reimbursements, issues of fraud and abuse, and ever-increasing regulations.

Key words: Outpatient prospective payment system, ambulatory surgery center payment system, Government Accountability Office, Medicare Modernization and Improvement Act, interventional techniques

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Medicare has offered coverage for surgical procedures performed in free standing or hospital-based ambulatory surgical centers (ASCs) since 1982, even though, the first ASCs were established in the early 1970s. In 1976, there were 67 ASCs in United States. In 1982, there were only 30 surgical procedures that met government guidelines for coverage. Since the 1980s, the share of surgeries performed in outpatient settings has grown significantly. As of 2009, Medicare payments were $3.2 billion with 5,260 Medicare certified ASCs (1,2). There are now approximately over 300 surgery centers designating themselves as single specialty, interventional pain management centers.

The landscape of ASCs has changed substantially since June 1998, when the Healthcare Financing Administration, now the Centers for Medicare and Medicaid Services (CMS) proposed an ASC rule that would eliminate 60% of interventional procedures and substantially cut payments for the remaining 40% of the procedures. The next issue was related to the Medicare Modernization Act (MMA) of 2003 which once again altered the landscape of the payment system (3,4). Subsequent to the MMA requirement, Medicare's new payment system for ASCs started in 2008 and entered the final phase on January 1, 2011.

1.0 Health Care Spending in the United States

Despite advances in biomedical knowledge and higher per capita health care expenditures in the world, the quality and outcomes of health care vary dramatically across the United States (5,6). Innovations in health care are escalating at an astounding pace, adding complexity to the broad arena of health care interventions and systems (6-9). Further, the demonstration of pervasive, persistent, and unexplained variability in clinical practice, high rates of inappropriate care, and escalating health care expenditures have fueled a steadily increasing demand for cost controls and clinical effectiveness (6,10-38). Consequently, there is demand and expectation for not only clinical effectiveness, but cost effectiveness, also along with other attributes of medical care, resulting in multiple guidelines and regulations (5,38-57).

Health care spending in 2008 was $1.95 trillion (58). Medicare accounted for 23% or $444 billion, which includes direct patient care spending and excludes certain administrative and business costs. Further, spending by

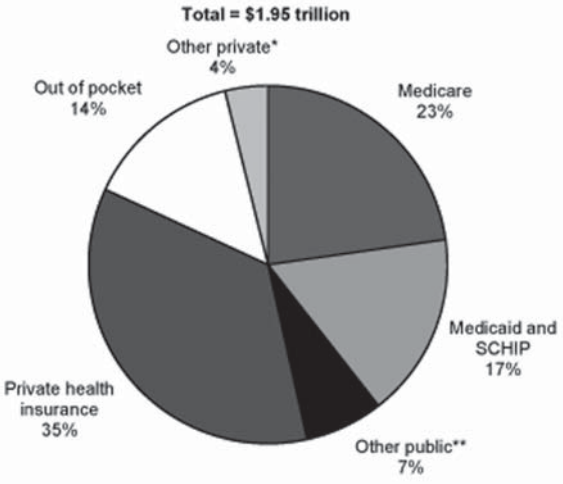
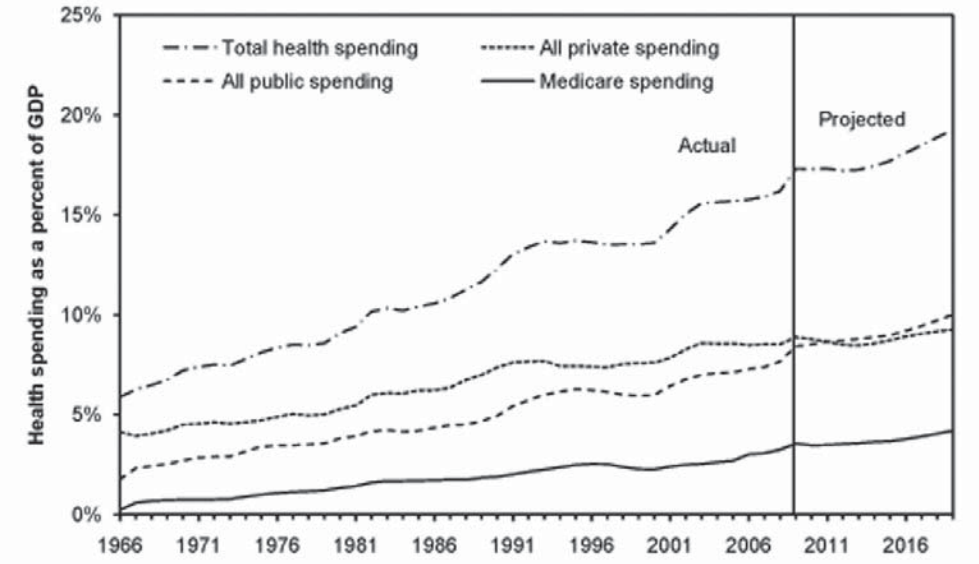


Fig. 1. *Medicare made up over one-fifth of spending on personal health care in 2008.*
Source: CMS Office of the Actuary

all public programs — including Medicare, Medicaid, State Children's Health Insurance Program (SCHIP), and other programs — accounted for 47% of health care spending. Medicare is the largest single purchaser of health care in the United States. Thirty-five percent of the spending was financed through private health insurance payers and 14% was from consumer out-of-pocket spending (Fig. 1). However, by 2019, those percentages are projected to be 52% public spending and 48% private spending (Fig. 2).

In addition, total health spending consumes an increasing proportion of national resources, accounting for a double-digit share of gross domestic product (GDP) annually since 1982. As a share of GDP, total health spending has increased from about 6% in 1965 to about 16% in 2008. It is projected to reach almost 20% of GDP in 2019. Medicare spending also has grown as a share of the economy from less than 1% when it was started in 1965 to about 3% in 2008. Projections suggest that Medicare spending will make up 4% of GDP by 2019. However, these estimations may change based on the Patient Protection and Affordable Care Act (the ACA, for short) (29-32,59-63).

Medicare spending among fee-for-service (FFS) beneficiaries grew strongly in most sectors from 2000 to2005, however, hospital inpatient expenses remained on the top followed by physician expenses, then by



Note: GDP (gross domestic product). Total health spending is the sum of all private and public spending. Medicare spending is one component of all public spending.

Fig. 2. *Health care spending has grown more rapidly than GDP, with public financing making up nearly half of funding.*
Source: CMS, Office of the actuary, National Health Expenditure Accounts, 2010

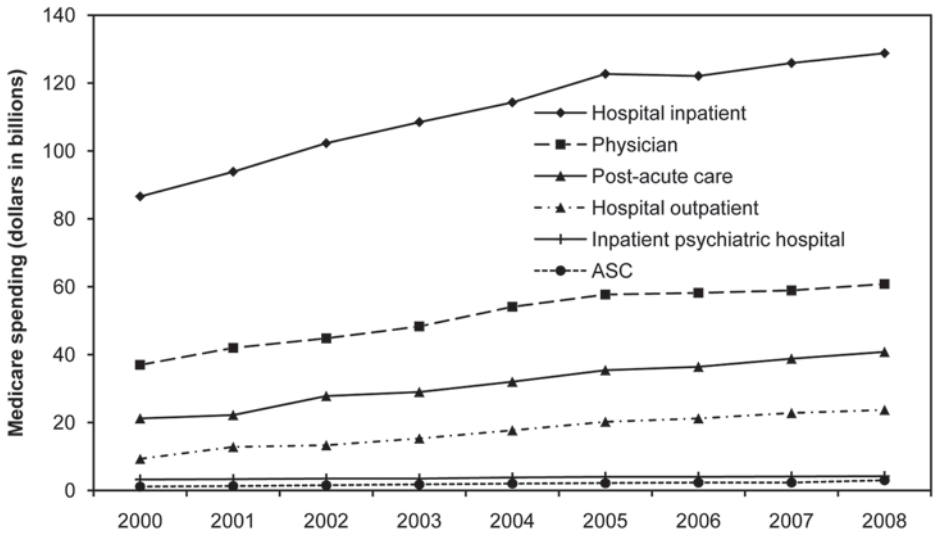


Fig. 3. *Aggregate Medicare spending among FFS beneficiaries, by sector, 2000–2008.*

Source: CMS, Office of the Actuary, and the 2009 annual report of the Boards of Trustees of the Medicare Trust Funds.

post-acute care, hospital outpatient, inpatient psychiatric hospital, and finally ASC at the bottom (Fig. 3). However, spending per beneficiary remains strong in most sectors. Even then ASCs remained at the bottom. Medicare spending per beneficiary in FFS Medicare increased steadily in most sectors (Fig. 4).

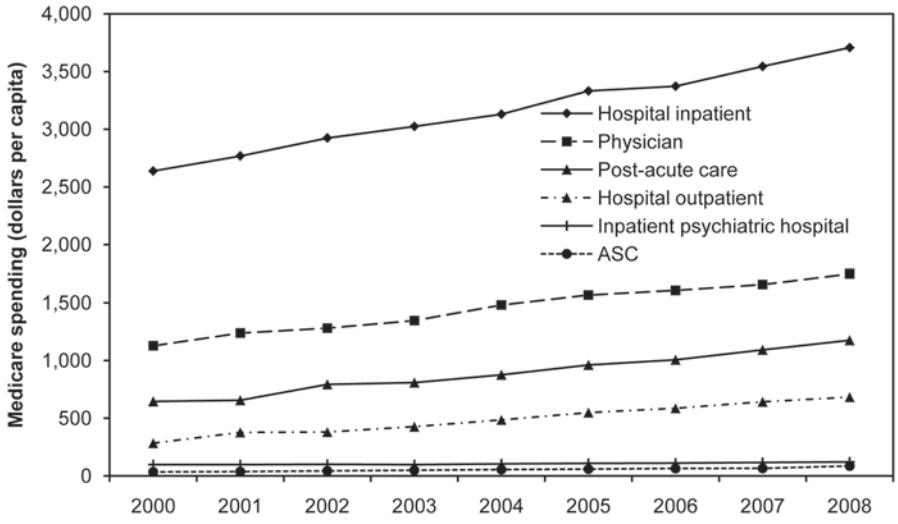


Fig. 4. *Per capita Medicare spending among FFS beneficiaries, by sector, 2000–2008.*

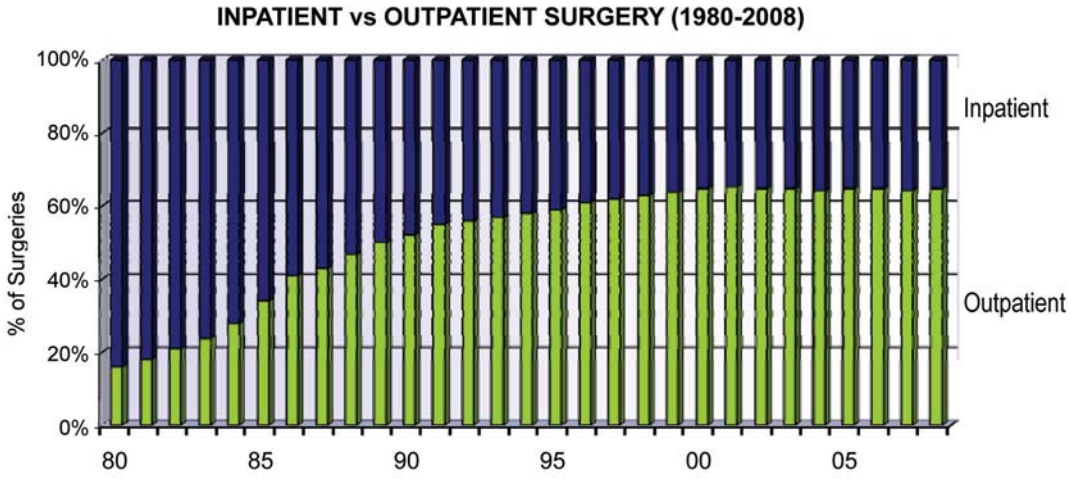


Fig. 5. *Illustration of surgical trends in the United States.*
Source: Intellimarker. Ambulatory Surgical Centers Financial & Operational Benchmarking Study. Fifth Edition. VMG Health, July 2010 (67).

2.0 Ambulatory Surgery

2.1 Changing Dynamics

Until 1970, virtually all surgery was performed in hospitals. With the development of ASCs and site-of-service differential payments for in-office procedures, the dynamics have changed (64-93). Figure 5 illustrates surgical trends in the United States with outpatient surgeries outpacing inpatient surgeries by 1989 (65-67). By 2008, approximately 65% of procedures were performed in all outpatient settings (including hospital outpatient departments [HOPDs]), whereas inpatient volume decreased to 35%, falling from over 80% of inpatient surgeries in 1980 (67).

Approximately 57 million outpatient procedures are performed annually in the United States; 14 million of which occur in elderly patients (71,74). It has been described that ASCs offer improved efficiency in health care delivery, allowing patients to spend less time in the health care setting. Their quicker patient turnover rates may also increase provider productivity (71). Despite these benefits, the majority of ASCs are owned, in part, by the physicians who staff them, and the financial incentives related to ownership have been alleged potentially to alter provider behavior (71).

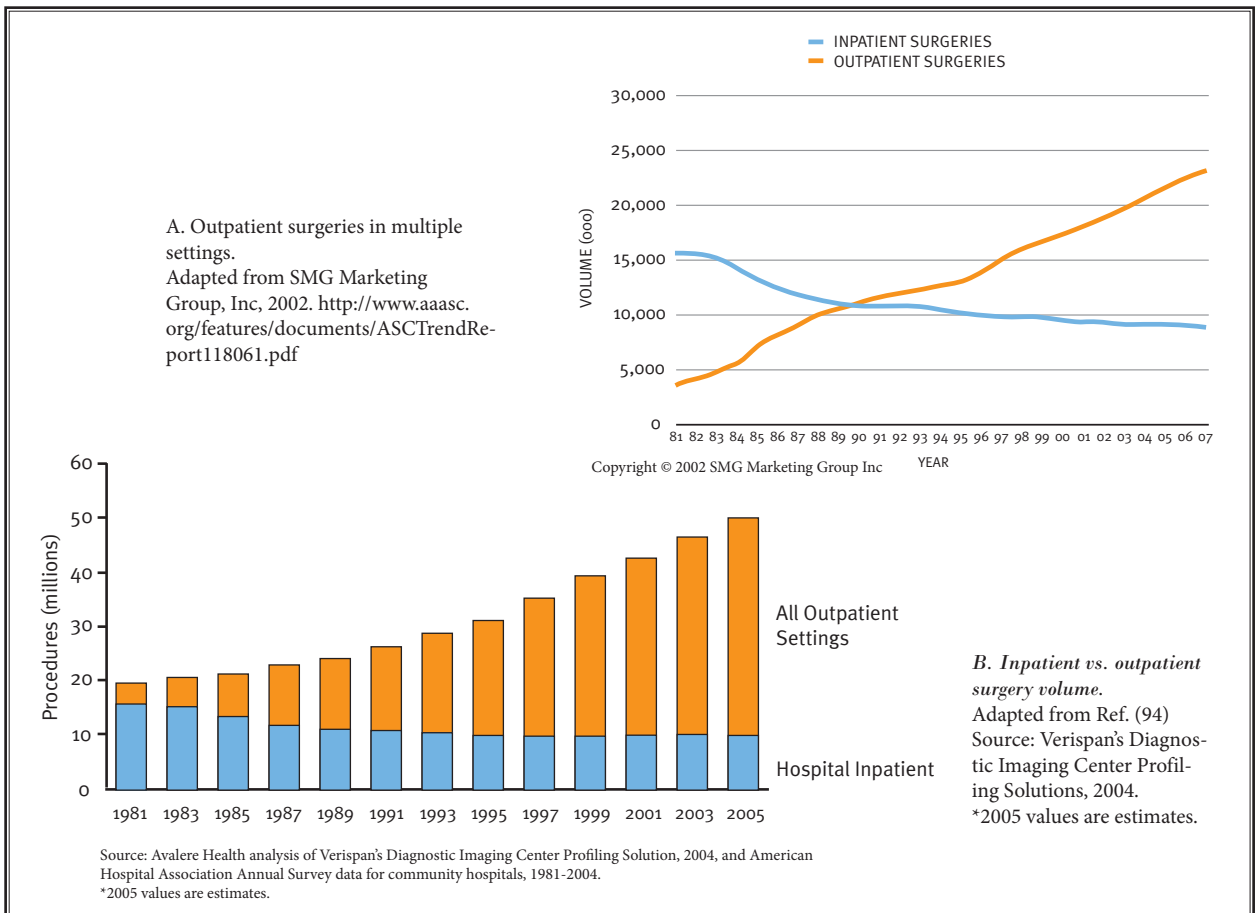
Figure 6 illustrates surgical trends in the United States, showing that outpatient surgery is quickly migrating to non-hospital settings. Since 1981, the share of outpatient surgeries performed in hospitals has fallen from over 90% to 45%, while the share performed in ASCs and physician offices has grown from less than 5% to 38% and 17%, respectively. From 1997 to 2004, the volume of ASC procedures provided to Medicare beneficiaries rose 145%, while the number of ASCs increased by 67% (94-101).

The procedures performed in physician offices increased to over 10 million in 2007. HOPD surgeries also increased significantly.

2.2 Ambulatory Surgery Expenditures

Table 1 illustrates the number of Medicare certified ASCs and total ASC payments from 1999 to 2009. Medicare certified ASCs increased from 2,786 in 1999 to 5,260 in 2009, an overall increase of 89% and an annual growth of 9%. ASC payments have increased from $1.2 billion in 1999 to $3.2 billion in 2009, overall a 167% increase, with an annual increase of 16.7%. There were 5,876 freestanding ASCs as the close of 2008 (67).

In recent years, growth has been much slower. Growth ranged about 7%, whereas it started declining to approximately 6% in 2006 and 2007 and 4.4% in 2008, and 2.1% in 2009. Further declines are being



A. Outpatient surgeries in multiple settings.
Adapted from SMG Marketing Group, Inc, 2002. http://www.aaasc.org/features/documents/ASCTrendReport118061.pdf

B. Inpatient vs. outpatient surgery volume.
Adapted from Ref. (94)
Source: Verispan's Diagnostic Imaging Center Profiling Solutions, 2004.
*2005 values are estimates.

Source: Avalere Health analysis of Verispan's Diagnostic Imaging Center Profiling Solution, 2004, and American Hospital Association Annual Survey data for community hospitals, 1981-2004.
*2005 values are estimates.

Fig. 6. *Migration of outpatient surgical procedures to non-hospital settings.*

Table 1. *Number of Medicare-certified ASCs and total Medicare payments from 1999 to 2009: Ten year growth.*

	1999	2000	2001	2002	2003	2004	2005	2006	2008	2009
Total Medicare payments (billions)	$1.2	$1.4	$1.6	$1.9	$2.2	$2.5	$2.7	$2.9	$3.1	$3.2
Net percent growth from previous year		16.6%	14.3%	18.8%	15.8%	13.6%	8%	7.4%	3.4%	2.1%
% of increase from 1999	-	17%	33%	58%	83%	108%	133%	142%	158%	167%
Number of Medicare Certified ASCs	2,786	3,028	3,371	3,597	3,887	4,136	4,506	4,707	5,151	5,260
Net percent growth from previous year		8.7%	11.3%	6.7%	8.1%	8.7%	6.4%	9.0%	16%	2%
% of increase from 1999	-	9%	21%	29%	40%	48%	62%	69%	85%	89%

Table 2. *Growth in expenditures and volume and intensity of HOPD services under OPPS from CY2001 to CY2008.*

OPPS growth	CY2001	CY2002	CY2003	CY2004	CY2005	CY2006	CY2007	CY2008
Incurred cost (billions USD) percent increase	17.702	19.561 10.5%	21.156 8.2%	23.866 12.8%	26.572 11.3%	29.338 10.4%	31.641 7.8%	34.960 10.5%
Increase from 2001	-	10.5%	19.5%	34.8%	50.1%	65.7%	78.7%	97.5%
Volume and intensity percent increase	-	3.5	2.5	7.6	7.4	8.6	6.4	NA
Increase from 2001		3.5	6.0	13.6	21.0	29.6	36.0	NA

NA=not available

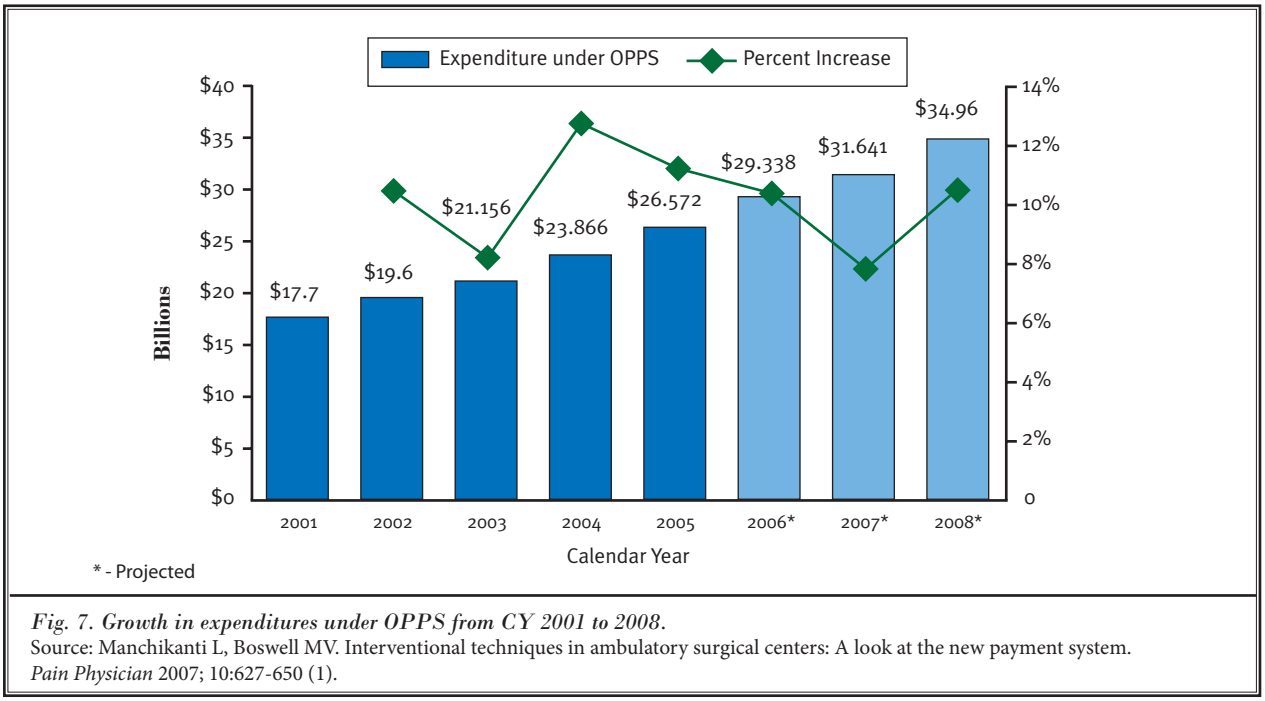


Fig. 7. Growth in expenditures under OPPS from CY 2001 to 2008.
Source: Manchikanti L, Boswell MV. Interventional techniques in ambulatory surgical centers: A look at the new payment system. *Pain Physician* 2007; 10:627-650 (1).

noted into 2010 and it is expected that multiple surgical centers will be going out of business, reducing the number of operating centers to a lower level (Table 1) (68,69). In 2008, the ASC growth rate reached its highest point of 16% since 1999, with a decrease to 2% in 2009 (67-69).

The growth in HOPD procedures also has skyrocketed as illustrated in Table 2 and Fig. 7 (15,29,95-97). The phenomenal growth in expenditures under the Outpatient Prospective Payment System (OPPS) was approximately $18 billion in 2001, increasing to $39 billion in 2011 (projected), constituting an overall increase of

116% and an annual increase of 10.6%. Volume and intensity increased 3.5% to 6.4% each year from 2001 to 2008 (15,29,95-97).

In-office procedures have increased substantially in pace with ASCs and hospital outpatient growth (15,22,29,95-97,100-103).

2.3 Interventional Pain Management Procedures

The rapid growth of pain management services in ASCs (15,22,95,100-102,104-107) and in a larger ambulatory market as a whole, may reflect the recent development of techniques and a growing recognition by providers and Medicare beneficiaries that pain is a treatable condition (37,38,108-146). Consequently, pain management has been characterized as a relatively a new service in ASCs (Fig. 8). Contributions to growth in Medicare allowed charges by type of service from 2002 to 2007 were 29% for eye procedures, 32% for gastrointestinal procedures, 17% for pain management, 8% for orthopedics, and 18% for all other procedures (Fig. 9). However, pain management evolved from representing 4% of Medicare ASC spending in 2000 to 10% in 2007. Further, it has been noted that growth in interventional pain management (IPM) techniques is not as a result of procedures shifting from the HOPD to free standing centers; it is mostly driven by a growth in the overall numbers of procedures across all sites of services (102).

There has been rapid growth, or at times explosive growth, of interventional techniques over the last 10 years or so (Table 3) (15). Multiple manuscripts have been published studying the growth including an analysis from the Office of Inspector General Health and Human Services (OIG-HHS) (15,22,100-102,104). Manchikanti et al (15) in an analysis of growth of interventional techniques in managing chronic pain in Medicare population in an evaluation from 1997 to 2006 showed that interventional techniques increased significantly in Medicare beneficiaries. Overall, there was an increase of 137% in patients utilizing IPM services with an increase of 197% in IPM services, per 100,000 Medicare beneficiaries. Figure 10 illustrates overall growth patterns from 1997 to 2006 in Medicare beneficiaries. The majority of the increases were attributed to exponential growth in the performance of facet joint interventions. The study illustrated that epidural procedures increased 117%, facet joint interventions 543%, discography 159%, disc decompression 316%, spinal cord stimulation 518%, and other types of nerve blocks 84%, with an overall increase of

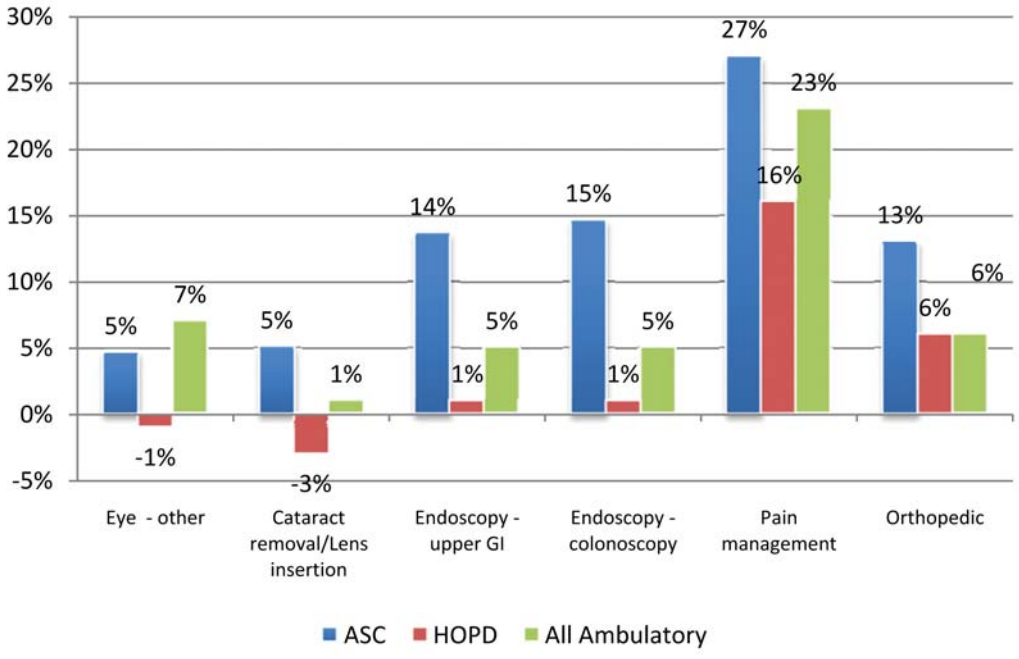


Fig. 8. *Average annual growth per capita in Medicare-allowed ASC services by category, 2000 to 2007.*

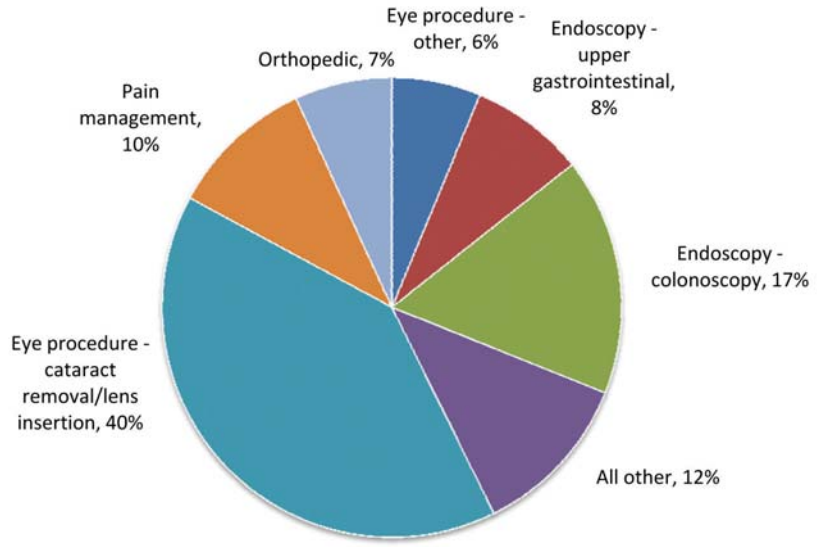


Fig. 9. *ASC share of Medicare allowed charges by type of service, 2007.*
Source: KNG Health analysis of PSPS files. Includes Medicare FFS claims only.

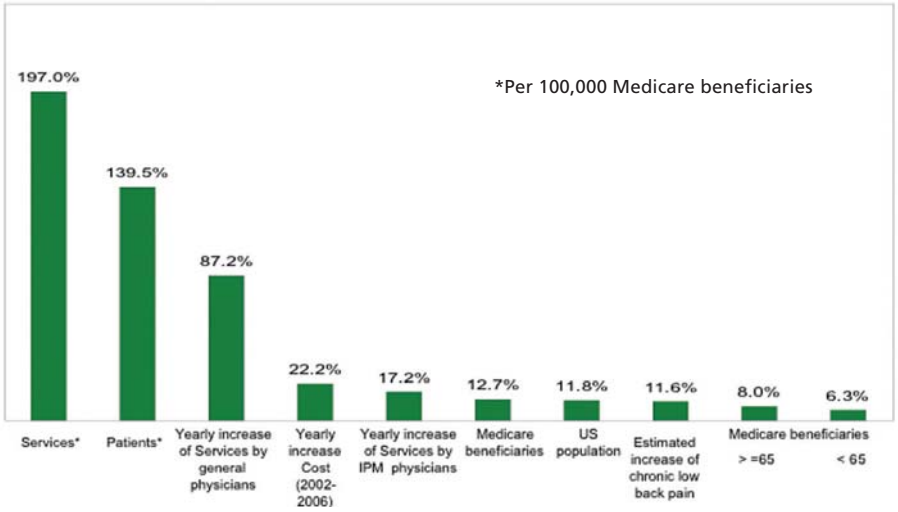


Fig. 10. *Illustration of overall growth patterns (percent)of interventional techniques from 1997 to 2006 in Medicare beneficiaries.* Source: Manchikanti et al, Pain Physician 2009; 12:9-34.

7% per 100,000 Medicare beneficiaries. Interestingly enough, services increased 198% per 100,000 Medicare beneficiaries in patients younger than 65 years on Medicare, compared to 189% for patients at age 65 or over. However, baseline services were 5,376 for patients less than 65 years of age, whereas they were 3,322 for Medicare beneficiaries of 65 years or older.

Based on settings, facility and physician charges, overall charges for interventional techniques increased 70% with services also increasing 74% per 100,000 population, with an overall increase of 86% from 2002 to 2006. The increases in payments were 97% for ASC settings, 60% for HOPD settings, and 164% for in-office settings from 2002 to 2006.

Table 3. *Summary of the frequency of utilizations of various categories of interventional procedures (excluding continuous epidurals, intraarticular injections, and trigger point and ligament injections) in Medicare beneficiaries in 1997, 2002, and 2006.*

	1997 Services	2002 Services	2006 Services	Change from 2002 to 2006	Change from 1997 to 2006
Epidural procedures	768,360 (55.8%)	1,179,800 (47.7%)	1,879,060 (40.8%)	59%	145%
Per 100,000 Medicare beneficiaries	1,998	2,913	4,336	49%	117%
Percutaneous adhesiolysis	NA	14,760 0.6%	17,500 (0.4%)	19%	NA
Per 100,000 Medicare beneficiaries	NA	36	41	11%	
Facet joint interventions	233,200 (16.9%)	607,760 (24.6%)	1,688,180 (36.6%)	178%	624%
Per 100,000 Medicare beneficiaries	606	1,501	3,895	160%	543%
Sacroiliac joint interventions	NA	100,820 (4.1%)	208,980 (4.5%)	107%	NA
Per 100,000 Medicare beneficiaries	NA	249	482	94%	
Discography	7,820 (0.6%	19,060 (0.8%)	22,820 (0.5%)	20%	192%
Per 100,000 Medicare beneficiaries	20	47	53	12%	159%
Disc decompressions	440 (0.0%)	1,540 (0.1%)	2,060 (0.04%)	34%	368%
Per 100,000 Medicare beneficiaries	1	4	5	25%	316%
Vertebroplasty/Kyphoplasty	NA	26,140 (1.1%)	88,900 (1.9%)	240%	NA
Per 100,000 Medicare beneficiaries	-	65	205	218%	-
Intrathecal implantable pumps	5,000 (0.4%)	6,740 (0.3%)	7,240 (0.2%)	7%	45%
Per 100,000 Medicare beneficiaries	13	17	17	0%	29%
Spinal cord stimulators	5,640 (0.4%)	14,340 (0.6%)	39,280 (0.9%)	174%	596%
Per 100,000 Medicare beneficiaries	15	35	91	156%	518%
Other types of nerve blocks	356,540 (25.9%)	501,960 (20.3%)	656,340 (14.2%)	31%	84%
Per 100,000 Medicare beneficiaries	927	1,239	1,514	22%	63%
Total	1,377,000	2,472,920	4,610,360	86%	235%
Per 100,000 Medicare beneficiaries	3,580	6,106	10,638	74%	197%

Source: Manchikanti L, Singh V, Pampati V, Smith HS, Hirsch JA. Analysis of growth of interventional techniques in managing chronic pain in Medicare population: A 10-year evaluation from 1997 to 2006. *Pain Physician* 2009; 12:9-34 (15).

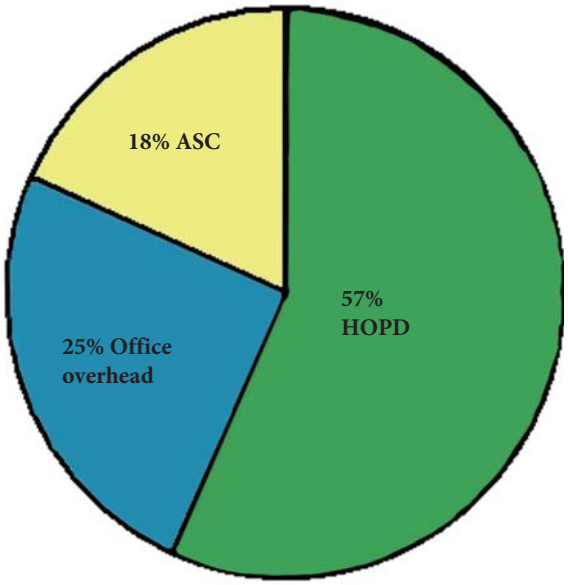


Fig. 11. *Medicare payments for facility services by type of facility in 2006.*

In 2006, HOPD total facility charges were approximately $780 million compared to overall facility expenditures for IPM services of 1.4 billion — 57% (Fig 11) (102). In comparison, Medicare benefit payments by type of service in 2006 were 5% for HOPD services, an 11.4-fold difference compared to all IPM services (102).

3.0 Evolution of Asc Payment Systems

In June 1998, the proposed ASC rule was so drastic for interventional pain management that the only remaining procedures that could be performed in ASCs were epidural injections and neurolytic lumbar facet joint nerve blocks (147). Based on public comments and demand, Congress intervened and the proposed rule was delayed for several years. During this period, multiple new codes were developed to describe interventional pain management and the procedures appropriately. In 2000, CMS, at the request of the American Society of Interventional Pain Physicians (ASIPP), added 9 replacement codes to the approved procedure list.

Subsequent publication of the final rule (of the 1998 proposed rule), which appeared in 2002 preserved all the interventional procedures and, in fact, added a few others (64). A subsequent rule in 2005 was also based on an old payment system (148). Medicare's initial ASC payment rates were based on ASC costs and charge data from 1979 and 1980 (64). CMS was required by law to review the ASC payment rates periodically and adjust them as appropriate. CMS last revised the ASC payment rates in 1990, using ASC data on costs and charges that CMS collected in 1986 (64). Since the payment rates were last revised, there has been substantial growth in both the number of ASC facilities and procedures performed, as well as changes in medical practice and technology.

While the ASC setting was originally intended to be an alternative to hospital inpatient care, the procedures performed in ASCs are frequently performed in the HOPD setting. However, Medicare has paid ASCs and HOPDs through different payment systems. Until 2000, HOPD payment systems were based on charge data which was developed into OPPS. ASCs continue to be paid under the old system, whereas HOPD surgical procedures are paid under OPPS. Procedures performed in ASCs are placed into payment groups based on similar costs, whereas HOPD procedures are placed into payment groups known as Ambulatory Payment Classification (APC) groups, based on both cost and clinical similarity. In addition, the payment rates for HOPDs are revised annually based on cost and charge data included in reports. Hospitals are required to submit to CMS each year.

To address the issues, the MMA of 2003 requires the Government Accountability Office (GAO) to conduct a study that compares the relative costs of procedures performed in ASCs to the relative costs of procedures performed in HOPDs (3). Further, MMA granted broad statutory authority to the Secretary of HHS to design a new ASC payment system based on OPPS (3).

In August 2006, CMS published the OPPS and ASC proposed rule (149). CMS proposed a more significant expansion of the approved list of procedures that can be safely performed in an ASC setting. The rule (based on MMA, which has to be budget neutral) resulted in certain procedures increasing while many others showing decreases. The proposal will result in payments at a rate of 62% of HOPD payments for ASCs in 2007 and a blended formula of 50/50 ASC and HOPD payments for 2008.

In November 2006, the GAO released its report titled "Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System" (149). The GAO determined that the payment groups in the OPPS accurately reflect the relative cost of procedures performed in ASCs. The GAO's analysis also identified differences in the cost of procedures in the

2 settings. The median cost ratio among all ASC procedures was 0.39 and when weighted by Medicare claims, volume was 0.84. Thus, it was determined that costs of procedures in ASCs are substantially lower than the corresponding costs in HOPDs. CMS stated that the GAO's recommendation is consistent with its August 2006 proposed revisions to the ASC payment system (8).

In August 2007, CMS (150,151) issued a final rule revising the payment system for services furnished in ASCs. CMS stated that the ASC final rule expands beneficiary access to surgical procedures in ASCs and implements steps to make ASC payments more accurate, while aligning payments across Medicare's payment systems to encourage efficient and appropriate choices of outpatient settings for ambulatory surgical procedures. The final rule allowed ASCs to be paid for any surgical procedure that CMS determines does not pose a significant safety risk to Medicare beneficiaries when performed in an ASC and that is not expected to require an overnight stay. Consequently, the final rule added about 790 procedures for ASC payment beginning in CY2008. The proposed OPPS/ASC rule added several additional procedures, which would result in approximately 3,300 surgical procedures being covered under the revised ASC payment system.

Thus, in January 2008, Medicare began paying for facility services provided in ASCs — using a payment system based on the HOPD OPPS. Medicare also pays for the related physician services including surgery and anesthesia under the physician fee schedule. Like the OPPS, the new ASCs payment system sets payments for individual services using a set of relative rates, a conversion factor (or average payment amount), and adjustments for geographic differences in input services. The new ASC system was being phased in over 4 years, from 2008 to 2011.

4.0 Setting the Payment Rates

The relative weight for most procedures in the ASC payment system are based on the relative weights in the OPPS. These weights are based on the median cost of the service in that payment group. The ASC system uses a conversion factor or average payment amount (152) to translate the relative weights into dollar amounts. The ASC conversion factor is based on a percentage of the OPPS conversion factor. CMS sets this percentage to ensure budget neutrality: total payments under the new ASC payment system should equal total payments under the old ASC payment system. The 2010 ASC conversion factor was 16.1% of the OPPS conversion factor ($41.87) and it is $41.93 for 2011. The ASC rates were less than the OPPS rates because of the budget neutrality requirements.

CMS uses methods different from the ones described above to set ASC payment rates for new, office-based procedures; separately payable radiology services; separately payable drugs; and device intensive procedures. For new, office-based procedures or services that CMS began paying for in ASCs in 2008 or later that are performed in physician offices at least 50% of the time, payment is the lower of the ASC rate. Based on the methodology described in Fig. 12 are the practice expense portion of the physician fee schedule rate that applies when service is furnished in a physician's office, the amount which covers the equipment, supplies, non-physician staff, and indirect costs of a service. Further, CMS minimized financial incentives to shift services from physician offices to ASCs, by capping ASC rates at physician fee schedule rates. CMS also applied the same policy to separately payable radiology services. CMS applies the same policy to separately payable radiology services and also drugs, etc.

In addition, device-intensive procedures are defined as OPPS services where the device cost is packaged into the procedure payment and the cost of the device accounts for more than half of the total payments such as intrathecal infusion pumps or spinal cord stimulators. When these procedures are provided in ASCs, CMS divides the payment for these services into a device portion (which includes the cost of the device) and a non-device portion. CMS pays the ASC the same amount it would pay under the OPPS for the device portion of the service, but pays 62.1% of the OPPS amount for the non-device portion of the service.

CMS also adjusted input prices to account for geographic differences. CMS adjusts the labor portion of the ASC rate (50% by the hospital wage index). CMS does not adjust the non-labor portion, the remaining 50%. The labor portion of the rate is based on a survey of ASCs conducted by the GAO.

As in the OPPS, ASC payment rates are adjusted when multiple surgical procedures are performed during the same operating session. In this case, the ASC receives full payment only for the procedures with the highest payment rates; payments for the other procedures are reduced to one-half of their usual rates for all other procedures.

CMS updates the ASC relative weights annually based on changes to the OPPS procedure groups and

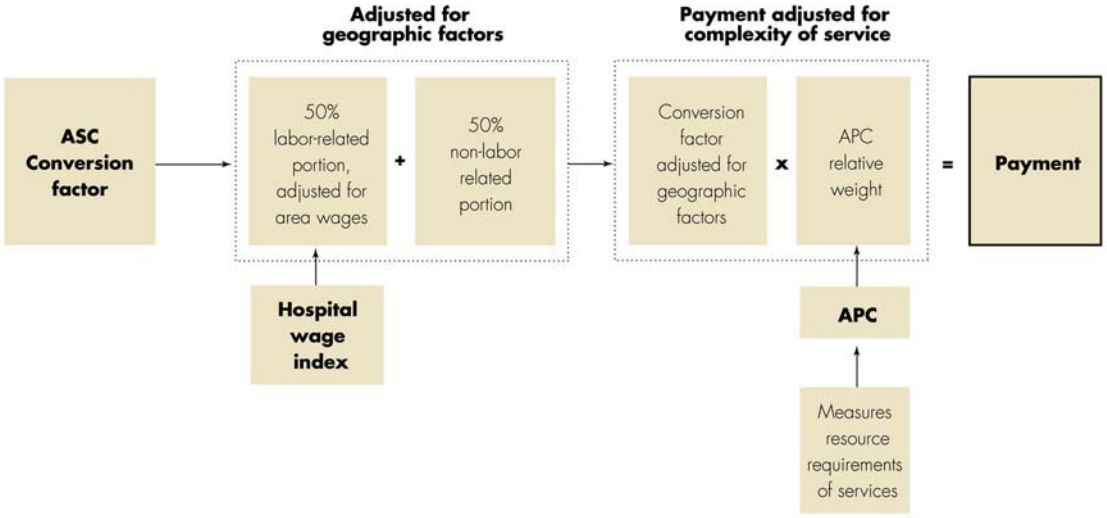


Fig. 12. *Ambulatory surgery center prospective payment system.*

Source: Ambulatory Surgical Centers Payment System: Payment basics. MedPAC. Revised October 2010. MedPAC. www.medpac.gov/documents/MedPAC_Payment_Basics_10_ASC.pdf (152).

the relative weights and the physician fee schedule practice expense amounts. CMS annually reviews and revises the OPPS procedure groups and their weights. The review considers change in medical practice and technology, the addition of new services, new outpatient cost data, and other information.

Using new OPPS relative weights could increase or decrease the total ASC spending, because CMS adjusts the new weights so that projected program spending based on the current mix of services does not change. To ensure that ASC spending does not change as a result of the new weights, CMS adjusts each ASC relative weight by the same factor. This factor in 2010 was 0.9567; in other words, each ASC weight was reduced by 4.3%. This factor in 2011 is 0.9090; in other words, each ASC weight is reduced by 4.98%. This effect is seen despite that in 2010, the ASC conversion factor was increased by 1.2%, based on the change in the consumer price index (CPI) for all urban consumers (CPI-U). The ACA of 2010 requires that, beginning in 2011, the annual update for ASC services (based on the CPI-U) will be reduced by a productivity adjustment which is somewhat similar to the sustained growth rate (SGR) (30,31).

However, in a document released by the ASC Coalition (102), it is described that HOPD and ASC payment policies cause ASC and HOPD rates to diverge with the HOPD update, the market basket, and is consistently larger than the ASC update, the CPI. A second budget neutrality adjustment (rescaler) of ASC weights erodes relationship to the HOPD rate. The ACA prevents the OPPS update from being negative as a result of the productivity adjustment (30,31). However, the same is not true for ASCs and rates could further diverge. Figure 13 shows exacerbation of underlying problems calculating the ASC rate as a percent of the HOPD rate which will reduce to 57% by 2011, which could eventually reduce further (153).

In the above figure, it was illustrated that the payments could reduce to 57% of HOPD by 2011; however the final schedule illustrates that ASCs will be paid, on average, 56% of what HOPDs would be for providing the same service. The changes in the rates for 2011 range from an 85% decrease to a 340% increase. However, the changes for the 10 most commonly performed procedures will vary only from a 7% decrease to a 2% increase and the rates for all but 2 of them will decline in 2011 compared to 2010 rates. These 10 highest volume procedures accounted for 57% of the total number of surgical procedures performed in ASCs in 2009. Among the top 10 procedures, the bottom 4 procedures are interventional techniques with lumbar interlaminar epidural, lumbar transforaminal epidural, and lumbar facet joint injections first and second levels. However, among the top 10 procedures, 2009 volume

was over 1.1 million for cataract surgery (CPT 66984) compared to the 10th code (CPT 64493), paravertebral facet joint injection, first level, of 127,783. All the codes combined were less than the number one code with less than 800,000 procedures (Table 4).

Figure 14 illustrates 2011 changes by specialty with almost all specialties seeing an increase at a maximum for 14% for otolaryngology, followed by gynecology and orthopedics about 12% increase, with decreases noted for 5.3% for gastroenterology, 0.1% for ophthalmology, and a 1% increase for IPM (154).

Figure 15 illustrates changes by specialty from 2008 to 2010. Fiscal year 2010 marked the third year of the new Medicare OPPS for ASCs. The 2010 rates were based on 25% historical ASC group or payment system and 75% on the new OPPS methodology, in contrast to 2011 which is 100% OPPS methodology. The highest volume ASC procedures, which all fell under the ophthalmology, gastroenterology, and pain management specialties, received declines in reimbursement between 2% and 26%, with an average decrease being 7%.

The rate changes for IPM for most commonly performed codes are as follows as illustrated in Table 5 with rate changes for ASCs for top IPM procedures which show a decrease of almost 70% for add-on codes and approximately 12% for primary codes. However, compared to 2010, 2011 payments have minimal changes for primary codes and significant changes, some codes due to secondary misvaluing by Medicare as high as 34%.

4.1 Reasons for Changes in Rates

Various reasons are described for the changes in rates including inflation increase and productivity reduction, changes in procedures' costs, changes in physicians' rates, wage index changes, patient cost-sharing waived for colorectal cancer screening, the expiration of new technology intraocular lens status, newly covered procedures, coding changes, and drugs biologics and radiologic changes. The final calculation appears to be 56% of HOPD instead of 62% as originally described. Figure 16 illustrates the growing discrepancy between ASC and HOPD rates from 2008 to 2011 (154).

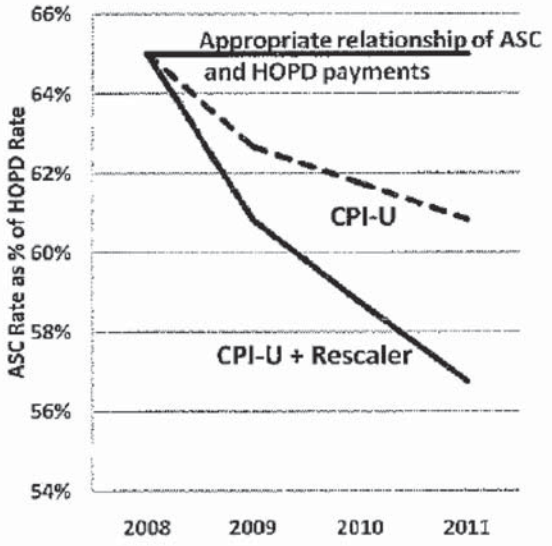


Fig. 13. *Declining ASC reimbursement compared to HOPD based on ACA.*

Source: Nueterra Health care. Building Partnerships. www.nueterrahealthcare.com (153).

Table 4. *Illustration of 2011 rate changes: Top 10 highest ASC volume procedures.*

CPT Short Descriptor		2009 Volume	2010 Rate	2011 Rate	Percent Change
66984	Cataract surg w/iol 1 stage	1,133,546	$961.34	$951.27	-1%
43239	Upper gi endoscopy biopsy	499,053	$369.03	$344.10	-7%
45380	Colonoscopy and biopsy	336,907	$379.80	$361.93	-5%
45378	Diagnostic colonoscopy	286,499	$379.80	$361.93	-5%
66821	After cataract laser surgery	271,776	$233.75	$217.37	-7%
45385	Lesion removal colonoscopy	270,310	$379.80	$361.93	-5%
62311	Inject spine l/s (cd)	228,424	$295.63	$294.00	-1%
64483	Inj foramen epidural l/s	226,979	$295.63	$294.00	-1%
64494	Inj paravert f jnt l/s 2 lev	191,097	$102.27	$103.38	1%
64493	Inj paravert f jnt l/s 1 lev	127,783	$288.11	$294.00	2%

Source: Medicare's 2011 payment rates Are you prepared? FOCUS November/December 2010. http://ascassociation.org/2011MedicareND2010.pdf (154)

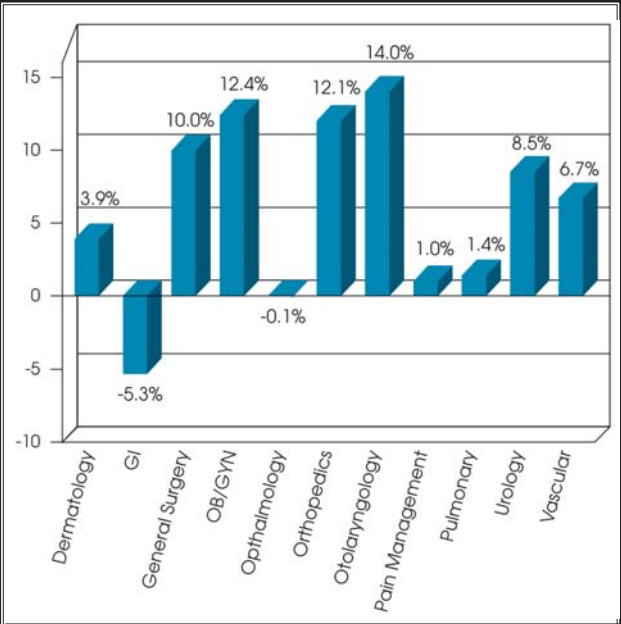


Fig. 14. *Illustration of 2011 change by specialty.*
Source: Medicare's 2011 payment rates – Are you prepared? FOCUS November/December 2010. http://ascassociation.org/2011MedicareND2010.pdf (154).

Even so, for 2011, the rates of all ASC procedures will be increased by 1.5% to account for inflation. The new health care reform law requires that ASC rates be further reduced across the board by a productivity adjustment. The productivity adjustment represents how much CMS estimates the average provider should save through anticipated productivity gains in the economy at large. Further, the health care reform law mandates that CMS apply a productivity adjustment to the Medicare rates of most providers including HOPD rates. However, HOPD rates are not subject to a full productivity adjustment until 2012. For 2011, this productivity adjustment means that all ASC procedures will be reduced by 1.3%. Combining this reduction with the 1.5% inflation increase results in a net increase of 0.2% to the rates of all ASC procedures in 2011.

Changes in procedures' costs are also taken into consideration. Each year, CMS adjusts the rates of ASC procedures to reflect the changes and the cost associated with performing those procedures. As the cost of performing a procedure goes up, Medicare pays more and conversely, as the cost of performing a procedure goes down, Medicare reduces the reimbursement. This

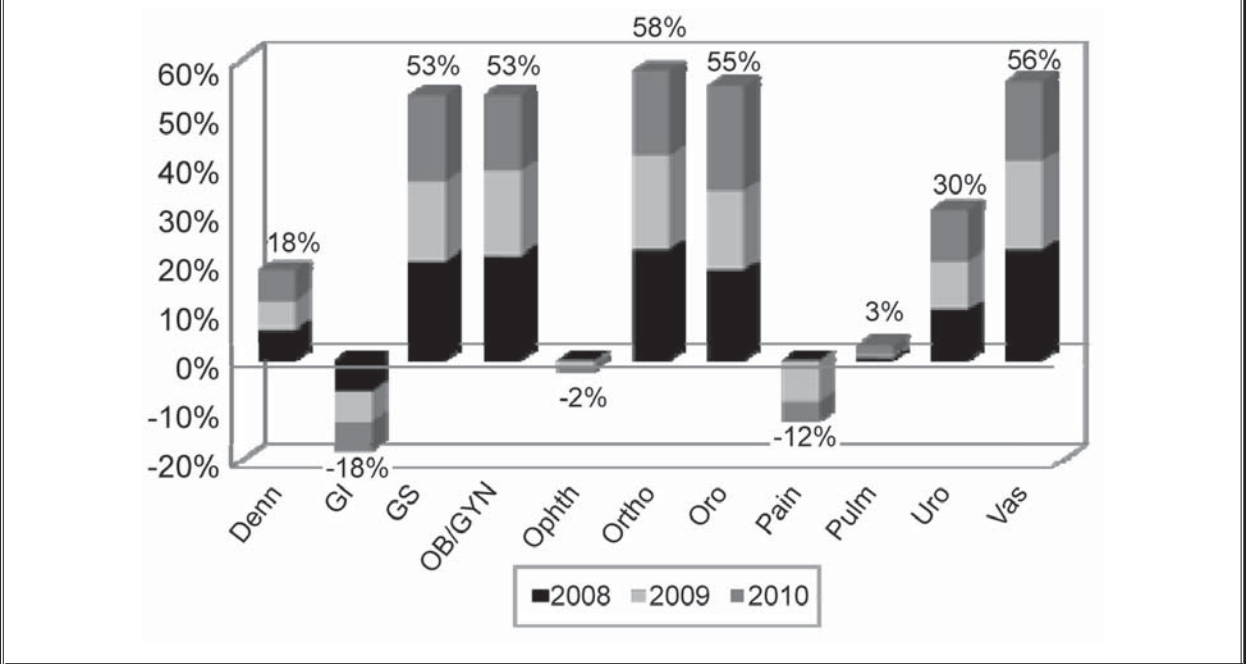


Fig. 15. *Changes by speciality of ASC payments from 2008 to 2010.*
Source: Intellimarker. Ambulatory Surgical Centers Financial & Operational Benchmarking Study. Fifth Edition. VMG Health, July 2010 (67).

Table 5. *Illustration of rate changes for ASCs for top interventional pain management procedures.*

CPT	Description	Payment Rates				
		2007	2010	2011	% of Change 2010	2011 Final from 2007
62263	Percutaneous epidural adhesiolysis -2 or 3 days	$333.0	$295.98	$294.00	-0.7%	-11.7%
62264	Percutaneous epidural adhesiolysis – 1 day	$333.0	$477.56	$495.72	3.8%	48.9%
62287	Disc decompression	$1,339.0	$1,440.35	$1,444.14	0.3%	7.9%
62310	Cervical epidural	$333.0	$295.98	$294.00	-0.7%	-11.7%
62311	Lumbar epidural	$333.0	$295.98	$294.00	-0.7%	-11.7%
62318	Epidural or subarachnoid, catheterization, C/T	$333.0	$295.98	$294.00	-0.7%	-11.7%
62319	Catheterization, epidural, L/S	$333.0	$295.98	$495.72	67.5%	48.9%
62350	Tunneled intrathecal or epidural catheter for long-term medication administration via an	$446.0	$1,339.38	$1,623.99	21.2%	264.1%
62355	Removal or previously implanted intrathecal or epidural catheter	$446.0	$504.58	$495.72	-1.8%	11.1%
62360	Implant or replacement of device for intrathecal or epidural drug infusion;	$446.0	$1,339.38	$1,623.99	21.2%	264.1%
62361	Implantation or replacement of device for epidural drug infusion; non-programmable	$446.0	$12,211.86	$12,221.29	0.1%	2640.2%
62362	Implant spine infusion pump	$446.0	$12,211.86	$12,221.29	0.1%	2640.2%
62365	Remove spine infusion device	$446.0	$1,223.77	$1,444.14	18.0%	223.8%
63650	Implant neuroelectrodes	$446.0	$3,495.96	$3,707.45	6.0%	731.3%
63685	Implant neuroreceiver	$446.0	$12,877.21	$13,816.04	7.3%	2997.8%
63688	Revise/remove neuroreceiver	$333.0	$1,354.69	$1,126.88	-16.8%	238.4%
64479	Cervical transforaminal epidural injections	$333.0	$295.98	$294.00	-0.7%	-11.7%
64480	Cervical on transforaminal epidural injections add-on	$333.0	$191.48	$150.41	-21.4%	-54.8%
64483	Lumbar/sacral transforaminal epidural injections	$333.0	$295.98	$294.00	-0.7%	-11.7%
64484	Lumbar/sacral transforaminal epidural injections add-on	$333.0	$191.84	$150.41	-21.6%	-54.8%
64490	Cervical and thoracic facet joint injections, 1st level (old 64470)	$333.0	$288.84	$294.00	1.8%	-11.7%
64491	Cervical and thoracic facet joint injections, 2nd levels (old 64472)	$333.0	$102.38	$103.38	1.0%	-69.0%
64492	Cervical and thoracic facet joint injections, 3rd Level	$333.0	$102.38	$103.38	1.0%	-69.0%
64493	Paravertebral facet joint or facet joint nerve; lumbar/sacral, 1st level (old 64475)	$333.0	$288.44	$294.00	1.9%	-11.7%
64494	Paravertebral facet joint or facet joint nerve; lumbar/sacral, 2nd level (old 64476)	$333.0	$102.38	$103.38	1.0%	-69.0%
64495	Paravertebral facet joint or facet joint nerve; lumbar/sacral, 3rd level	$333.0	$102.38	$103.38	1.0%	-69.0%
64622	Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, single level	$333.0	$477.56	$495.72	3.8%	48.9%
64623	Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, each	$333.0	$295.98	$294.00	-0.7%	-11.7%
64626	Destruction by neurolytic agent, paravertebral facet joint nerve; cervical or thoracic, single	$333.0	$295.98	$294.00	-0.7%	-11.7%
64627	Destruction by neurolytic agent, paravertebral facet joint nerve; cervical or thoracic, each	$333.0	$156.44	$103.38	-33.9%	-69.0%

adjustment is made in a budget neutral manner, meaning that any increase in the rate of procedures must be offset by a decrease in the rates of other procedures.

Wage index change is also an important factor in calculating ASC rates. CMS makes annual changes for the changes in the cost of wages; however, this is based on local reimbursement. Consequently, some areas will see significant changes in 2011, 38% of areas will have a 2011 wage index value within 1% of the 2010 values, more than 1% increase will be seen in 32% of the locations and more than 1% decrease will be seen in 30% of the locations.

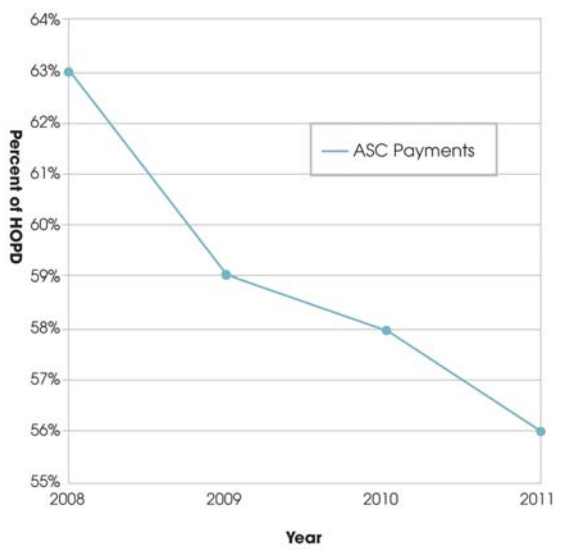


Fig. 16. *Illustration of the growing discrepancy between ASC and HOPD rates.*

Source: Medicare's 2011 payment rates – Are you prepared? FOCUS November/December 2010. http://ascassociation.org/2011MedicareND2010.pdf (154).

5.0 Changes of Conditions of Coverage

On August 31, 2007, CMS published proposed rules to revise the definitions of certain terms used, and also proposed to add several new regulations for ASCs pertaining to ASC governing body and management, evaluation of quality, laboratory and radiological services, patient rights, infection control, and patient admission, assessment, and discharge, to promote and protect patient health and safety (155-156). For the most part, the original regulations published in 1982 have not been changed.

Based on the final rule of November 18, 2008 for hospital OPPS and ASC payment final rule, theseincluded multiple other revisions that took effect on May 18, 2009 (157). They include:

- Revision of the definition of an ASC, adding language indicating that the expected duration of ASC services would not exceed 24 hours;
- Revisions to and reorganization of the Governing Body and Management Conditions for Coverage (CfC), including addition of explicit responsibilities for the quality assurance/performance improvement program and for a disaster preparedness plan;
- Revisions to the Surgical Services CfC concerning anesthetic risk and evaluation;
- Renaming of the Evaluation of Quality CfC as "Quality Assessment and Performance Improvement," and the addition of detailed regulatory standards;
- Reorganization of the Laboratory and Radiologic Services, and addition of a requirement for Radiologic services provided in the ASC to meet the Hospital Condition of Participation at 42 CFR 482.26;
- Addition of Patient Rights;
- Addition of Infection Control;
- Addition of Patient Admission, Assessment and Discharge.

Further, a more detailed guidance has been provided for existing regulations along with development of a detailed survey protocol which is more stringent than either the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Accreditation Association for Ambulatory Health Care (AAAHC). The protocol incorporates 2 improvements to the ASC survey process developed in a 2008 ASC pilot survey project: use of a detailed infection control survey instrument, and addition of a case observation or tracer component to the survey. In addition, it also calls for use in more cases of a two-person team to conduct the health portion of an ASC survey.

5.1 Basic Requirements

5.1.1 Definitions

Ambulatory surgical centers, or ASC, means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions.

According to the interpretive guidelines of the definition of an ambulatory surgical center, its key characteristics are that it is a distinct entity; operates exclusively for the provision of surgical services to patients not requiring hospitalization, with the ASC's services expected not to exceed 24 hours in duration following admission; has an agreement with Medicare to participate in an ASC; and complies with the conditions for coverage. The meaning of a distinct entity is that an ASC does not have to becompletely separate and distinct physically from another entity, if, and only if, it is temporally distinct. In other words, the same physical premises may be used by the ASC and other entities, as long as they are separated in their usages by time.

ASCs must offer only surgical services. Separate ancillary services that are integral to the surgical services, i.e., those furnished immediately before, during, or immediately after a surgical procedure, may be provided. The ASC may not, however, offer services unrelated to the surgeries it performs. Further, surgical services must be provided only to patients who do not require hospitalization after the surgery. Further, ASC surgical services must be ones that ordinarily would not take more than 24 hours, including not just the time for the surgical procedure, but also pre-op preparation and recovery time, following the admission of an ASC patient. These limitations apply to all of the ASCs surgical services, not just to surgeries on Medicare beneficiaries who use an ASC (157).

ASCs also should have an agreement with CMS to participate in Medicare as an ASC. Finally, an ASC must comply with each of the requirements found in the ASC manual.

5.1.2 Compliance with State Licensure Law

An ASC must comply with state licensure requirements. State licensure requirements generally exist for both health care facilities and health care professionals. States vary considerably in their licensure requirements for entities that meet the Medicare definition of an ASC. Some states may not require separate licensure of these facilities, although all states require licensure of health care professionals providing services within the ASC. Some states may require separate licensure for some, but not all ASCs within their state. Thus, in states where a separate facility license is required for a facility providing ambulatory surgical services, the ASC must have a current license that has not expired or been suspended or revoked. Finally, the ASC must also be in compliance with state licensure requirements (157).

5.2 Governing Body and Management

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASCs total operation. The governing body has oversight and accountability for the Quality Assessment and Performance Improvement (QAPI) program, ensures that the facility policies and programs are administered so as to provide quality healthcare in a safe environment, and develops and maintains a disaster preparedness plan (157).

The ASC must have a designated governing body that exercises oversight for all ASC activities. The governing body is responsible for establishing the ASC's policies, making sure that the policies are implemented, and monitoring internal compliance with the ASC's policies as well as assessing those policies periodically to determine whether they need revision. The regulation particularly stresses the responsibility of the governing body for:

- Direct oversight of the ASC's QAPI program;
- The quality of the ASC's health care services;
- The safety of the ASC's environment;
- Development and maintenance of a disaster preparedness plan.

In the case of an ASC that has one owner, that individual constitutes the governing body. Although the governing body may delegate day-to-day operational responsibilities to administrative, medical, or other personnel, the ASCs governing body retains the ultimate responsibility for the overall operations of the ASC and quality of its services. The regulation also emphasizes the governing body's responsibilities in the areas of QAPI and disaster preparedness. Delegations of governing body authority should be documented in writing. The governing body is responsible for creating a safe environment where ASC patients can receive quality health care services. This means the governing body is not only responsible for adopting formal policies and procedures that govern all operations within the ASC, but also that it must take actions to ensure that these policies are implemented. Through its direct oversight and accountability for the ASCs QAPI program, it is expected that the ASC is better able to improve care being furnished to its patients (157).

5.2.1 Contract Services

When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. ASCs may contract with third parties for provision of the ASC's services, including the ASCs environment. However, such a contract does not relieve the ASCs governing body from its responsibility to oversee the delivery of these ASC services. Given that many ASCs operate closely with a physician practice or clinic, or that some ASCs share space with other ASCs or other types of healthcare facilities operating at different times, use of a wide range of contract services may be common in ASCs. The ASC must assure that the contract services are provided safely and effectively. Contractor services must be included in the ASC's QAPI program.

5.2.2 Hospitalization

The ASC must have an effective procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the ASC; this hospital must be local. Further, this hospital must be a local Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services. Finally, the ASC must have a written transfer agreement with a hospital that meets Medicare requirements, or ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements.

The ASC must be able to transfer a patient immediately to a local hospital when the patient experiences a medical emergency that the ASC is not capable of handling, or which requires emergency care extending well beyond the 24-hour timeframe for ASC cases.

5.2.3 Disaster Preparedness Plan

The ASC must maintain a written disaster preparedness plan. The ASC coordinates the plan as appropriate. The ASC provides for the emergency care of patients, staff, and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC. The ASC coordinates the plan with State and local authorities, as appropriate. The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan (157).

The intent of disaster preparedness plan regulation is for an ASC to have in place a disaster preparedness plan to care for patients, staff, and other individuals who are on the ASC's premises when a major disruptive event occurs. The governing body of the ASC is responsible for the development of this plan.

A wide range of events could occur, and are considered in this category, such as fire, flood, mass release of a biochemical hazard, electrical failure, failure of the water supply, and failure of key equipment needed to sustain the operations of the ASC among others.

Comprehensive emergency management includes hazard identification, hazard mitigation, preparedness, response, and recovery.

The regulation also requires that the ASC must coordinate its disaster preparedness plan with state and local authorities that have responsibility for emergency management within the state.

5.3 Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

Surgery in an ASC may only be performed by a qualified physician. With respect to the ASCs, a physician is defined to include a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, and a doctor of podiatric medicine. In all cases, a physician must be licensed in the state in which the ASC is located and practicing within the scope of the license.

Further, the regulation also requires that each physician who performs surgery in the ASC has been determined to bequalified and granted privileges for the specific surgical procedures. The ASCs governing body is responsible for reviewing the qualifications of all physicians who have been recommended by qualified medical personnel and granting surgical privileges as the governing body determines appropriate.

The ASC must have written policies and procedures that address the criteria for clinical staff privileges in the ASC and the process that the governing body uses when reviewing physician credentials and determining whether to grant privileges and the scope of the privileges for each physician.

5.3.1 Anesthetic Risk, Evaluation, and Discharge

A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range a patient having that procedure in an ASC, given that the ASC does not provide services to patients requiring hospitalization.

The assessment must be specific to each patient; it is not acceptable for an ASC to assume, for example, that coverage of a specific procedure by Medicare or an insurance company in an ASC setting is a sufficient basis to conclude that the risks of the anesthesia and surgery are acceptable generically for every ASC patient. The requirement for a physician to examine the patient immediately before surgery is not to be confused with the separate requirement for a pre-admission history of physical assessment performed by a physician,

although it is expected that the physician will review the materials from such a pre-admission examination as part of the evaluation. Consequently, the ASC must have approved policies and procedures to assure the assessment of anesthesia-related and procedural risks is completed just prior to every surgical procedure.

If a state establishes licensure limitations on the type of procedures an ASC may perform that are based on patient classifications and would permit ASCs to perform fewer procedures than they would under the Medicare requirements, then the ASC must conform to those state requirements.

Next, before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist, in accordance with the applicable state health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery. This part of the evaluation of the patient's recovery from anesthesia, to determine whether the patient is recovering appropriately, must be completed and documented before the patient is discharged from the ASC.

5.3.2 Administration of Anesthesia

Administration of anesthesia must only be by a qualified anesthesiologist or a physician qualified to administer anesthesia, a certified nurse anesthetist, or an anesthesiologist's assistant, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist. However, an ASC may be exempted from the requirements for physician supervision of CRNAs, if the state is exempted by CMS and the governor of that state opts out.

5.4 Quality Assessment and Performance Improvement

The ASC must develop, implement, and maintain an ongoing, data-driven QAPI program. The QAPI requires an ASC to take a proactive, comprehensive and ongoing approach to improving the quality and safety of the surgical services it delivers. The QAPI presumes that ASCs employ a systems approach to evaluating their systems and processes, identifying problems that have occurred or that potentially might result from the ASCs practices and getting to root causes of problems rather than just superficially addressing one problem at a time.

The scope of the program must include, but not limited to, an ongoing program – i.e., the program is a continuing one, not just a one-time effort. Evidence of this would include, but is not limited to, things like collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems identified in the analyses, as well as new data collection to determine if the corrective actions were effective. The program should also be data-driven – i.e., the program must identify in a systematic manner what data it will collect to measure various aspects of quality of care; the frequency of data collection; how the data will be collected and analyzed; and evidence that the program uses the data collected to assess quality and stimulate performance improvement.

The organization must set priorities for the program activities and for its performance improvement that focus on high risk, high volume, and problem-prone areas; consider incidence, prevalence, and severity of problems in those areas; and affect health outcomes, patient safety, and quality of care.

The program must incorporate quality indicators data, including patient care and other relevant data regarding services furnished in the ASC. Further, the ASC must use the data collected to monitor the effectiveness and safety of its services and quality of its care; and identify opportunities that could lead to improvements and changes in its patient care.

The program activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. In addition, the ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

Consequently, the ASC must not only have identified a number of indicators or measures of quality and patient safety, but it must actively collect data related to those measures at the intervals called for by its QAPI program. Staff responsible for collection of the data should be trained in appropriate techniques to collect and maintain the data.

Performance improvement projects conducted annually must reflect the scope and complexity of the ASC services and operations. In addition, the ASC must document the projects that are being conducted with documentation at a minimum to include reasons for implementing the project and a description of the projects results.

With reference to the QAPI program the governing body has multiple responsibilities. It must ensure that the

QAPI program is defined, implemented, and maintained by the ASC; addresses the ASC's priorities and that all improvements are evaluated for effectiveness; specifies data collection methods, frequency, and details; clearly establishes its expectations for safety; and adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

5.5 Environment

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients. The ASC must comply with requirements governing the construction and maintenance of a safe and sanitary physical plant, and safety for fire and emergency equipment, and emergency personnel. With regard to physical environment, the ASC must provide a functional and sanitary environment for the provision of surgical services. Further, the ASC must have a separate recovery room and waiting area, thus, the ASC is required to have both a waiting area and a recovery room, which must be separate from each other as well as other parts of the ASC. This may not be shared with another health care facility or physician office during operating hours.

The physical environment also includes that the ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities. Thus, ASCs are required to have a program to follow-up on each patient after discharge, in order to identify and track infections associated with the patient's stay in the ASC.

The ASC must also establish safety regulations from fires meeting the provisions applicable to ambulatory health care centers in the 2000 edition of the Life Safety Code of the National Fire Protection Association (NFPA), regardless of the number of patients serviced. However, in consideration of a recommendation by a state survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship upon an ASC, but only if the waiver would not adversely affect the health and safety of the patients. The ASC also must be in compliance with the emergency lighting code.

Because ASCs are not permitted to provide care to patients exceeding 24 hours, there are, for purposes of compliance with the NFPA Life Safety Code, requirement, subject to a combination of health care and business occupancy requirements. They are, therefore, unlike hospitals and other facilities that keep patients more than 24 hours, which are considered health care occupancies.

TheASC also must have emergency equipment available to the operating room, at least which includes an emergency call system; oxygen; mechanical ventilator assistance equipment including airways, manual breathing bag, and ventilator; cardiac defibrillator; cardiac monitoring equipment; tracheostomy set; laryngoscope and endotracheal tubes; suction equipment; and emergency medical equipment and supplies specified by the medical staff.

AThe ASC must provide personnel trained in the use of emergency equipment and cardiopulmonary resuscitation must be available whenever there is a patient in the ASC. Whenever there is a patient who has been registered in the reception area and not yet discharged from the ASC, including patients in the waiting area, in pre-operative preparation, and surgery, or in the recovery room, the ASC must also have clinical personnel present who have appropriate training and competence in the use of the required emergency equipment and supplies.

5.6 Medical Staff

The CMS rules that regulate the medical staff of the ASC must be accountable to the governing body. The organization of the medical staff is left to the discretion of the governing body, but however the staff is organized, the ASC must have an explicit written policy that indicates how the medical staff is held accountable by the governing body. The policy must address all of the requirements. Medical staff privileges may be granted both to physicians and non-physician practitioners, consistent with their permitted scope of practice in the state, as well as their training and clinical experience.

It is also possible for an ASC to be owned and operated by one physician, who could be both the sole member of the governing and also the sole member of the ASC's medical staff. However, in such cases, the physician owner must nevertheless implement a formal process for complying with all medical staff regulatory requirements.

In reference to membership and clinical privileges, members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

With reference to reappraisals, medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

In reference to other practitioners on the medical staff, if the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

5.7 Nursing Services

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

The ASC must ensure that the nursing service is directed under the leadership of a registered nurse. The ASC must have documentation that it has designated an RN to direct nursing services.

There must be sufficient nursing staff with appropriate qualifications to assure the nursing needs of all ASC patients are met. This implies that there is ongoing assessment of patients' needs for nursing care, and that identified needs are addressed. The number and types of nursing staff needed will depend on the volume and types of surgery the ASC performs.

In reference to organization and staffing of nursing, patient care responsibilities must be delineated.

5.8 Medical Records

The ASC must maintain complete, comprehensive, and accurate medical records to assure adequate patient care.

The ASC must have a complete, comprehensive and accurate medical record for each patient. Material required under other conditions, such as the history and physical examination, or documentation of allergies to drugs and biologicals, must be incorporated into the medical record in a timely fashion. The ASC must use the information contained in each medical record in order to assure that adequate care is delivered to each ASC patient. The ASC must ensure the confidentiality of each patient's medical record.

The ASC must review a sample of active and closed medical records for completeness and accuracy in accordance with federal and state laws and regulations and ASC policy. If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form.

The organization of medical records puts responsibility on the ASC to develop and maintain a system for the proper collection, storage, and use of patient records.

The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

(1) Patient identification;
(2) Significant medical history and results of physical examination;
(3) Pre-operative diagnostic studies (entered before surgery), if performed;
(4) Findings and techniques of the operation including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body;
(5) Any allergies and abnormal drug reactions;
(6) Entries related to anesthesia administration;
(7) Documentation of properly executed informed patient consent;
(8) Discharge diagnosis.

5.9 Pharmaceutical Services

The regulations state that the ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

In reference to administration of drugs, drugs must be prepared and administered according to established policies and acceptable standards of practice.

In addition, adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

Further, blood and blood products must be administered only by a physician or registered nurses.

Finally, orders given orally for drugs and biologicals must be followed by a written order that is signed by the prescribing physician.

5.10 Laboratory and Radiological Services

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory meeting CMS requirements.

In reference to radiological services, the ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients, radiological services must meet the hospital's conditions of participation for radiological services. The radiological services must be provided in a safe manner.

The radiologic services, particularly ionizing radiology services, must be free from hazards for patients and

personnel. Thus, proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials. Periodic inspection of equipment must be made and hazards identified must be properly corrected.

Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with state law, of other practitioners authorized by the medical staff and the governing body to order the services.

The medical staff must establish, in accordance with CMS regulations and other federal and state laws, regulations and guidelines, the qualifications necessary for radiologist's appointment to the medical staff.

A qualified full-time, part-time or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. Further, only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

5.11 Patient Rights

The ASC must inform the patient, or the patient's representative, of the patient's rights and must protect and promote the exercise of such rights.

1) In addition, the ASC must provide the patient or patient's representatives' with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands.

(i) In addition, the ASC must post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the state agency to whom patients can report complaints, as well as the website for the Office of the Medicare Beneficiary Ombudsman.

ii) The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.

2) In reference to advance directives, the ASC must comply with the following requirements: (i) Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable state health and safety laws and, if requested, official state advance directive forms. (ii) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care. (iii) Document in a prominent part of the patient's current medical record whether or not the individual has executed an advance directive.

3) The ASC must have a procedure for submission and investigation of grievances:

(i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC;

(ii) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(iii) All allegations must be immediately reported to a person in authority in the ASC;

(iv) Only substantiated allegations must be reported to the state authority or the local authority, or both.

(v) The grievance process must specify timeframes for review of the grievance and the provisions of a response. (vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished;

(vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed;

The ASC must establish the exercise of rights and respect for property and person with the patient having the right to exercise his or her rights without being subjected to discrimination or reprisal. Further, they must be facilitated towards grievances regarding treatment or care that is furnished. Patients must be fully informed about a treatment or procedure and the expected outcome before it is performed.

If a patient is adjudged to be incompetent under ap-

plicable state health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under state law to act on the patient's behalf. If a state court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law.

The ASC must also protect patient privacy and safety, recognizing that the patient has the right to personal privacy and receive care in a safe setting. Further patient must be free from all forms of abuse or harassment and confidentiality of clinical records must be maintained.

5.12 Infection Control

The ASC must maintain an infection control program that seeks to minimize infections and communicable disease. This regulation requires the ASC to maintain an active program for the minimization of infections and communicable diseases. The ASCs infection control program must:

- Provide a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases;
- Be based on nationally recognized infection control guidelines;
- Be directed by a designated health care professional with training in infection control;
- Be integrated into the ASCs QAPI program;
- Be ongoing;
- Include actions to prevent, identify and manage infections and communicable diseases, and
- Include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC.

The ASC must maintain ongoing infection control program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

The ASC's infection control program must be under the direction of designated and qualified professional who has training in infection control.

The infection control program must be an integral part of the ASCs QAPI program and it must be responsible for providing a plan of action for preventing, identifying, and managing infections and communicable disease and for immediately implementing corrective and preventive measures that result in improvement.

5.13 Patient Admission, Assessment, and Discharge

The ASC's must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

The core objectives of this condition are to ensure that:

- The patient can tolerate a surgical experience;
- The patient's anesthesia risk and recovery are properly assessed;
- The patient's post-operative recovery is adequately evaluated;
- The patient received effective discharge planning;
- The patient is successfully discharged from the ASC.

In reference to admission and pre-surgical assessment, not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician or other qualified practitioner in accordance with applicable state health and safety laws, standards of practice, and ASC policy. Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable state health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals.

In addition, the patients' medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure. In addition, the patient's post-surgical condition must be assessment assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable state health and safety laws, standards of practice, and ASC policy, and post-surgical needs must be addressed and included in the discharge notes.

The ASC must provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup appointment with the physician, and ensure that all patients are informed,

either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for followup care.

Further, the ASC must ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable state health and safety laws, standards of practice, and ASC policy.

Finally, the ASC must ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.

6.0 Surgical Procedures

CMS defines a surgical procedure as any procedure described within the range of Category I Current Procedural Terminology (CPT) codes that the CPT Editorial Panel of the AMA defines as surgery, surgical procedures described by Level II Healthcare Common Procedure Coding System (HCPCS) codes, or by Category III CPT codes. The Level II HCPCS codes or category III CPT codes must be directly crosswalked or be clinically similar to procedures in the CPT surgical range that CMS has determined do not pose a significant safety risk and do not require an overnight stay when performed in an ASC. CMS also defines covered surgical procedures as those procedures for which payment is made under the revised ASC payment system.

6.1 Covered Surgical Procedures

CMS had identified surgical procedures eligible for an ASC. They exclude those surgical procedures that are on the OPPS inpatient list, procedures that are packaged under the OPPS, CPT unlisted surgical procedure codes, and surgical procedures that are not recognized for payment under the OPPS. CMS excludes procedures that standard medical practice dictates are expected to require active medical monitoring and care at midnight following the procedure or overnight stay as well as procedures that could pose a significant safety risk. Procedures identified as posing a significant safety risk when performed in an ASC include those that result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, are emergent or life threatening in nature, or commonly require systemic thrombolytic therapy.

Covered surgical procedures have been updated for each year in 2007, 2008, 2009, 2010, and 2011.

Even though providers have repeatedly requested for expansion of the list and without restrictions, CMS reasserted that they are continuing their established policies without modification for determining which procedures are ASC covered surgical procedures.

Medicare recognizes Category I CPT codes, Category III CPT codes, and Level II HCPCS codes, which are used when approved. CPT and HCPCS code changes that affect ASCs are addressed both through ASC quarterly update change requests (CRs) and through the annual rule making cycle. CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the American Medical Association (AMA) and makes these codes effective outside of the formal rule making process via ASC quarterly update CRs. Consequently, Medicare finalized the policy in the November 24, 2010, final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations of the annual OPPS-ASC final rule with a comment period regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether they are office-based procedures (97). CMS has included multiple interventional codes (CPT 0228T to 0231T), which include multiple transforaminal epidural injections CPT 64479-64484 and also include facet joint nerve blocks CPT 64490-64495 under ultrasound. In addition, for 2011, CMS also added 6 new codes.

Further, CMS also refused to add CPT codes 63001 to 63076 describing laminectomy, laminotomy, discectomy, etc., stating that there was a safety risk. In this process, CMS also has designated multiple ASC covered surgical procedures designated as device-intensive received by 2011 which included CPT codes 61885 through 64581 involving multiple implantables for interventional pain physicians.

6.2 Policy and Payment Recommendations

The March 2010 Medicare Payment Advisory Commission (MedPAC) report to the Congress Medicare Payment Policy included multiple recommendations specifically for the ASC payment system in 2011. This recommendation stated that Congress should implement a 0.6% increase in payment rates for ASC services in CY 2011 concurrent with requiring ASCs to submit cost and quality data. CMS decided not to require ASCs to submit cost data to the secretary for CY 2011; however, they stated their intention to implement ASC quality reporting in a future rule making. Further, the ACA requires CMS to develop a plan on implementing a value-based purchasing program for ASCs that will consider measures of quality and efficiency in ASCs, among

other requirements (30). CMS is requiring a plan to implement an ASC value-based purchasing program to Congress, as required by the ACA (158-161).

7.0 Impact of Stark Rules

The CMS rules for the physician fee schedule expanded Stark regulations, which may also affect ASC, even so, Stark has not imposed any restrictions on ASCs (150,154,162). Some of the key concepts relevant to ASCs include anti-markup rules, under arrangements, percentage-based compensation, and per-click arrangements.

Investment in an ASC must comply with the federal Anti-Kickback statute's safe harbor provisions. The Anti-Kickback statute prohibits anyone from offering, paying, soliciting, or receiving any remuneration in exchange for the referral of Medicare or Medicaid business. The Anti-Kickback Statute contains certain exceptions, known as safe harbors, which allow conduct that would otherwise violate the statute. The Safe Harbor for investments in ASCs has 4 categories: surgeon owned ASCs; single specialty ASCs; multi-specialty ASCs; and hospital/physician ASCs. Safe Harbor protection requires full compliance with all of the standards of any one category. The standards require, in part, that each physician investor (1) be in a position to refer patients directly to the ASC and perform surgery on such referred patients; (2) derive at least one-third of his medical practice income from procedures he performs at the ASC and (3) perform at least one-third of the procedures that may be performed in an ASC setting at the investment entity ASC if the investment is in a multi-specialty ASC.

Anti-markup rules pertain to several types of imaging services and reassignment from a full-time employee and amounts charged, which cannot include any space or equipment lease payments, etc., that may have some effect on ASCs.

Under arrangments might have some effect on ASCs, as well as hospitals. CMS has essentially stated that most of the existing under arrangements and per-click models would be deemed illegal under the new Stark III rules. The Stark Act previously defined "entity" as the person or entity that presented the claim to Medicare, not the person or entity actually performing the designated health service. This allowed physicians to have a financial relationship with the entity performing the service, such as a joint venture, but not with the entity billing for the service such as a hospital, without implicating the Stark Act. However, the proposed rules have expanded the definition of "entity" to include either the person or entity that presented the claim to Medicare or the person or entity actually performing the designated health service. Thus, it appears that any type of relationship will implicate the Stark Act prohibitions.

Percentage-based compensations are also restricted. These payments would not be acceptable for any type of exceptions under the Stark Act, except for percentage-based relations, which may still be acceptable to determine payments for direct physician services. Thus, percentage-based equipment and office space leases could potentially be considered as program abuse, along with other arrangements that go beyond direct physician services.

The rule also provides limitations on per use or per-click space and equipment leases and such arrangements, which may have significant effects on ASCs. Thus, per unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor or lessor to the lessee.

8.0 Waste, Abuse, And Fraud

The Department of Justice released on February 7, 2011, the largest health care fraud takedown thus far, with more than 110 physicians, nurses, and other dependents from 9 cities being charged for their alleged participation in Medicare fraud schemes involving more than $225 million in false billing (107). Medicare Fraud Strike Force operations are part of the Health Care Fraud Prevention & Enforcement Action Team (HEAT), a joint initiative announced in May 2009 between the Department of Justice (DOJ) and Health and Human Services (HHS) to focus their efforts to prevent and deter fraud and enforce current anti-fraud laws around the country. Since their inception in March 2007, Strike Force operations in 9 districts have charged more than 990 individuals who collectively have falsely billed the Medicare program for more than $2.3 billion. In addition, the HHS and CMS, working in conjunction with the OIG-HHS, are taking steps to increase accountability and decrease the presence of fraudulent providers.

In a report from September 2008, OIG-HHS, reported that Medicare paid over $2 billion in 2006 for interventional pain management (interventional pain management procedures) (103). This report also showed that from 2003 to 2006, the number of Medicare claims for facet joint injections increased by 76% (103). Overall, payments for facet joint injections increased from $141 million in 2003 to $307 million in 2006, represent-

Table 6. *Improperly paid Medicare facet joint injections services, physician claims, 2006.*

	Sample		Projected	
Type of Error	**Services**	**Allowed Amount**	**Services**	**Allowed Amount**
Documentation	196	$35,835	38%	$81 million
Coding	173	$11,670	31%	$21 million
Medical Necessity	43	$7,394	8%	$17 million
(Overlapping Errors)	(71)	($12,247)	(14%)	($23 million)
Total	341	$42,651*	63%	$96 million

Source: OIG analysis of medical review results, 2008 (105).
* Numbers do not sum to total because of rounding.

ing both physician and facility payments. Friedly et al (19) documented that between 1994 and 2001, there was a 271% increase in lumbar epidural steroid injections and a 231% increase in facet joint injections. They also showed that the total inflation-adjusted reimbursement cost (professional fees only) for lumbosacral injections increased from $24 million to over $175 million. The findings of the OIG report (103) also illustrated that 63% of facet injection services allowed by Medicare in 2006 did not meet the Medicare program requirements, resulting in approximately $96 million in improper payments. Medicare also allowed an additional $33 million in improper payments for associated facility claims. Facet joint injection services provided in an office were more likely to have an error than those provided in an ASC or HOPD. The error rates were lower in a facility setting compared to an office setting (51% versus 71%). Further, based on specialty error, the rate in an office setting, interventional pain management -09 scored the best with a 12% error rate, whereas several specialties scored a 100% error rate. Anesthesiology had a 63% error rate, pain medicine (-72) a 56% error rate, and physical medicine and rehabilitation a 50% error rate. Tables 6-8 illustrate the errors in 2006 in the Medicare population for facet joint injections. Finally, the OIG report also illustrated that approximately 35% of Medicare facet joint injections were performed by non-interventional pain physicians, 19% by general practitioners, internists, and family practice physicians, while the remaining 16% were performed by orthopedic surgeons, neurologists, and rheumatologists.

Manchikanti et al (99) showed overall increases in IPM services were 74% per 100,000 Medicare beneficiaries from 2002 to 2006. However, for general physicians, the increases were 349%, compared to 69% for interventional pain management and 40% for other specialties. Consequently, the yearly increase for general physicians was 87.3%, whereas it was 17.3% for interventional pain management. Overall, the increase of interventional techniques has been shown to be 234% over a period of 10 years from 1998 to 2008 with an annual increase of 23.4% as illustrated in Fig. 17.

Table 7. *Error rate by setting and error type for Medicare facet joint injection services—physician claims, 2006.*

Type of Error	Office	Facility
Documentation	49%	22%
Coding	30%	32%
Medical Necessity	10%	5%
Any Error	71%	51%

Source: OIG analysis of medical review results, 2008 (105).

The OIG also published a report on inappropriate Medicare payments for transforaminal epidural injection services which reported that 34% of transforaminal epidural injection services allowed by Medicare in 2007 did not meet Medicare requirements, resulting in approximately $68 million in improper payments (104). The number of Medicare physician claims for transforaminal epidural injection services increased by 130% from 2003 to 2007. Over 295,000 Medicare beneficiaries received transforaminal epidural injection services in 2007. Nineteen percent of transforaminal epidural injection services had a documentation error, which was more likely to occur in office settings. Thirteen percent of transforaminal epidural injection services had a medical necessity error, 8% had a coding error, while 7% had an overlapping error.

From 2003 to 2007, Medicare physician payments for transforaminal epidural injections, increased by almost 150%. Physician payments for transforaminal

Table 8. *Physician specialty error rate in an office setting for sample.*

		Any Error in Office*		Services in Office*		
Specialty	Specialty Code	Sample Frequency	Sample Percentage	Sample Frequency	Sample Percentage	Percentage of Services With an Error in Office
Neurosurgery	14	3	2%	3	1%	100%
General Surgery	02	1	1%	1	0%	100%
Pathology	22	1	1%	1	0%	100%
Nurse Practitioner	50	1	1%	1	0%	100%
Emergency Room	93	1	1%	1	0%	100%
Physician Assistant	97	1	1%	1	0%	100%
General Practice	01	36	25%	37	18%	97%
Internal Medicine	11	13	9%	15	7%	87%
Family Practice	08	7	5%	9	4%	78%
Neurology	13	8	6%	11	5%	73%
Rheumatology	66	5	4%	7	3%	71%
Pediatric Medicine	37	2	1%	3	1%	67%
Orthopedic Surgery	20	9	6%	14	7%	64%
Anesthesiology	05	30	21%	48	23%	63%
Pain Management	72	14	10%	25	12%	56%
Physical Medicine and Rehabilitation	25	8	6%	15	7%	53%
Interventional Pain Management	09	2	1%	17	8%	12%
Diagnostic Radiology	30	0	0%	1	0%	0%

* Figures are based only on the sample and are not projected to the population.
Source: OIG analysis of medical review results, 2008 (51).

epidural injections increased from $57 million in 2003 to $141 million in 2007. These payments represent approximately 11% of all Medicare physician payments for interventional pain management services.

Another fraud and abuse prevention effort is the creation of Recovery Audit Contractors (RACs) for Medicare and Medicaid. The RACs detect and correct past improper payments so that CMS and carriers, Fiscal Intermediaries (FIs), and Medicare Administrative Contractors (MACs) can implement actions that will prevent future and improper payments. This is expected to result in providers avoiding submitting claims that do not comply with Medicare rules, leading to CMS lowering its error rate, and protecting taxpayers and future Medicare beneficiaries. This program now has been extended to Medicaid. RAC legislation is based on the MMA (3), Section 306 and Tax Relief and Health Care Act of 2006, Section 3002 (4), which required a permanent and nationwide RAC program by no later than 2010. Further, both statutes gave CMS the authority to pay the RACs on a contingency fee basis. RACs review claims on a post-payment basis. However, RACs will not be able to review claims paid prior to October 1, 2007, even though RACs will be able to look back 3 years from the date the claim was paid.

9.0 Current Issues Facing And Future Of Ambulatory Surgery Centers

With the beginning of 2011, ambulatory surgery centers have entered a period of declining reimbursement, increasing regulatory changes in environment, and new ownership models.

Across the country, ASCs are facing rapidly declining reimbursement rates – a problem that many facilities unfortunately lack the negotiating clout to reverse. Further, some states are currently introducing legislations that could lower reimbursement rates even further.

With enactment of ACA, numerous changes may be on the horizon.

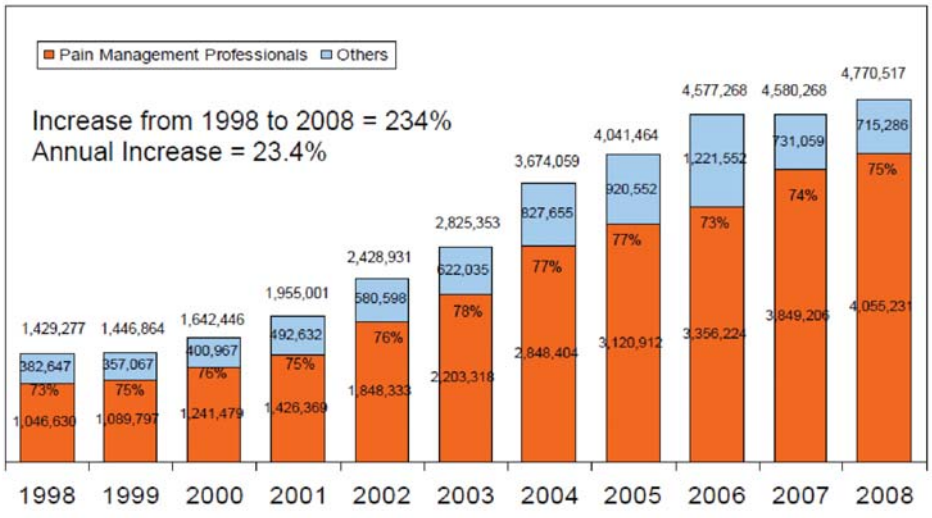


Fig. 17. *Illustration of overall increase of interventional techniques from 1998 to 2008.*

9.1 Value-Driven Health Care

The Institute of Medicine (IOM) report on medical errors, in confluence with ongoing concerns of health care costs and hyperinflation, consolidated efforts to improve health care quality and galvanized purchases and providers alike, which led to the development of quality measures tied to reimbursement (81). President George W. Bush endorsed the need for transparency and high quality in health care (163), with then Secretary of Health and Human Services, Michael Leavitt, expanding on the "cornerstones of value-driven health care" (164). The 4 cornerstones described by the Secretary of Health and Human Services in 2007 included health information technology (IT) standards, quality standards, price standards, and incentives.

9.1.1 Health Information Technology Standards

The available evidence supports the use of standardized electronic health records (EHRs) transmissible across different care and reimbursement settings to benefit consumers, providers, and purchasers by reducing errors, service duplication, and cost (165,166). While a national health information network, the idealized implementation of this interoperable IT, has been estimated to require $400 billion in capital investment and 5-year operating costs (167), there is a general lack of support for the government to underwrite the cost (168), plus there is no proven track record (167,168). Instead, initially the federal government has advanced work toward achieving health information flow through setting standards and other quality initiatives and plans to use its purchasing power to award future contracts to providers that meet health IT standards. Multiple advantages of electronic documentation in ambulatory surgery centers has been described (169). In a national health statistics report (170), it was shown that 62.4% of hospital-based ambulatory surgery centers reported using electronic medical record (EMR) systems, almost triple the percentage reported by free standing ASCs (22.3%). The American Recovery and Reinvestment Act (ARRA) of 2009 (171-173) may accelerate the pace of EHR adoption by health care providers, because it includes funding to promote adoption and use of EHR systems. Starting in 2011, physicians who can demonstrate meaningful use of interoperable systems may receive extra Medicare payments over 5 years.

9.1.2 Quality Standards

Measuring and reporting quality data is an integral part of health care in all settings. Regarding quality standards, ASCs provide high quality care with better patient outcomes, low infection rates, over 90% patient satisfaction, and comprehensive regulatory standards (102). Further, ASCs have shown significant transparency working with CMS to develop quality measures and adapting voluntary public reporting of outcomes. Based on a 2008 ASC Association outcomes monitoring project, 56% of ASCs reported no infections, whereas post-surgical wound infection rates per patient encounters were extremely low in 44% of the surgery centers.

However, in an evaluation of infection control assessment of ASCs (174), evaluating 68 ASCs out of over 5,000, (32 in Maryland, 16 in North Carolina, and 20 in Oklahoma.) Surveyors from CMS, trained in the use of the audit tools, assessed compliance with specific infection control practices, focusing on 6 areas of infection control: hand hygiene, injection safety, medication handling, equipment reprocessing, environmental cleaning, and handling of blood glucose monitoring equipment. Of these, 46 or 67.6% of ASCs had a least one lapse in infection control with 12 of 68 ASCs or 17.6% had lapses identified in 3 of the 5 infection control categories. Common lapses included using single-dose medication vials for more than one patient, failing to adhere to recommended practice regarding processing of equipment, and lapses in handling of blood glucose monitoring equipment. In an editorial following this manuscript (175,176), ASCs were accused of improper conduct and infections were considered as uncontrollable. However, this study had multiple deficiencies focusing on process, rather than effects. Further, the majority of issues are related to single-dose vials. The rule was not established until January 1, 2010. Reprocessing of equipment is not such a major issue utilized by many ASCs. Finally glucose monitoring equipment may not even be an ASC issue; if it is, it is easily correctable. None of the above have shown to be responsible for suboptimal care, further, surgery center samples were extremely small and these issues have not been shown to increase infection rate unless persons are not following the basic infection control principles as illustrated over centuries (177-188) Finally, the application of these issues to interventional pain management settings is related to only single-dose vials. Others have described multiple requirements (189,190) and in essence infection control has become a cottage industry for consultants.

Since 2008, CMS has had authority to implement a quality reporting system for ASCs and reduced payments to providers who don't meet certain standards. However, thus far it has been neither proposed nor implemented. This delay has upset the hospital industry, which is already required to report HOPD quality indicators to CMS. However, ASC industry also, even without CMS requirements, have started quality collaboration with 6 quality measures: rates of patient falls, burns, hospital transfer or admission, surgical site hair removal, appropriate antibiotic timing, and situations involving wrong site, side, patient, procedure, or implant. The initial data also have already been published.

However, 2 federal initiatives to measure ASC quality are expected in the next few years. It is expected that outlines of those programs may come into focus this year as rule making gets under way. The CMS initiative, expected to start in 2012, would most likely involve a pay-for-reporting system in which ASCs would keep their full reimbursement if they met reporting requirements. The other ASC quality initiative would be part of HHS's planned value-based purchasing system for hospitals, ASCs and other health care facilities. The program, mandated by the health care reform law, would pay providers for performance on quality measures. A proposed rule for the program was expected in January but still hasn't been issued, and is now expected in May. Even then, actual federal reporting by ASCs could still be years away, since there is no proposed rule and ASCs continue to be in a holding pattern.

The ACA calls on CMS to conduct a study on whether to expand Medicare's acquired conditions policy to ASCs, among other provider types. The acquired conditions policy is one of several new Medicare initiatives intended to reward quality and penalize poor care. Under the acquired conditions policy, Medicare payments are reduced when patients incur a secondary diagnosis that was not present upon admission such as a foreign object was retained after surgery or the patient has a surgical site infection. Medicare's acquired conditions policy currently applies only to hospitals but could apply to ASCs, depending on the results of the CMS study.

These measures have been shown to be similar to the hospital outpatient surgical centers. Further, patient satisfaction also has been illustrated in over 90% of the freestanding ASCs, similar to HOPDs. The ACA focuses on accountable care organizations (ACOs) and value-based purchasing.

The ACA describes ACOs as "groups of providers of services and suppliers meeting criteria specified by the Secretary of Health and Human Services who work together to manage and coordinate care for Medicare fee-for-service beneficiaries. Under a Medicare program created by the ACA, ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings (29-32,59-63) which currently exist primarily as demonstration projects, will become part of the Medicare system January 1, 2012. If successful, they will reduce utilization and costs while providing the best acute and, particularly long-term care for patients (191-193). However, no such proof exists to show that ACOs are accountable and cost saving measures with high quality services. It has been complained that the value-based purchasing proposal which is based

on ACOs is flawed (194). Further, its implementation in hospital settings is in doubt. Value-based purchasing and ACOs is not a new issue. It has been evaluated for several years thus far. Thus, the new legislation also requires CMS to develop a plan to implement a value-based purchasing program for ASCs. Under current law, hospitals are required to report quality data to CMS, and payments are reduced if the hospital fails to report adequately. The new law will begin transitioning the pay-for-reporting program to an actual pay-for-performance program for hospitals under which Medicare payments will be increased or reduced depending on hospitals' performance on specified quality measures relative to its peers.

9.1.3 Price Standards

The third cornerstone is related to price. Cost effectiveness is an important aspect of health care even though it has been stated on occasions that it should not be used in coverage policies, etc. Even so, as we understand that is the first item each and every payer likes to address. As early as 1994 it was shown that costs and outcomes of inpatient versus outpatient hernia repair were significantly lower, with significantly higher costs in inpatient (82). Further, preoperative testing, which is expensive, has been shown to be minimal in ASC settings. Traditionally, preoperative testing has been part of the screening process for appropriate preoperative care and selection, costing $18 billion annually (83). Ambulatory surgery is by definition low-risk surgery and patients who are usually in good physical condition are expected to be discharged home safely. Mortality in healthy patients is 0.06% to 0.4% (195-197). Further, it has been long accepted that no routine testing is indicated and preoperative tests without specific indications lack utility (83). Few abnormalities detected by non-specific testing result in changes in management, even in the elderly, and rarely have said changes benefited patients or lack of testing affected safe anesthesia and surgery (198). It has also been demonstrated that eliminating routine testing does not increase risk (199-201). Even though most of the work was performed for cataract procedures, these findings can potentially be extrapolated to other low-risk surgeries, specifically interventional techniques. Further, routine testing with abnormal tests may have medicolegal implications of not following up on abnormal test results, and such results can also lead to injury at least in one in 2,000 associated with further work-up. Routine testing has a frequency of abnormal results in 0.0% to 2.6% in multiple studies reviewed (1202-205); however, when selective testing is done, abnormal results are more frequent with 30% in one study (206).

On the issue of cost effectiveness, it has been shown that in 2009 savings ranged from 45% to 61% compared to hospital co-pay for 5 commonly performed procedures including cataract surgery, upper GI endoscopy, diagnostic colonoscopy, colonoscopy, and biopsy, and after cataract laser surgery. Overall, Medicare rates were 41% less in ASCs in 2009; however, for 2011, savings appear to be 43% for Medicare. Since a majority of carriers follow Medicare standards, this can be translated to all settings. Thus, it has been estimated that if all ASC services were performed in hospitals, Medicare expenditures would increase by $2 billion in 2009. As the aging population increases, outpatient surgeries are going to be higher and the requirement for surgery centers will continue to increase. The aging population not only will require procedures such as cataracts, but all age populations will require surgery centers for many prophylactic evaluations and multiple surgical procedures such as interventional techniques. Consequently, ASCs support public health needs despite decreasing payments for various specialties as illustrated above and a widening gap with HOPD payments which are increasing while ASC payments are declining.

Th effect of ASCs in health care service areas and elderly care along with physician ownership have been evaluated in multiple studies (70-73,75,77,79,88). However, a significant proportion of surgery centers are owned by hospitals and physicians. Physician only ownership was approximately 63% and corporate only ownership was 7% as of 2008. It has been always agreed upon that operational efficiency of surgery centers is generally superior to hospital settings; competition from ASCs has not affected hospital surgical output (92). This study (92), showed that an ASC only appears to influence a hospital's outpatient surgical volume if the facilities are within a few miles of each other. Even so, the average reduction in hospital volume is only 2% to 4%, which is not nearly enough to offset the new procedures performed by an entering ASC. In another evaluation (77) it was shown that opening of an ASC did not appear to have an overly detrimental effect on competing hospitals. It lead to a significant increase in the population based rate of renal stone surgery in the hospital service area. The explanation provided was the role of physician financial incentives and unmet surgical demand; however, it has been inadequately or inappropriately has been evaluated that physician ownership results in higher use rates of surgeries based on

financial incentives linked to ownership of either specialty hospitals or ASCs (70). However, while physician ownership is associated with increasing use of ASCs, the extent to which this is attributable to previously unmet demand continues to be unclear (70-75). One of the requirements may be that the safe harbor compliance as required for ASCs with performance of at least one-third of the outpatient surgeries in ASCs. Overall, there is an increased surgical rate with ASCs; however, this is due to transfer from expensive settings, meeting unmet needs, low cost, better service, better organization, and finally the convenience and advances in medicine with new procedures available.

9.1.4 Incentives

Incentives for value-driven health care include encouraging cost-effectiveness, efficiency, and quality. These are available in ASC settings with high patient satisfaction.

10.0 Future Of Ambulatory Surgery Centers

While overall ASCs' future appears to be optimistic, in the near perspective, specifically in 2011, it will be challenging, either the same or worse than 2010. This is based on slow growth, an increase in unemployment, increase in number of citizens without health insurance, those who have insurance but without coverage, high deductibles, high copays, and the political atmosphere.

Even though conditions may improve, it appears that the net number of ASCs will not be growing much. Multiple ASCs have been closing down in recent years.

Infection control continues to be an issue with negative press and expensive maintenance.

ASCs also will be applying greater quality measures, as well as EHRs.

11.0 Conclusion

Concern over the financial solvency of ASCs specializing in interventional pain management is dependent in general on Medicare reform, and in particular on how all other payers will react. With third party payers following Medicare, with most of them paying at the same level as Medicare, and very few above, and some paying below Medicare, in the face of an increasing Medicare population, interventional pain management is at a critical juncture. Although a multitude of issues apply to ASCs, interventional pain management is one of the 2 most negatively affected specialties, whereas others are beneficiaries. Consequently, increasing payments to hospitals, nursing homes, and Medicare Advantage plans while decreasing payments to ASCs, and attempting to balance the budget on physician payments and ASC payments, will be disastrous to access and quality of care. Such an approach may increase Medicare expenses and will not contribute to savings as these segments constitute less than 25% of total payments.

The present problems faced by interventional pain management ASCs may occur in any type of health care system, whether it is a universal health care system or some modification of a universal health care system. CMS leads and functions as a benchmark, resulting in a ripple effect (37,38,107). Beyond reduction in payments, CMS and the entire health care system in the United States may benefit from savings derived from other avenues, including regulatory cost savings, medical tort reform, quality-oriented health facility regulations, effective pay-for-performance regulations, and cost-effectiveness as a price control. Further, CMS and the payer community, public, Congress, the administration, and physicians must consider potential health and economic consequences of misplaced priorities. To maximize the health of Americans, we should pursue interventions in proportion to the ability of those interventions to improve outcomes.

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