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Interventional Pain Management at Crossroads: The Perfect Storm Brewing for a New Decade of Challenges

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The health care industry in general and care of chronic pain in particular are described as recession-proof. However, a perfect storm with a confluence of many factors and events —none of which alone is particularly devastating — is brewing and may create a catastrophic force, even in a small specialty such as interventional pain management. Multiple challenges related to interventional pain management in the current decade will include individual and group physicians, office practices, ambulatory surgery centers (ASCs), and hospital outpatient departments (HOPD).

Rising health care costs are discussed on a daily basis in the United States. The critics have claimed that health outcomes are the same as or worse than those in other countries, but others have presented the evidence that the United States has the best health care system. All agree it is essential to reduce costs. Numerous factors contribute to increasing health care costs. They include administrative costs, waste, abuse, and fraud. It has been claimed the U.S. health care system wastes up to $800 billion a year. Of this, fraud accounts for approximately $200 billion a year, involving fraudulent Medicare claims, kickbacks for referrals for unnecessary services, and other scams. Administrative inefficiency and redundant paperwork accounts for 18% of health care waste, whereas medical mistakes account for $50 billion to $100 billion in unnecessary spending each year, or 11% of the total. Further, American physicians spend nearly 8 hours per week on paperwork and employ 1.66 clerical workers per doctor, more than any other country. It has been illustrated that it takes $60,000 to $88,000 per physician per year, equal to one-third of a family practitioner's gross income, and $23 to $31 billion each year in total to interact with health insurance plans. The studies have illustrated that an average physician spends $68,274 per year communicating with insurance companies and performing other non-medical functions. For an office-based practice, the overall total in the United States is $38.7 billion, or $85,276 per physician.

In the United States there are 2 types of physician payment systems: private health care and Medicare. Medicare has moved away from the Medicare Economic Index (MEI) and introduced the sustainable growth rate (SGR) formula which has led to cuts in physician payments on a yearly basis.

In 2010 and beyond into the new decade, interventional pain management will see significant changes in how we practice medicine. There is focus on avoiding waste, abuse, fraud, and also cutting costs. Evidence-based medicine (EBM) and comparative effectiveness research (CER) have been introduced as cost-cutting and rationing measures, however, with biased approaches.

This manuscript will analyze various issues related to interventional pain management with a critical analysis of physician payments, office facility payments, and ASC payments by various payor groups.

Key words: Interventional pain management, interventional techniques, physician payment reform, ambulatory surgery center payment, hospital outpatient department payments, sustained growth rate formula, targeted growth rate formula, fraud, abuse, administrative expenses, evidence-based medicine, health care costs

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A perfect storm occurs when a confluence of many factors or events — none of which alone is particularly devastating — creates a catastrophic force (1). While such a confluence is devastating, it is rare, especially for a small evolving specialty such as interventional pain management. As we move into a new decade that is evolving from uncertainties, increases in the cost of health care, overutilization, health reform, misdirected and misapplied evidence-based medicine (EBM), and comparative effectiveness research (CER) are directing interventional pain management into a perfect storm.

The health care industry in general, and care of chronic pain in particular, are described as recession-proof since the need for health care services doesn't wane with the health of the economy. This is generally true for acute conditions and general medicine. People do not stop getting sick during a down economy or stop seeking treatment for their conditions. For patients needing interventional pain management, a lack of finances, the loss of jobs, and increasing co-pays lead them to defer medical spending for their conditions that require interventional pain management in favor of paying for daily necessities. Because of a multitude of factors, such as downward pressure on patients seeking interventional pain management, reimbursement, and increasing operational costs, physicians can find themselves in financial difficulties. The levels of distress are highly variable. For some businesses, the only options available are deciding whether to continue operating the business and try to improve profits; close the business to avoid future losses; or sell the business to a buyer that may be able to operate it more successfully (2). These options may not be realistic for interventional pain physicians.

The downturn and troubled times are not limited to individual or group physicians. They also extend to other settings including office practices, ambulatory surgery centers (ASCs), and to a minor extent, to hospital outpatient departments (HOPDs). In this manuscript, we will critically analyze various issues related to Medicare in interventional pain management with critical analysis of physician payments, office facility payments, ASC payments, the role of other payors (private, TRICARE, Medicaid), and other issues related to interventional pain management.

1.0 Explosion of Health Care Costs in the United States

The United States spends substantially more in health care expenditures per person and as a nation than any other country in the world (3). However, the critics claim that health outcomes are the same as or worse than those in other countries (4,5). Others however claim that the United States has the best health care system (6-8).

Health at a Glance 2009, Organisation for Economic Co-operation and Development (OECD) Indicators (3), estimated total expenditures on health measures considered as the final consumption of health care goods and services, plus capital investment in health care infrastructure; including spending by both public and private sources (including households) on medical services and goods, public health and prevention programs and administration. Based on this report, in 2007, the United States continued to outspend all other OECD countries by a wide margin. Spending on health goods and services per person in the United States, in 2007, increased to $7,290 — almost 2.5 times the average of all OECD countries.

1.1 Factors Contributing to Increasing Health Care

Numerous explanations for the higher costs of U.S. health care have been provided. One of the major costs in the United States is administrative costs, which exceed $145 billion (9). However, this does not include employers' costs for purchasing and managing employees' health insurance. It has been estimated that the private employer insurance market wastes more than $50 billion in administrative costs (9), leading to a total cost of nearly $200 billion per year in administrative costs alone.

The second factor is overutilization, abuse, and fraud (1,6,7,10-17). Overuse with abuse, waste, and fraud, coupled with higher costs in the United States, are considered to be responsible for the most important contributors to the high cost of U.S. health care (1). In fact, according to the findings released, Medicare alone is estimated to have wasted more than $98 billion in taxpayer money in fiscal 2009, with over 50% of it ($54 billion) coming from improper payments related to Medicare fee-for-service (FFS), Medicaid, and Medicare Advantage (MA) (15). Further, in 2009 the government reported questionable Medicare payments

of roughly $36 billion, which is expected to be revised upward to about $48 billion next year when the Department of Health and Human Services (HHS) converts to a new methodology that will use stricter documentation requirements (15,16). Senator Charles Grassley (16) estimated that of the $470 billion spent on Medicare, about $60 billion of that spending each year is lost to fraud, waste, and abuse. Since Medicare expenditures are projected to increase at an average annual rate of 7.1% this year, the rate will grow as well, according to Senator Grassley. However, abuse, fraud, and waste are not limited to Medicare itself. They extend to private insurers and all other sectors of the U.S. economy. One example is that the U.S. government spent $92 billion on corporate welfare (not including corporate bailouts) compared to $71 billion on homeland security (17). Further, the federal government made at least $72 billion in payment errors in 2008, and spends $123 billion annually on non-existent federal programs.

Despite this, the health care volume of services in the United States is not considered extreme. Hospitalizations are lower than the OECD average (3). Further, it is stated that U.S. patients have fewer physician visits annually per capita than the OECD average (3,9,18,19). In contrast to the volume, in which the United States is not the leader, there are almost 3 times as many magnetic resonance imaging (MRI) scanners in the United States as the OECD average, higher only in Japan (1,3,9,18). Further, the United States has the fourth highest per capita consumption of pharmaceuticals (19), consuming more new drugs than do patients in other countries (19). Further, more expensive pharmaceuticals, as well as higher prices both for older and newer drugs, help explain why the United States spent $752 per capita in 2005 on drugs, whereas France, with the next highest expenditure, spent $559 and Japan just $425 (18,19).

Overall the U.S. health care system has been stated to waste up to $800 billion a year; of this, fraud accounts for approximately $200 billion a year. The fraud takes the form of fraudulent Medicare claims, kickbacks for referrals for unnecessary services, and other scams (20). Administrative inefficiency and redundant paperwork accounts for 18% of health care waste, whereas medical mistakes account for $50 billion to $100 billion in unnecessary spending each year, or 11% of the total. Further, American physicians spend nearly 8 hours per week on paperwork and employ 1.66 clerical workers per doctor, more than in any other country (21). It has been illustrated that it takes $60,000 to $88,000 per physician per year, equal to one-third of a family practitioner's gross income, and $23 to $31 billion each year in total to interact with health insurance plans (22). Further, it has been demonstrated the United States spends $38.7 billion a year on office-based practices with an overall cost of $85,276 per physician for billing and insurance activities in a medical group (23). These expenses are higher for surgical specialties including interventional pain management.

2.0 Physician Payment System

In the United States, physicians are paid for their personal services. This payment also includes the overhead expenses for maintaining an office and providing the services. The payment system is highly variable in the private insurance market; however, governmental systems have a formula-based payment, mostly based on the Medicare payment system.

2.1 Medicare Payment System

Since the inception of Medicare programs in 1965, several methods have been used to determine the amounts paid to physicians for each covered service. Initially, payment systems compensated physicians on the basis of their charges and allowed physicians to balance their books by billing beneficiaries for the full amount above what Medicare paid for each service. While these were considered to be the "golden years" by physicians practicing in the 1960s, this halcyon era was short lived. In1975, just 10 years after the inception of the Medicare program, payments changed so as not to exceed the increase in the Medicare Economic Index (MEI). Nevertheless, the policy failed to curb increases in costs, leading to the determination of a yearly change in fees by legislation from 1984 to 1991 (24).

In 1992, the fee schedule essentially replaced the prior payment system that was based on physicians' charges. Finally, after multiple attempts at modification, the system was replaced by a new mechanism — the sustainable growth rate (SGR) system in 1998. In 2009, multiple attempts were made by Congress to repeal the formula. The House of Representatives passed such a bill, but replaced it with another formula which is considered the same or more onerous than SGR (25). In its current form, H.R. 3961 replaces SGR with a target growth rate (TGR). This may result in elimination of the projected cuts with a clean slate, but physicians would see their Medicare rates slashed again in 2011. The TGR formula may result in the following: 1) allow physician payment rates to be slashed if government-set spending targets are exceeded (historically they

have been every year since 1997); 2) tie spending targets to the gross domestic product (GDP) similar to SGR, consequently, physicians would continue to be unfairly punished when the economy slows down; 3) tie physician reimbursement rates to utilization, continuing to punish providers who focus on delivering high-quality care while rewarding those who focus on volume.

2.1.1 Resource-Based Relative Value System

Since January 1, 1992, Medicare has paid for physicians' services based on national uniform relative value units (RVUs), based on the relative resources used in furnishing services. The national RVUs are established for physician work, practice expense (PE), and malpractice expense (ME) (26).

Starting in 1998, practice expense relative value units (PERVUs) were also developed with consideration of general categories of expenses (such as office rent and wages of personnel, but excluding MEs) comprising PEs. Separate PERVUs were established for procedures that can be performed in both non-facility settings, such as physicians' offices, and a facility setting, such as a HOPD. The difference between the facility and non-facility RVUs reflects the fact that a facility typically receives separate payment from Medicare for its costs of providing the service, apart from payment for physicians' services. Consequently, the non-facility RVUs reflect all of the direct and non-direct PEs of providing a particular service — essentially representing the facility portion of the office expense.

Similar to PERVUs, resource-based malpractice relative value units (MPRVUs) were established for services furnished on or after 2000. The MPRVUs were based on malpractice insurance premium data collected from commercial and physician–owned insurers from every state.

Since the initial implementation, RVUs have been refined several times. The first 5-year review of the physician work RVUs was effective in 1997; the second 5-year review was effective in 2002. The third 5-year review of physician work RVUs was effective on January 1, 2007. As part of the 2007 final rule, the Centers for Medicare and Medicaid Services (CMS) implemented a new methodology for determining resource-based PERVUs and are transitioning it over a 4-year period. This has led to significant cuts in physician payments and office overhead payments for interventional techniques.

Adjustments to RVUs are budget neutral. Further, to calculate the payment for every physician's service, the components of the fee schedule, namely physician work, PE, and MPRVUs, are adjusted by a geographic practice cost index. The index reflects the relative costs of physician work, PE, and ME in an area compared to the national average cost for each component.

2.1.2 Sustained Growth Rate (SGR) Formula

The SGR formula which is in effect now continues to hamper physician payments. The mechanism of the SGR includes 3 components that are incorporated into a statutory formula: first, expenditure targets, which are established by applying a growth rate (calculated by formula) to spending during a base period; second, the growth rate period; and third, the annual adjustments of payment rates for physicians' services, which are designed to bring spending in line with expenditure targets over time. Further, as described earlier, the relative value of a physician fee schedule is based on 3 components — physician work, PE, and MEs that are used to determine a value ranking for each service to which it is applied. On average, the work component represents 52.5% of a service's relative value, the PE component represents 43.6%, and the malpractice component represents 3.9% (27). The volume and intensity of services have increased on average about 4.5% from 1997 through 2009. Since 2002, spending (as measured by the SGR method) has consistently been above the targets established by the formula (27-29). Figure 1 illustrates changes in the volume and intensity of total Medicare physician services from 1980 to 2007.

Figure 2 illustrates FFS Medicare spending for physician services from 1998 to 2008. It has increased approximately 9% per year.

The SGR reductions in payment rates for physician services resulted in a cut of 4.8% in 2002, with CMS deciding on sustained cuts of 4.4% in 2003 and beyond. In 2003, Congress responded by increasing payments for physician services by 1.6% instead of the projected 4.4% cut (30). In 2004 and 2005, the Medicare Modernization Act replaced the scheduled rate reduction with an increase of 1.5%. In 2006, the Deficit Reduction Act (DRA) held 2006 payment rates at their 2005 level, overriding an impending 4.4% reduction (31). In 2007, Congress again approved holding the 2008 payments at the 2005 level, thereby avoiding a proposed 5.1% reduction (32). In 2008 and 2009 temporary measures were also undertaken. Based on this, in the absence of congressional action for CY 2010, the 2010 physician update, the conversion factor for services after April 1, 2010, may face the 21.2% cut unless blocked by congressional action (33). The only benefit for enacting the targeted growth rate formula passed by H.R. 3961 will be for a clean slate (25).

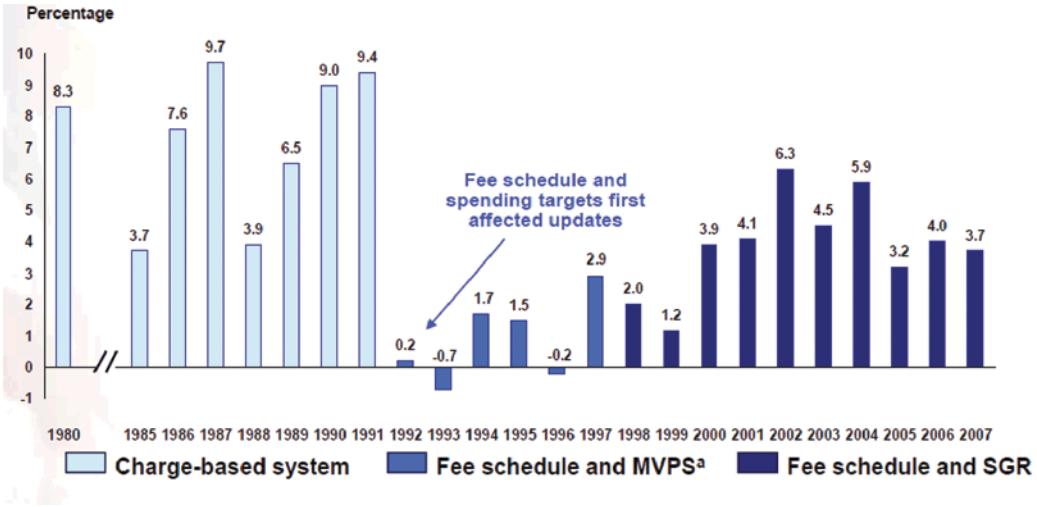


Fig. 1. *Changes in volume and intensity of total Medicare physician services — 1980–2007.*
Source: GAO analysis of data from CMS and the Boards of Trustees of the Federal Hospital Insurance (HI) and Federal Supplementary Medical Insurance (SMI) Trust Funds.
http://www.nhpf.org/library/handouts/Miller-Steinwald.slides_01-15-09.pdf

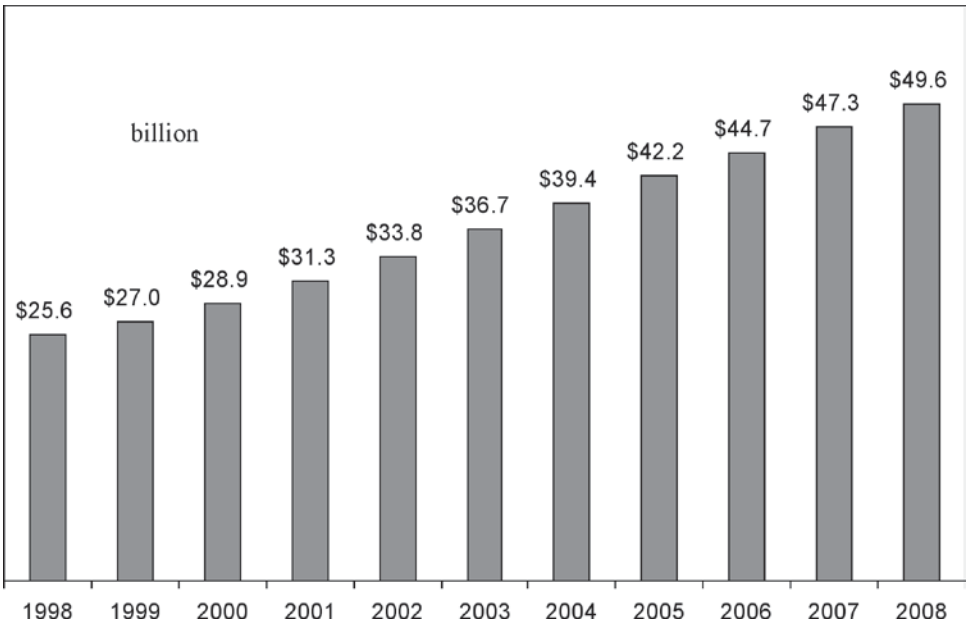


Fig. 2. *FFS Medicare spending for physician services, 1998–2008.*
Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group

2.2 Consultation Services

In March 2006, the Office of the Inspector General (OIG) published a report entitled, "Consultations in Medicare: Coding and Reimbursement" (34). The findings in the OIG report, based on claims paid by Medicare in 2001, indicated that Medicare allowed approximately $1.1 billion more in 2001 than it should have for services that were billed as consultations. Approximately 75% of services paid as consultations did not meet all applicable program requirements resulting in improper payments (34). Most of these errors (47%) were billed as the wrong type or level of consultation. The second most frequent error was for services that did not meet the definition of a consultation (19%). The third most common category of improperly paid claims was a lack of appropriate documentation (9%).

CMS proposed, beginning January 1, 2010, to neutrally eliminate the use of all consultation codes by increasing the work RVUs for new and established office visits, increasing the work RVUs for initial hospital and initial nursing facility visits, and incorporating the increased use of these visits into PE and MPRVU calculations.

The methodology for the revision of resource-based MPRVUs also underwent extensive revisions. The primary determinants of malpractice liability costs continue to be physician specialty, level of surgical involvement, and the physician's malpractice history. CMS collected malpractice premiums data from major insurance providers in every state. CMS proposed a resource-based methodology for developing MPRVUs for technical component services such as diagnostic tests. The MPRVUs for technical component services and the technical component portion of global services were based on historically allowed charges that had not been made resource-based due to a lack of available malpractice premium data for non-physician suppliers. CMS has collected the data over the last few years and incorporated it into the new methodology. CMS explained that the rationale for a different payment for a consultation service is no longer supported because documentation requirements are now similar across all E/M services.

AMA has published consultation codes in its 2010 CPT. Multiple private payors, some MA Plans, and TRICARE may continue to value consultation codes.

2.2.1 Key Points of the Changes for Medicare

- Effective January 1, 2010, local Part B carriers will no longer recognize AMA CPT consultation codes for inpatient facility and office/outpatient settings where consultation codes were previously billed for services in various settings. These codes range from 99241 to 99245 and 99251 to 99255 (35).
- In the past, consultation codes required specific documentation. However, conventional medical practice is that physicians making a referral and physicians accepting a referral would document the request to provide an evaluation for the patient. Thus, in order to promote proper coordination of care, CMS recommends that these physicians should continue to follow appropriate medical documentation standards and communicate the results of an evaluation to the requesting physician (35).
- In the case of multiple physicians being involved in the care of a patient, the principal physician of record will append modifier "-AI" Principal Physician of Record, to the E/M code when billed. This modifier will identify the physician who oversees the patient's care from all other physicians who may be furnishing specialty care. All other physicians who perform an initial evaluation on this patient will record the E/M code for the complexity level performed.
- In the office or other outpatient setting where an evaluation is performed, physicians should report CPT codes (99201 to 99215) depending on the complexity of the visit and whether the patient is a new or established patient to that physician.
- Medicare will also no longer recognize the consultation codes for purposes of determining Medicare secondary payments.

2.3 MedPAC Report to Congress

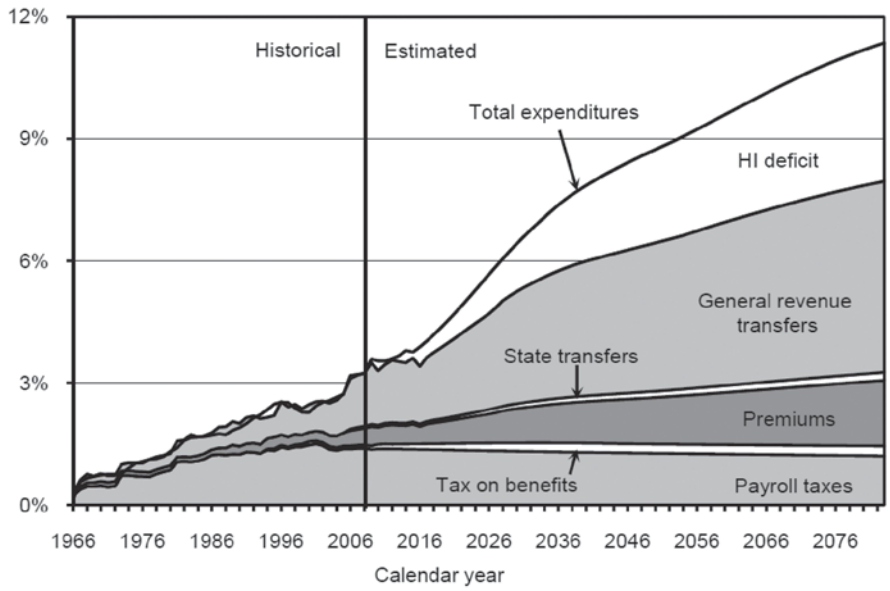
In a report to Congress, the Medicare Payment Advisory Commission (MedPAC) provided Medicare's payment policy (36). MedPAC reported that Medicare and other purchasers of health care in our nation face enormous challenges with increasing health care costs for individuals and private and public payors, while quality frequently falls short of patients' needs. The commission has recommended a number of measures to increase the accountability of providers and the value of care, such as pay for performance, measuring resource use, penalizing high readmission rates, and research comparing the effectiveness of medical treatments. MedPAC predicted the marked variation in both service use and quality of care across the nation, suggesting that opportunities exist for reducing spending while improving quality for beneficiaries. Medicare trustees and others warn of a serious mismatch between the benefits and

the payments the program currently provides and the financial resources available for the future. Medicare's trustees note that if the benefits and payment systems remain as they are today, over time the program will require major new sources of financing for Part A and will automatically require increasing shares of general tax revenues for Part B and Part D. The trustees project that dedicated payroll taxes will make up a smaller share of Medicare's total revenue and that a large deficit between spending for Part A hospital insurance (HI) and revenue from dedicated payroll taxes will develop (Fig. 3) (37).

The commission recommended that for 2010 Congress update payments for physician services by 1.1%. However, the commission remained concerned that primary care services were undervalued and at a significant risk of being under provided, despite some recent increase in payments for primary care services. Consequently, the commission recommended that Congress increases payments for primary care services when provided by practitioners who focus on primary care; however, utilizing a budget neutral formula within the fee schedule — resulting in a reduction in payments for specialists. The commission also recognized that there has been rapid technological progress in diagnostic imaging over the past several years which has enabled physicians to diagnose and treat illness with greater speed and precision. However, the rapid volume growth of costly imaging services, as per MedPAC, may be driven, at least in part, by prices that are too high. The commission also stated that high payment rates for imaging services essentially means that payment rates for primary care and other services are lower, based on a budget neutrality formula.

2.4 Medicare Advantage (MA) Programs

The MA programs provide Medicare beneficiaries with an alternative to the FFS Medicare program. It enables them to choose a private plan to provide their health care. Those private plans can use alternative



Note: GDP gross domestic product, HI Hospital Insurance. These projections are based on the trustees' intermediate set of assumptions. Tax on benefits refers to a portion of income taxes that higher income individuals pay on Social Security benefits that is designated for Medicare. State transfers (often called the Part D "clawback") refer to payments called for within the Medicare Prescription Drug, Improvement, and Modernization (MMA) Act of 2003 from the states to Medicare for assuming primary responsibility for prescription drug spending.

Fig. 3. Medicare faces serious challenges with long-term financing.
Source: 2009 Annual Report of the Boards of Trustees of the Medicare Trust Funds (37).

delivery systems and care management techniques. They also have the flexibility to innovate. While the commission supports the private plans in the Medicare program, it continues to consistently express concerns about the MA payment system.

In MedPAC's analysis of data on enrollment, availability, payments, benefits, and quality they found the following (36): first, about 22% of Medicare beneficiaries were enrolled in MA plans in 2008 and all beneficiaries have access to an MA plan in 2009; second, plans provide enhanced benefits to enrollees and overwhelmingly these benefits are not financed out of plan efficiency, but rather by the Medicare program and other beneficiaries, and at a high cost. MedPAC has estimated that each dollar's worth of enhanced benefits in private FFS plans costs the Medicare program over $3. Third, quality is not uniform among MA plans or plan types. MedPAC commented that high quality plans tend to be established health maintenance organizations; more recent plans have lower rankings on many measures.

MedPAC's report to Congress stated that 9.9 million Medicare beneficiaries were enrolled in MA plans as of November 2008 and payments to MA plans continue to exceed what Medicare would spend for similar beneficiaries in FFS; MA payments per enrollee are projected to be 114% of comparable FFS spending for 2009. All-in-all, it appears that the MA program continues to be more costly than the traditional program.

Even so, MA plans pay physicians and facilities at a lower rate than Medicare with higher co-payments and significant deductibles for non-participating providers, which is not recognized. As per the MedPAC report, Medicare is paying at 80% for private payors. Private payors follow a similar philosophy as government payors and pay a certain percentage higher than Medicare reimbursement. Thus, cuts in Medicare will have a ripple effect with major benefits for the private insurance industry and substantial losses to providers.

3.0 Hospital Outpatient Prospective Payment System

Outpatient Prospective Payment System (OPPS) operates on a rate-per-service basis that varies according to the ambulatory payment classification (APC) group to which the service is assigned (38). The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary co-payment (38). This rate is divided into a labor-related amount and non-labor related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital is located.

All services and items within an APC group are comparable clinically and with respect to resource use. By law, certain expenses, exceptions, services, and items within an APC group cannot be considered comparable with respect to the use of resources if the highest median or mean cost for an item or service in the APC group is more than 2 times greater than the lowest median cost for an item or service within the same APC group.

The hospital OPPS was first implemented for services furnished on or after August 1, 2000. In 2000 the Secretary of HHS established the APC Panel. This expert panel, which may be composed of up to 15 representatives and providers subject to OPPS, reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. The APC panel is technical in nature.

CMS published the final rule on OPPS as well as ASC payment systems (38). The APC relative weights and payments for calendar year (CY) 2010 were calculated using claims from CY 2008 that were processed before January 1, 2009, and continued to be based on the median hospital costs for services in the APC groups. Based on the 2010 fee schedule, hospitals will receive an inflation update of 2.1% in their payment rates for services furnished to Medicare beneficiaries in outpatient departments. Growth in expenditures and volume and intensity of HOPD services under OPPS has been greater than physician services themselves or at least equal; yet HOPDs continue to receive their updates. Figure 4 illustrates the phenomenal growth in expenditures under OPPS from approximately $18 billion in 2001, increasing to approximately $35 billion in 2008, but decreasing to $30.6 billion (projected) in 2009, and $32.2 billion (projected) in 2010.

4.0 Ambulatory Surgical Center Payment Systems

Ambulatory surgery center (ASC) means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization. To be able to participate in Medicare, a surgical center has to have a participating agreement with Medicare and also meet the conditions set forth. In general, private payors would like Medicare participation and an additional accreditation by other agencies or their own certification.

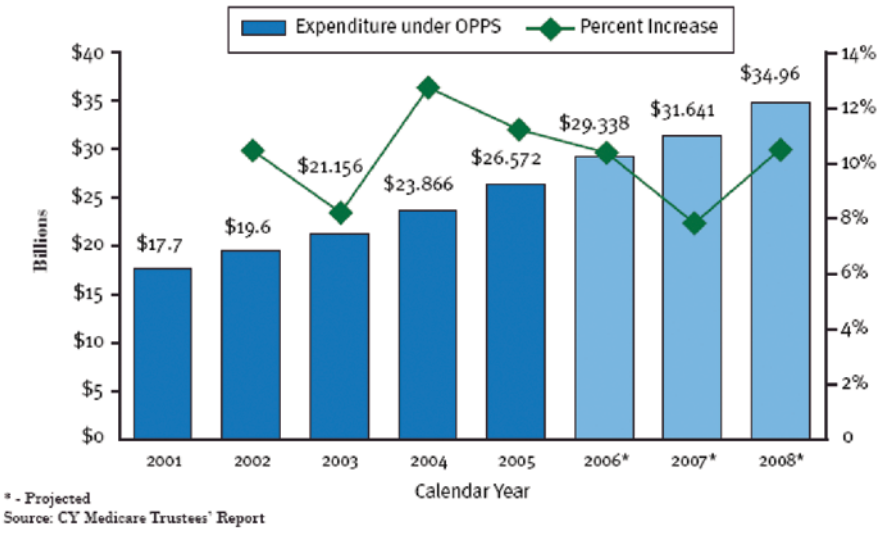


Fig. 4. *Growth in expenditures under OPPS from CY 2001 to 2008.*

4.1 Medicare and Ambulatory Surgery Centers (ASCs)

Even though ASCs date back to 1970, Medicare only began approving payments for ASCs for certain surgical procedures in 1982. Allowed procedures for ASCs have increased from 97 performed in 1982 to over 2,800 different procedures for Medicare beneficiaries. There are now approximately 5,000 Medicare-certified surgery centers in the United States. Total ASC payments were $1 billion in 1996 increasing to $3.4 billion in 2010.

4.1.1 Evolution of Medicare Payment System

Medicare's initial ASC payment rates were based on ASC costs and charge data from 1979 and 1980 (39). CMS was required by law to review ASC payment rates periodically and adjust them as appropriate. CMS last revised ASC payment rates in 1990, using ASC data on costs and charges that CMS collected in 1986 (39). In 2000, HOPDs were changed to OPPS, while ASCs continued to be paid under the old system. Procedures performed in ASCs were placed into payment groups based on similar costs; whereas HOPD procedures are placed into payment groups known as APC groups, based on both cost and clinical similarity. In addition, the payment rates of HOPDs are revised annually based on cost and charge data included in the reports.

In 1998, an ASC rule was proposed; subsequently this rule was delayed. The final rule published in 2002 continued to apply the old system based on payment groups. A subsequent rule in 2005 also was based on the old payment system (40).

However, multiple concerns continued to emerge with regards to differences in payment systems in hospital outpatients and ASCs. To address these issues, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Government Accountability Office (GAO) to conduct a study that compared the relative costs of procedures performed in ASCs to the relative costs of the same procedures performed in HOPDs (30). MMA also granted a broad statutory authority to the Secretary of HHS to design a new ASC payment system based on OPPS.

In August 2006, CMS published the OPPS and ASC proposed rule (41). In this rule 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; reimbursements for some procedures increased, while others decreased. The proposal resulted in a payment rate of 62% for HOPDs and ASCs in 2007, and a blended formula of 50/50 ASC and HOPD payments for 2008.

In November 2006, the GAO released its report on ASC payment systems (39). The GAO determined that the payment groups in OPPS accurately reflect the relative cost of procedures performed in ASCs. 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; when weighted by Medicare claims, volume was 0.84. Thus, it was determined that the costs of procedures in ASCs are substantially lower than corresponding costs in HOPDs. CMS also stated that GAO's recommendation is consistent with its August 2006 proposed revision to the ASC payment system.

Thus, payment for covered surgical procedures under the revised ASC payment system follows general principles of OPPS and APC. The 2010 final rule (38) also announced that ASCs will receive a 1.2% inflation update.

The list of covered surgical procedures designated as device-intensive had some changes in the CY 2010 final rule. CMS designated several procedures as device-intensive among these multiple interventional procedures: implantable neurostimulators, electrodes, and intrathecal infusion systems with CPT codes as shown in Table 1. Consequently, device-intensive procedures include a significantly higher offset percentage.

Table 1. *ASC covered surgical procedures designated as device-intensive for CY 2010.*

CY 2010 CPT code	CY 2010 short descriptor	Final CY 2010 ASC payment indicator	Final CY 2010 OPPS APC	OPPS APC title	Final CY 2010 device-dependent APC offset percentage
61885	Insrt/redo neurostim 1 array.	H8	0039	Level I Implantation of Neurostimulator Generator	85
61886	Implant neurostim arrays ...	H8	0315	Level II Implantation of Neurostimulator Generator	88
62361	Implant spine infusion pump.	H8	0227	Implantation of Drug Infusion Device	83
62362	Implant spine infusion pump.	H8	0227	Implantation of Drug Infusion Device	83
63650	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	58
63655	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64
63685	Insrt/redo spine generator.	H8	0039	Level I Implantation of Neurostimulator Generator	85
64553	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	58
64555	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	58
64560	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	58
64561	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	58
64565	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	58
64573	Implant neuroelectrodes	H8	0225	Implantation of Neurostimulator Electrodes, Cranial Nerve.	73
64575	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64
64577	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64
64580	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64
64581	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64

Finally, despite a recommendation from MedPAC for cost reporting data, CMS has not proposed to require ASCs to submit cost data to the Secretary for CY 2010. However, CMS will implement ASC quality measures reporting and reduce the payment update for ASCs that failed to report those required measures.

4.2 Calculation of the ASC Conversion Factor and ASC Payment Rates

In 2007, CMS established a policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and relative payment weights. Consistent with that policy, the revised payment was implemented so that it would be budget neutral. The initial ASC conversion factor was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to the estimated total Medicare payments under the prior (CY 2007) ASC payment system. That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 equal to aggregative Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system; taking into consideration the cap on ASC payment systems in CY 2007 as required by law. For CY 2008, CMS adopted the OPPS relative payment weights as the ASC relative payment weights for most services; and, consistent with the final policy, they calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. However, for covered office-based surgical procedures and covered ancillary radiology services, the established policy is to set the relative payment weights so that the national unadjusted ASC payment rate does not exceed the unadjusted non-facility PERVU amount. Thus, any increases based on any other factors would lead to a comparable downward adjustment to the conversion factor, ensuring that the only increase in payments to ASCs are those allowed by the update factor. Further, CMS also continues to utilize relative payment weight scaling methodology without modification. The final CY 2010 ASC payment weight scale is 0.9567. The final ASC conversion factor for 2010 has been calculated as $41.873, which is the product of the CY 2009 conversion factor of $41.393 multiplied by 0.9996 and the 1.2% consumer price index for all urban consumers.

4.3 Discrepancies between ASCs and HOPD

In a study evaluating disparities in the use of ambulatory surgical centers in Florida (42), a cohort of discharges for urologic, ophthalmologic, gastrointestinal, and orthopedic procedures was created and evaluated. The study showed that compared to the lowest group, patients of higher socioeconomic status were more likely to have procedures performed in ASCs. Overall, the middle socioeconomic status group was the most likely group to use an ASC. ASCs provided significant cost savings by means of lower overall costs and lower overall co-payments (43). Thus, ASCs would be especially important for patients of the lowest socioeconomic status groups. In addition, ASCs also showed significant superiority in efficiency over HOPD.

4.4 An Avalanche of 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 (44,45). For the most part, the original regulations published in 1982 have not been changed.

4.4.1 General Conditions and Requirements

Participation as an ASC is limited to facilities that meet the definition and have in effect an agreement obtained from CMS. To qualify for an agreement, the ASC must be in compliance with all CMS requirements and meet all the conditions set forth as determined by CMS surveys; or be accredited by an approved accredited body.

4.4.2 Governing Body and Management

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment.

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 a local Medicare participating hospital or a local non-participating hospital that meets the requirements for payment for emergency services.

The ASC must have a written transfer agreement with such a hospital or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

4.4.3 Surgical Services

- Evaluation and Anesthesia
  - 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.
  - Standards include: a physician must examine the patient immediately, evaluate the risk before surgery, evaluate the risk of anesthesia, and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.
  - Further, anesthetics must be administered by only a qualified anesthesiologist or a physician qualified to administer anesthesia, such as a certified registered nurse anesthetists, an anesthesiologist 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 the anesthesiologist's assistant, under the supervision of an anesthesiologist.
- Discharge
  - All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

4.4.4 Evaluation of Quality

The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive, self-assessment of the quality of care provided, including medical necessity of the procedures performed and appropriateness of care; and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

4.4.4.1 Environment

- The ASC must have a safe and sanitary environment, properly constructed, equipped and maintained to protect the health and safety of patients.
  - This includes the physical environment, which must be functional, equipped with appropriate equipment, and must have a separate recovery room and waiting area.
- The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.
  - CMS has mandated an elaborate infection control program, with training and dedicated staff.
- The ASC must meet the provisions applicable to ambulatory health care centers of the 2000 edition of the life safety code of the National Fire Protection Association, regardless of the number of patients served. However, the provisions of the life safety code do not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients in an ASC.
- The ASC must be equipped with emergency lighting systems and all other equipment and personnel must be trained in the use of emergency equipment and cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

4.4.4.2 Medical Staff

The medical staff of the ASC must be accountable to the governing body. Members of the medical staff must be legally and professionally qualified for the physicians to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with the recommendations from qualified medical personnel. In addition, the scope of procedures performed in an ASC must be periodically reviewed and amended as appropriate.

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.

4.4.4.3 Nursing Services

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

4.4.4.4 Medical Records

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. To meet the standard, the ASC must develop and maintain a system for the proper collection, storage, and use of patient records. Form and content of the record includes a separate record for each patient, which is accurate, legible, and promptly completed.

4.4.4.5 Pharmaceutical Services

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.

Administration of drugs must be performed appropriately with proper preparation and administration according to established policies and acceptable standards of practice.

1) Further, adverse reactions must be reported to the physician responsible for the patient and must be documented in the record;
2) Blood and blood products must be administered by only physicians or registered nurses, and;
3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the practicing physician.

4.4.4.6 Laboratory and Radiologic Services

If the ASC performs laboratory services, it must meet requirements. 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.

The ASC must have procedures for obtaining radiologic services from a Medicare-approved facility to meet the needs of patients.

5.0 Coding, Billing, and Compliance

5.1 Current Procedural Terminology

Current Procedural Terminology developed and updated by the AMA, is the most commonly used coding system (46). The CPT nomenclature is a listing of descriptive terms, guidelines, and identifying codes for reporting medical services and procedures (46).

5.2 Correct Coding Issues

In consideration of the monumental changes in outpatient coding resulting from the many proposals in 1999 and onwards, compounded by the development of multiple new codes and revision of codes, along with deletion of codes by the AMA over the years and the use of modifiers and APC by CMS, National Correct Coding policies have become crucial for the practice of interventional pain management (47,48).

The National Correct Coding Council was created by the CMS Health Care Financing Administration (HCFA), which initiated the National Correct Coding Committee (NCCC) to develop strategies for the Bureau of Program Operations to control improper coding leading to inappropriate or increased payments in Part B claims. As a direct outgrowth of NCCC's work, HCFA established the NCC policy in 1996 and eventually implemented the Medicare Correct Coding Initiative (CCI) to identify and isolate inappropriate coding, unbundling, and other irregularities in coding. Several versions of the NCC policies have been released in the form of NCC manuals. Today NCC policies are available at no cost. NCCC's policies are based on established coding conventions defined in the AMA CPT Manual, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practices, and review of current coding practices.

6.0 Impact on Interventional Pain Management

Interventional pain management is affected by payment systems for physicians, office overhead, ASCs, HOPD payments, ambulatory surgical center payments, overuse, abuse, waste and fraud, CPT changes, and NCC policies.

6.1 Physician Payments for Interventional Techniques

To address the numerous difficulties and issues related to service and determination of costs for various components, a new physician practice information survey (PPIS) was established in 2007. The PPIS, administered in 2007 and 2008, was designed to update the specialty-specific practice expense per hour (PE/HR) data used to develop PERVUs. The PPIS is a multispecialty, nationally represented PE survey of both physicians and non-physician providers using a consistent survey instrument and methods highly consistent with those used in the past. The PPIS gathered information from 3,656 respondents across 51 physician specialties and health care professional groups. One hundred responses were from interventional pain management practitioners. Their survey was separate from pain medicine and anesthesiology. The PPIS is considered the most comprehensive source of PE survey information available to date. CMS proposed to utilize the PE/HR developed using PPIS data for all Medicare recognized specialties that participated in the survey for payments effective January 1, 2010, including interventional pain management. While there have been positive and negative comments about PPIS data, for interventional pain management it opened the avenue which we have been trying to open for the last decade. As shown in Table 2, interventional pain management is one of the beneficiaries of PPIS along with multiple other specialties, including pain

Table 2. *Indirect PE/HR for the specialties that have PPIS survey data.*

Specialty	Previous indirect PE/HR	Final rule indirect PE/HR	Previous indirect %	Final rule indirect %
All Physicians	$59.04	86.36	67	74
Allergy and Immunology	153.29	162.68	62	67
Anesthesiology	19.76	29.36	56	82
Audiology	59.04	72.17	67	85
Cardiology	131.02	88.04	56	65
Cardiothoracic Surgery	61.75	67.83	68	83
Chiropractor	49.60	65.33	69	86
Clinical Laboratory (Billing Independently)	66.46	68.32	37	37
Clinical Psychology	29.07	20.07	90	93
Clinical Social Work	29.07	17.80	90	97
Colon & Rectal Surgery	53.93	90.84	77	80
Dermatology	158.49	184.62	70	70
Emergency Medicine	36.85	38.36	88	94
Endocrinology	49.60	84.39	69	73
Family Medicine	52.79	90.15	62	76
Gastroenterology	101.30	96.78	70	75
General Practice	52.79	78.59	62	69
General Surgery	53.93	82.73	77	82
Geriatrics	49.60	54.14	69	74
Hand Surgery	98.56	148.78	72	77
Independent Diagnostic Testing Facilities	466.16	501.45	50	51
Internal Medicine	49.60	84.02	69	76
Interventional Pain Medicine	59.04	156.79	67	70
Interventional Radiology	118.48	82.56	58	81
Medical Oncology	141.84	145.81	59	59
Nephrology	49.60	66.00	69	80
Neurology	66.05	110.39	74	87
Neurosurgery	89.64	115.76	86	87
Nuclear Medicine	118.48	39.80	58	77
Obstetrics/Gynecology	69.74	99.32	67	67
Ophthalmology	103.28	170.07	65	70
Optometry	59.04	88.02	67	77
Oral Surgery (Dentist only)	96.01	173.19	71	65
Orthopaedic Surgery	98.56	131.40	72	81
Osteopathic Manipulative Therapy	59.04	53.93	67	93
Otolaryngology	96.01	141.54	71	75
Pain Medicine	59.04	122.42	67	70
Pathology	59.80	74.98	70	74
Pediatrics	51.52	76.27	62	69
Physical Medicine and Rehabilitation	84.92	110.13	71	84
Physical Therapy	35.17	57.26	65	84
Plastic Surgery	99.32	134.81	67	74
Podiatry	59.04	74.76	67	82
Psychiatry	29.07	30.10	90	94
Pulmonary Disease	44.63	55.26	76	74
Radiation Oncology (Hospital Based & Freestanding)	114.00	165.10	50	57
Radiology	118.48	95.60	58	71
Rheumatology	84.92	98.08	71	67
Urology	119.57	97.01	69	73
Vascular Surgery	60.10	83.98	63	73

Source: Department of Health and Human Services, Centers for Medicare & Medicaid Services. 42 CFR Parts 410, 411, 414, 415, 485, and 498. Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Final Rule; Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Advanced Diagnostic Imaging Supplier Accreditation Program; Notice. Final Rule with comment period. November 25, 2009 (26).

medicine and anesthesiology. Originally, interventional pain management was paid based on anesthesiology. Subsequently, with input from specialty societies, following the survey, as shown in Table 2, interventional pain management payments increased from $59.04 to $156.79, in contrast to pain medicine which went from $59.04 to $122.42, and anesthesiology which went from $19.76 to $29.36.

6.2 CPT Code Changes for Interventional Pain Management

A comprehensive revision of the spinal section of the CPT nervous system section in 2000 reflected the systematic organization of a series of codes to differentiate the specific spinal anatomy and types of substances injected (46,49). Further clarifications and definitions have been revised and appeared in subsequent years (47,48,50).

The 2010 CPT provides multiple changes to the existing terminology and codes with addition of new codes and replacement of certain codes and redefining of certain other codes (49,50).

Changes to CPT codes related to interventional pain management include neurostimulators, nerve blocks, and fluoroscopic guidance.

6.2.1 Neurostimulators (Spinal)

CPT codes 63650, 63655, and 63611-63664 describe the operative placement, revision, replacement, or removal of spinal neurostimulator system components to provide spinal electrical stimulation.

A neurostimulator system includes an implanted neurostimulator, external controller, extension, and collection of contacts. Multiple contacts or electrodes (4 or more) provide the actual electrical stimulation in the epidural space.

For percutaneously placed neurostimulator systems (63650, 63661, 63663), the contacts are on a catheter-like lead. An array defines the collection of contacts that are on one catheter.

For systems placed via an open surgical exposure (63655, 63662, 63664), the contacts are on a plate or paddle-shaped surface.

However, CPT 2010 advises not to report 63661 or 63663 when removing or replacing a temporary percutaneously placed array for an external generator.

The definitions are as follows:

- 63650 Percutaneous implantation of neurostimulator electrode array, epidural (63660 has been deleted. To report, see 63661-63664)
- 63661 Removal of spinal neurostimulator electrode percutaneously array(s), include fluoroscopy, when performed
- 63662 Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
- 63663 Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
  - Code 63663 should not be reported in conjunction with codes 63661, 63662 for the same spinal level.
- 63664 Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) place via laminotomy or laminectomy, including fluoroscopy, when performed
  - Code 63664 should not be used in conjunction with codes 63661, 63662 for the same spinal level.

6.2.2. Nerve Blocks

The definitions are as follows:

- 64400 Injection, anesthetic agent; trigeminal nerve, any division or branch
- 64449 lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)
  - Code 64449 should not be reported in conjunction with code 01996.
- 64450 other peripheral nerve or branch
- 64455 Injections(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (e.g., Morton's neuroma)
  - Code 64455 should not be reported in conjunction with code 64632.

Facet joint injection codes have been revised. Codes 64470-64476 have been deleted. The new codes are 64490-64495. Further, image guidance (fluoroscopy or CT) and any injection of contrast are inclusive components of 64490-64495. Imaging guidance and localization are required for the performance of paravertebral facet joint injections described by codes 64490-64495. If imaging is not used, codes 20550-20553 must be reported. If ultrasound guidance is used, code 64999 must be used.

For bilateral procedures, modifier 50 must be used.

In addition, when CPT recommends injection of the T12-L1 joint, or nerves innervating that joint, code 64493 should be used.

- 64490 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
- 64491 second level (list separately in addition to code for primary procedure)
- 64492 third and any additional level(s) (list separately in addition to code for primary procedure)
  - Code 64492 should not be reported more than once per day.
  - Codes 64491, 64492 should only be used in conjunction with 64490.
- 64493 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
- 64494 second level (list separately in addition to code for primary procedure)
- 64495 third and any additional level(s) (list separately in addition to code for primary procedure)
  - Code 64495 should not be reported more than once per day.
  - Codes 64494, 64495 should only be used in conjunction with code 64493.
- 64505 Injection, anesthetic agent; sphenopalatine ganglion

6.2.3 Fluoroscopic Guidance

Fluoroscopic has been redefined as follows:

- 77003 Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, or sacroiliac joint), including neurolytic agent destruction
  - Injection of contrast during fluoroscopic guidance and localization (77003) is included in codes 22526, 22527, 62263, 62264, 62267, 62270-62282, 62310-62319.
  - Fluoroscopic guidance for subarachnoid puncture for diagnostic radiographic myelography is included in supervision and interpretation codes 72240-72270.
  - For epidural or subarachnoid needle or catheter placement and injection, see codes 62270-62282, 62310-62319.
  - For sacroiliac joint arthrography, see code 27096, 73542. If formal arthrography is not performed and recorded, and a formal radiographic report is not issued, use code 77003 for fluoroscopic guidance for sacroiliac joint injections.
  - For paravertebral facet joint injection, see codes 64490-64495. For transforaminal epidural needle placement or injection, see codes 64479-64484.
  - For destruction by neurolytic agent, follow descriptions for codes 64600-64680.
  - For percutaneous or endoscopic lysis of epidural adhesions, codes 62263 and 62264 include fluoroscopic guidance and localization.

In support of the establishment of paravertebral facet injection codes 64490-64495, code 77003 has been revised by deleting the phrase paravertebral facet joint. The cross-reference regarding facet injections following code 77003 has also been revised to direct users to these codes.

6.2.4 Consultation Codes

While Medicare will not reimburse for any consultation codes, at least for now, private insurers may consider these codes appropriate, including TRICARE, Medicaid, and MA Plans. However, they may also reduce the reimbursement rate, making it the same as an office visit.

6.3 Correct Coding Issues

Correct coding policies have influenced the patterns of billing and coding of all facets of medicine, including interventional pain management. Installation of the Correct Coding edits went into effect January 1, 1996, and since then new versions have been released every 3 months; the latest version, 16.0, was released November 20, 2009, and went into effect January 1, 2010 (42). Appendix 1 illustrates common interventional pain management procedures with description of various codes and can found at www.painphysicianjournal.com/extras/lm20101202aooendix1.pdf.

6.4 Interventional Pain Management Techniques

For interventional pain management, multiple changes have been made with facet joint interventions where fluoroscopy is not reimbursed separately; however, there is an increase of 14% in RVUs which will translate into increased payments without a cut. For other procedures, the controversy still continues with regards to fluoroscopy. The AMA is developing new CPT codes for transforaminal epidural injections incorporating fluoroscopy into the code. Also, CMS is looking at stopping fluoroscopy payment for epidural injections, sympathetic blocks, and all types of somatic nerve blocks.

Appendix 2 illustrates physician payments for various interventional procedures with a projected cut and without a projected cut, but instead an increase of 1.1% and can be found at www.painphysicianjournal.com/extras/lm20101202aooendix2.pdf.

Table 3 illustrates the impact of interventional pain for physicians and office practices. As seen in this table office practices have been affected substantially.

6.5 ASC Policy and Payment Changes

In 2006, over 250 surgery centers designated themselves as a single specialty interventional pain management center.

Significant cuts are published in payments for interventional pain procedures with overall cuts for the top 9 interventional pain management codes ranging from 11.1% to 13.4% for 2007 for primary codes, and 42% to 69% for add-on codes; however, some procedures also get significant increases. The decreases from 2009 to 2010 are 3.6% to 6.1% for primary codes and 52% to 57% for add-on codes for the top 9 interventional pain management codes. Appendix 3 illustrates the ASC payment rates for interventional techniques and can be found at www.painphysicianjournal.com/extras/lm20101202aooendix3.pdf.

In addition to the payment changes, other regulatory changes include a separate waiting room, which prevents physicians from using a shared waiting room. This is an expensive proposition for small ASCs, many of which utilize a common waiting room. However, the standard may be met for not mixing patients by having 2 separate waiting rooms.

Regarding pharmaceuticals, the present interpretation is that all single dose vials must be used on one patient at one time and discarded. For a lumbar epidural, instead of $13 for Omnipaque, lidocaine, and steroid, the cost will be approximately $55, a 423% increase. To make matters worse, reimbursement for surgery centers has decreased by 12% since 2007, accounting for inflation.

For interventional pain physicians, new category III CPT codes implemented in July 2009 for ASC payment include 0200T, percutaneous sacral augmentation or sacroplasty including balloon sacroplasty, unilateral and 0201T for bilateral procedures. CMS also has not added any procedures which were not on the covered procedure list including discography interpretation. In reference to procedures designated as office-based procedures, CMS believes that it is appropriate that ASCs be paid no more for performing office-based procedures

Table 3. *Illustration of the impact of interventional pain for physicians and office practices.*

		2007 Final Compared to 2006	2008 Transitional Compared to 2006	2009 Transitional Compared to 2006	2010 (Without Cut) Compared to 2006
Physicians and other providers		875,000	900,000	**980,000**	over 1 million
Payments (Approximate)		$ 61.5 billion	$ 64.8 billion ($57.0 billion projected)	**NA**	**NA**
Conversion Factor		37.8975	38.0870	36.0666	36.0666
Overall cut		0	0.5% Increase from 2007	5.2% cut	0%
Facility	Epidurals*	-0.5% to -0.9%	-0.6% to -1.4%	**-5.4% to + 0.3%**	**2% to 4%**
	Facet Blocks#	0% to -0.5%	-0.9% to +0.1%	**-4.1% to -6.2%**	**0% to 13%**
Non-facility	Epidurals	-6.9% to -10.6%	-13.0% to -20.4%	**-25% to -34%**	**-16% to -26%**
	Facet Blocks	-7.8% to - 9.9%	-14.7% to – 19.1%	**-26% to – 33%**	**-39% to -51%**

Percentage of change from 2006 values
Epidurals – 62310, 62311, 64479-64484 Facet Blocks – 64490-64495 – Fluoro is bundled

than those procedures would be paid when performed in physicians' offices. Their rationale is to deter inappropriate migration of these surgical procedures to ASCs based on financial considerations, rather than clinical needs.

6.6 Private Insurance Payments

Most private insurers are basing their payments on Medicare payments with TRICARE and others paying less than Medicare. Some private insurers are paying slightly higher than Medicare; however, they continue to use a 2007 rate system which may be beneficial for interventional pain management, but results in payments lower than Medicare payments for services such as orthopedics, as well as intervention procedures such as adhesiolysis and radiofrequency neurotomy. Figure 5 also illustrates a comparison of the increase in practice costs and proposed Medicare cuts. This figure illustrates the Medicare expenditure index or practice cost inflation, which will increase by 34.5% from 2001 to 2016. However, considering actual practice inflation with mounting health care costs to cover employees and families with double-digit percentage increases each year, increasing shortages of nursing and medical professionals, the costs of employment, and other inflation costs, actual medical inflation and costs of conducting a medical practice have been estimated to increase approximately 5% to 10% each year (with a total increase of practice costs of 90% by 2016). Unless the current law is modified and the SGR formula is repealed, physicians will see payment cuts of 51% by 2016.

6.7 Growth of Interventional Techniques

Manchikanti et al (14) illustrated the overall increase of interventional pain procedures per 100,000 Medicare beneficiaries of 197%, with increases for epidural procedures of 117%, facet joint interventions of 543%, discography of 159%, disc decompression of 316%, and spinal cord stimulation of 518%. All types of other nerve blocks were 63%. They also showed increases from 2002 to 2006 for sacroiliac joint interventions of 94% per 100,000 Medicare beneficiaries and vertebral augmentation procedures of 218%. They also showed that there was an increase of 137% in patients utilizing interventional pain management services per 100,000 Medicare beneficiaries. The majority of the increases were attributed to the exponential growth of the performance of facet joint interventions. There was also

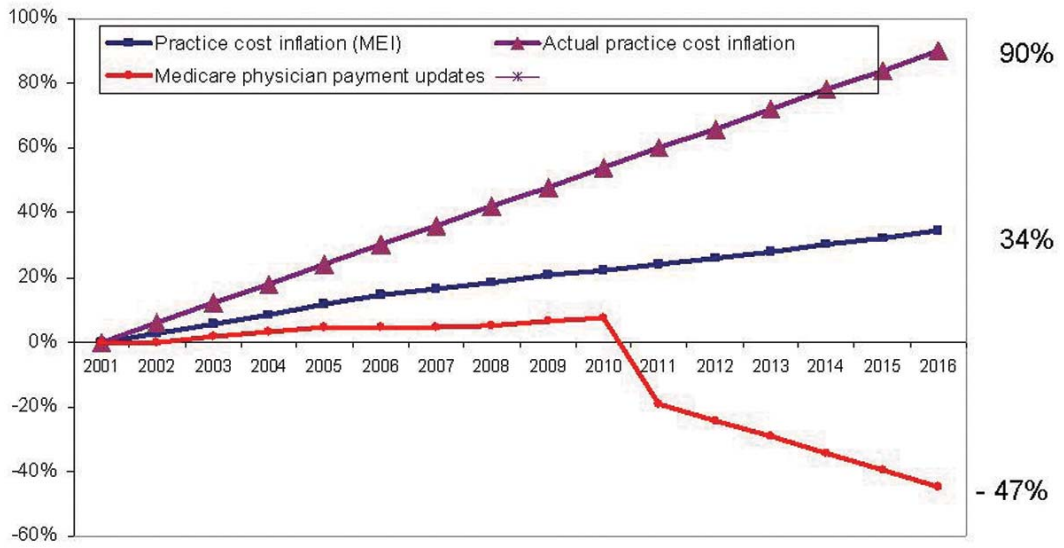


Fig. 5. *Comparison of increase in practice costs and proposed Medicare cuts.*

a 13.9% difference in the increase between the state with the lowest rate and the state with the highest rate in utilization patterns of interventional techniques (California — 37% versus Connecticut — 514%); and an 11.6-fold difference between Florida and California (431% versus 37% increase). In 2006, Florida showed a 12.7-fold difference compared to Hawaii, which had the lowest utilization rate.

HOPD expenses constituted the highest increase with fewer patients treated either in an ASC or in-office setting. Overall, HOPD payments constituted 5% of total 2006 Medicare payments, in contrast to 57% of total interventional pain management payments, an 11.4-fold difference.

Table 4 and Fig. 6 show increasing utilization of interventional techniques in the United States. These statistics also illustrate the proportion of interventional techniques performed by non-interventional physicians.

6.8 Waste, Abuse, and Fraud

In a report from September 2008, the Department of Health and Human Services, Office of Inspector General (HHS-OIG), reported that Medicare paid over $2 billion in 2006 for interventional pain management (interventional pain management procedures) (51). This report also showed that from 2003 to 2006, the number of Medicare claims for facet joint injections increased by 76% (51). Overall, payments for facet joint injections increased from $141 million in 2003 to $307 million in 2006, representing both physician and facility payments. Friedly et al (52) 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 (51) also illustrated that 63% of facet injection services allowed by Medicare in

Table 4. *Utilization of IPM services by specialty groups.*

	IPM services				Facet joint intervention services				Epidural procedures			
Speciality	2002 Services	2006 Services	% ↑ 2002	Annual increase	2002 Services	2006 Services	% ↑ 2002	Annual increase	2002 Services	2006 Services	% ↑ 2002	Annual increase
Extended IPM	1,999,000 (80.8%)	3,618,300 (78.5%)	81%	20.3%	529,220 (87.1%)	1,256,860 (74.5%)	137%	34.3%	1,080,320 (91.5%)	1,724,440 (91.3%)	60%	15%
Per 100,000 Medicare population	4,935	8,349	69%	17.3%	1,307	2,900	122%	30.5%	2,667	3,979	49%	12.3%
General Physicians	85,140 (3.4%)	409,400 (8.9%)	381%	95.3%	24,300 (4.0%)	314,420 (18.6%)	1194%	298.5%	22,780 (1.9%)	46,700 (2.5%)	105%	26.3%
Per 100,000 Medicare population	210	945	349%	87.3%	60	725	1109%	277.3%	56	108	92%	23%
Other Specialties	388,780 (15.7%)	582,660 (12.6%)	50%	12.5%	54,240 (8.9%)	116,900 (6.9%)	116%	29%	78,040 (6.6%)	117,000 (6.2%)	49%	12.3%
Per 100,000 Medicare population	960	1344	40%	10%	134	270	101%	25.3%	193	270	39%	9.8%
Total	2,472,920	4,610,360	86%	21.5%	607,760	1,688,180	178%	44.5%	1,181,140	1,888,140	60%	15%
Per 100,000 Medicare population	6,106	10,638	74%	18.5%	1,501	3,895	160%	40%	2,916	4,357	49%	12.3%

Extended IPM - Anesthesiology, Pain Management, Neurology, Neurosurgery, Orthopedic Surgery, Physical Medicine and Rehabilitation, and Psychiatry
General Physicians - General Practice, Family Practice & Internal Medicine

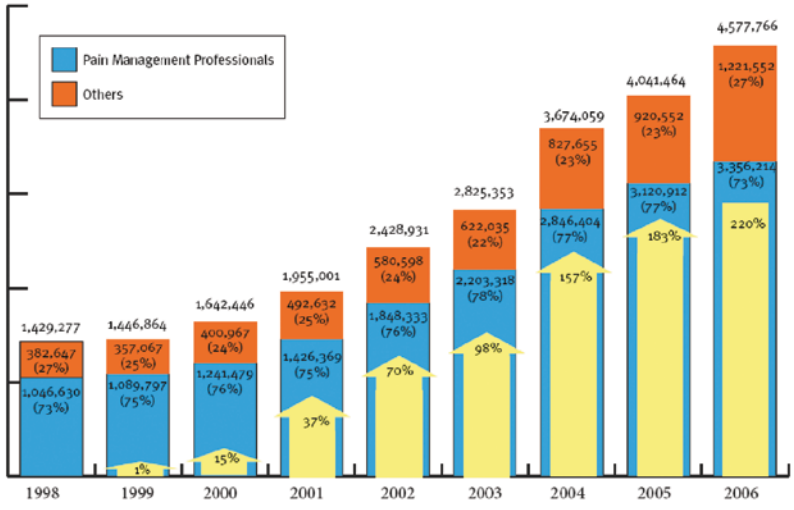


Fig. 6. *Increasing utilization of interventional techniques in the United States.*

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 5-7 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 (14) 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 (Table 4). Consequently, the yearly increase for general physicians was 87.3%, whereas it was 17.3% for interventional pain management.

7.0 Allegations of Lack of Evidence for Interventional Pain Management

Interventional pain management has been criticized for lack of evidence of the increasing prevalence of chronic pain and also lack of effectiveness of interventional techniques. However, enormous evidence is presented with regards to escalating disabilities and the economic impact of chronic pain (14,53-55). A recent study by Freburger et al (55) showed an annual increase of 11.6% of overall prevalence of low back pain across all demographic groups. The controversial issues of duration and chronicity of pain have been resolved with extensive literature illustrating that chronic pain lasts for months to years with recurrence and tends to relapse (56-77). Overall, high pain intensity and high interference has been reported in approximately 17% of the patients (78), whereas high pain intensity and disability have been reported in 25% of the patients with low back pain (79,80). In addition, the research also shows that pain prevalence and pain related disability are higher in the elderly (81). Finally, the health and economic impact of chronic pain has been stressed very frequently (54,69,82-87).

The literature concerning interventional pain management continues to be controversial with claims of ineffectiveness and inappropriate care (6,7,88-91). However, advances in the understanding the structural basis of chronic spinal pain, principles of evidence-based

Table 5. *Improperly paid medicare facet joint injection services physician claims, 2006.*

Type of Error	Sample		Projected	
	Services	Allowed Amount	Services	Allowed Amount
Documentation Coding Medical Necessity	196 173 43	$35,835 $11,670 $7,394	38% 31% 8%	$81 million $21 million $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 (51).
* Numbers do not sum to total because of rounding.

Table 6. *Error rate by setting and error type for medicare facet joint injection services—physician claims, 2006.*

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

Source: OIG analysis of medical review results, 2008. (51)

medicine, and comparative effectiveness research may have increased utilization (91-138).

7.1 Controlled Diagnostic Interventional Techniques

Precision diagnostic blocks are used to clarify multiple challenging situations, in order to determine the pathophysiology of clinical pain, the site of nociception, and the pathway of afferent neural signals. Diagnostic

Table 7. *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)

facet joint nerve blocks have been shown to have significant evidence classified as moderate to strong in the diagnosis of low back pain without radiculitis or disc herniation, utilizing multiple studies with strict criteria of 80% pain relief and the ability to perform previously painful movements with controlled diagnostic blocks (119,136-152). These studies showed the prevalence of lumbar facet joint pain is 21% to 40% in a heterogeneous population with chronic low back pain, and 16% in post lumbar surgery syndrome with confidence intervals (CIs) ranging from 9% to 23% in post surgery syndrome, and 14% to 53% in the heterogeneous population, with an overall average prevalence of 31% (95% CI; 28%–33%). They also showed false-positive rates of 17% to 49% with CIs ranging from 10% to 59% with an overall false-positive rate of 30% (95% CI; 27%–33%).

In contrast, in the diagnosis of lumbar discogenic pain, moderate evidence has been shown with a prevalence of 26% to 39% of discogenic pain with false-positive rates of 12.5% (104,132,133,139,153). However, the evidence for cervical and thoracic discogenic pain has been shown to be much less convincing with limited evidence. The prevalence of sacroiliac joint pain is estimated to range between 10% and 38% using a double block paradigm in the study population (132). The false-positive rate of single, uncontrolled, sacroiliac joint injections is 20% to 54% (144,154).

Multiple confounding factors also have been evaluated (153-159).

7.2 Contradictory Evidence of Therapeutic Interventions

7.2.1 Cochrane Review

Staal et al (89) evaluated low back pain treatments with facet joint interventions, as well as epidural injections. They concluded that there was moderate evidence with 2 trials including 210 patients that facet joint injections with corticosteroids are not significantly different from placebo injections for short-term pain relief and improvement of disability (160,161). However, Datta et al (138) utilized strict inclusion criteria of 80% pain relief with ability to perform previously painful movements with controlled diagnostic blocks and utilized at least 6 months of relief for short-term. Staal et al (89) also considered medial branch blocks for therapy. However, they utilized only one old study by Manchikanti et al (162). Staal et al (89) concluded that there was no difference even though they failed to take into consideration the design of the study — non inferiority or equivalence trial versus efficacy trial, based on lack of placebos. Datta et al (138) utilized stricter criteria as described above with utilization of 2 studies and appropriate analysis (111,162).

Similarly, in relation to epidural injections, they reached inappropriate conclusions (89). In contrast, American Society of Interventional Pain Physicians (ASIPP) guidelines (91) and multiple systematic reviews (114,115,117) reached different conclusions with Level I evidence for short and long-term relief (≤ 6 months and > 6 months) in managing chronic low back and lower extremity pain secondary to lumbar disc herniation and/or radiculitis and discogenic pain without disc herniation or radiculitis; Level II-1 or II-2 for caudal epidural injections in managing low back pain of post surgery syndrome and spinal stenosis. They also reached conclusions which were different for interlaminar epidural injections with Level II-2 – III for blind interlaminar epidural injections. For lumbar transforaminal epidural injections, the level of evidence was II-1 for short-term relief and Level II-2 for long-term relief in managing chronic low back and lower extremity pain.

7.2.2 American Pain Society Review

Chou et al (88) published a study of non-surgical interventional therapies for low back pain by searching manuscripts published through July 2008. Evidence selection included RCTs and systematic reviews. They concluded fair evidence of moderate benefit compared with placebo injection for short-term pain relief in patients with radiculopathy. Chou et al (88) also concluded that there was no evidence for diagnostic or therapeutic facet joint interventions based on inclusion of poorly conducted studies (160,163-172). In contrast, Datta et al (138) concluded that evidence for the diagnosis of lumbar facet joint pain with controlled local anesthetic blocks was Level I or II-1. The indicated level of evidence for therapeutic lumbar facet joint interventions was Level II-1 or II-2 for lumbar facet joint nerve blocks, Level II-2 or II-3 evidence for radiofrequency neurotomy, and Level III (limited) evidence for intraarticular injections.

7.2.3 American Academy of Neurology Assessment of Epidural Steroids

In 2007, Armon et al (90) published data on low back pain expenses in the United States in 1998. The abstract reports that there is insufficient evidence to recommend the use of epidural steroid injections to treat radicular cervical pain (Level U), even though the focus of the review was the use of epidural steroid injections

to treat radicular lumbosacral pain, and the studies included in the synthesis related solely to that focus. In a letter to the editor, Manchikanti et al (173) showed that Armon et al (90) included only 4 studies considered to have met the predetermined inclusion criteria, although previous studies have included larger numbers of randomized trials in systematic evaluation including the Cochrane review and European Guidelines (174-176). In contrast, the recent systematic reviews based on mainly randomized trials have shown significantly better evidence (114-116) than Armon et al (90). Further, even Chou et al (88) considered Armon et al's review (90) as being of low quality.

8.0 Pathway to a Perfect Storm

Interventional pain management is an evolving specialty. Interventional pain management is once again at the crossroads. Unless appropriate steps are taken, a perfect storm is brewing that will last through the next decade.

8.1 Definition of Chronic Pain

ASIPP has defined chronic pain as a complex and multifactorial phenomenon with pain that persists 6 months after an injury and/or beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal; that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years; that may continue in the presence or absence of demonstrable pathology; and may not be amenable to routine pain control methods with healing never occurring (87).

8.2 Interventional Pain Management

The National Uniform Claims defines interventional pain management as the discipline of medicine devoted to the diagnosis and treatment of pain and related disorders by the application of spinal interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatments.

8.3 Interventional Techniques

MedPAC described spinal interventional techniques as minimally invasive procedures, such as needle placement of drugs in targeted areas, ablation of targeted nerves, and some surgical techniques, such as discectomy and the implantation of intrathecal infusion pumps and spinal cord stimulators (92).

8.4 The Ingredients of the Brewing Storm

Multiple factors are contributing to this perfect storm. Appropriate steps must be taken to preserve the specialty. Emanuel and Fuchs (1) have described at least 7 factors which drive overuse; 4 are related to physicians and 3 are related to patients. These factors also apply to interventional pain management with a few additional ones.

These include the nature of the physician culture in the United States. It emphasizes thoroughness in medical school education and post graduate training, which is then carried over to practice, identifying and enumerating all possible diagnoses and the tests that would confirm or exclude them. Second, as per Emanuel and Fuchs (1), FFS payment misaligns incentives by creating over utilization coupled with current system bias toward paying significantly more for procedures, rather than for E/M, resulting in physicians' inclination to watch, wait, and communicate, which increases their propensity to order tests. This aspect also includes the powerful role for physician-directed pharmaceutical marketing which expends more than $10,000 for each physician. In addition, companies can selectively highlight favorable studies from massive research, with a lack of comparative effectiveness data for physicians.

A third aspect is medical malpractice loss, which results in defensive medicine and contributes to over utilization. Though, according to Emanuel and Fuchs (1), controversy about whether malpractice litigation and the concomitant real cost of premiums are increasing or decreasing.

With respect to patients, U.S. patients prefer high technology over high touch. It appears that in the medical sphere, this cultural value informs a patient perception that doing more tests and receiving more treatments and interventions is receiving better care. The next contributor for patient factors is direct-to-consumer marketing driving patients' requests for new and more costly medications. Finally, it is claimed that third party payments, despite deductibles, co-payments, and other out-of-pocket expenses, significantly shield patients' decisions from the true cost of health care.

While Emanuel and Fuchs (1) represent an extremely liberal view, there is truth to many of the arguments. Policy implications of the perfect storm in general for medicine and in particular for interventional pain management include addressing all the issues shown above. Overuse, over utilization, and abuse will only lead to reduction of costs — and as a consequence, reimbursements, leading the health care system into a single pay-

or system and hospital control of health care. As we see in other countries, it will take several years to develop an alternate system once a single payor nationalized system is instituted. Multiple aspects of the data from OECD may be biased or inaccurate and so is the data presented by both liberals and conservatives.

For interventional pain management, while we continue to follow medicine in general, it is important to realize we have issues related to overuse, abuse, financial incentives, and work on CER, EBM, accountability, and proven medical necessity and establishing indications for each and every procedure we perform.

9.0 Conclusion

The United States is in a revolt against medicine more than at any other time. Interventional pain management is an aggressive, evolving specialty with ownership being claimed by numerous specialties. It is imperative for all physicians, and especially interventional pain physicians, to maintain access and provide care based on evidence. We must put major financial incentives aside in favor of the system, rather than ourselves. This will create greater value for our services.

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Notes

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