SUBCHAPTER E. HEALTH FACILITY FEES 28 TAC §134.402

1. INTRODUCTION. The Texas Department of Insurance, Division of Workers' Compensation (Division) adopts amendments to 28 TAC §134.402 concerning Ambulatory Surgical Center Fee Guideline. The section is adopted with changes to the proposed text as published in the June 13, 2008 issue of the *Texas Register* (33 TexReg 4614) and error corrections published in the June 27, 2008 issue of the *Texas Register* (33 TexReg 5047).

2. REASONED JUSTIFICATION. These amendments are necessary to comply with the requirements of Labor Code §413.011 and §413.012. The rule was originally adopted in 2004 to comply with statutory mandates enacted in 2001 by House Bill (HB) 2600, 77th Legislature, Regular Session. HB 2600 amended Labor Code §413.011 to add new requirements for workers' compensation reimbursement policies and guidelines. Prior to adoption of the 2004 fee guideline, the Texas workers' compensation system did not have a fee schedule for health care provided in ambulatory surgical centers (ASCs). Therefore, those services were reimbursed on a case-by-case basis determination of what was fair and reasonable under what was then §134.1 of this title (relating to Use of the Fee Guidelines, repealed effective May 2, 2006).

Section 134.402 was amended in 2005 to address certain impacts of the new rule on participants in the Texas workers' compensation system. In 2007 the Centers for Medicare and Medicaid Services (CMS) significantly revised the Medicare ASC reimbursement methodology. In order to maintain the stability of the ASC reimbursement, the Commissioner of Workers' Compensation (Commissioner) amended §134.402 and retained the current ASC guidelines while researching and preparing to implement the new Medicare ASC reimbursement methodology. The amendments continued the use of reimbursement structures and amounts of the Medicare ASC 2007 rates for ASC facility services provided on January 1, 2008 through August 31, 2008. This continuation has afforded additional time for the Commissioner to determine and establish the appropriate ASC reimbursement methodology. The amendments structure, and utilize appropriate conversion factors or other payment adjustment factors geared to the Texas workers' compensation system.

Labor Code §413.011 establishes the statutory framework for Division fee guidelines for medical services. The statute requires the Commissioner to adopt health care reimbursement policies and guidelines that reflect reimbursement structures found in other health care delivery systems with minimal modifications as necessary to meet occupational injury requirements. In addition, Labor Code §413.011(a) requires the Commissioner to adopt the most current reimbursement methodologies, models, and values or weights used by the CMS to achieve standardization, including applicable payment policies relating to coding, billing, and reporting, and may modify documentation requirements as necessary to meet the requirements of Labor Code §413.053 (relating to Standards of Reporting and Billing).

Under Labor Code §413.011(b), the Commissioner is required to develop conversion factors or other payment adjustment factors in determining appropriate fees when developing these guidelines, taking into account economic indicators in health care by not adopting conversion factors or other payment adjustment factors based solely on those factors as developed by the CMS. The subsection further states that it does not directly itself adopt the Medicare fee schedule into Texas law.

Labor Code §413.011(d) requires that guidelines for medical services be fair and reasonable and designed to ensure the quality of medical care and to achieve effective medical cost control. The guidelines may not provide for payment of a fee in excess of the fee charged for similar treatment of an injured individual of an equivalent standard of living and paid by that individual or by someone acting on that individual's behalf. Notwithstanding §413.016 or any other provision of Title 5 of the Labor Code, §413.011(d-1) provides that an insurance carrier may pay fees to a health care provider that are inconsistent with the fee guidelines adopted by the Division if the insurance carrier or a network under Chapter 1305, Insurance Code, arranging for out-of-network services under Insurance Code §1305.006: (1) has a contract with the health care provider, that includes a specific fee schedule; and (2) complies with the notice requirements established under §413.011(d-2).

Additionally, Labor Code §413.012 requires the Commissioner to review and revise the medical policies and fee guidelines every two years to reflect fair and reasonable fees. Labor Code §413.0511(b)(1) also requires consultation with the Medical Advisor in developing, reviewing, and maintaining guidelines. Section 413.041 of the Labor Code requires health care practitioners and health care providers to submit to the Division financial disclosure information including ASC ownership interests.

These provisions are considered as the rule is amended. This section does not apply to political subdivisions with contractual relationships under Labor Code §504.053(b)(2).

Medicare

CMS regulates the Medicare and Medicaid programs. CMS has established a Medicare prospective payment system (PPS) for hospital/facilitybased services, which include inpatient and outpatient hospital care, ambulatory surgical services, and other facility-based services such as, but not limited to, rehabilitation, psychiatric, and long term care units. Medicare requires a deductible and co-pay from the patient until the patient reaches a certain level of expenditures. When setting reimbursement amounts, Medicare considers and

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includes this deductible and co-pay for facility services. CMS has directed extensive research in determining facility reimbursements in the Medicare system. Reimbursements are based on a facility's expected cost to provide a service rather than charged amounts, thus reimbursements differ by facility type. CMS establishes a predetermined amount of reimbursement which bundles or packages services. CMS updates reimbursements periodically based on a variety of factors, including weights (e.g., intensity), clinical issues, costs, inflation, and federal budget constraints. Reimbursement is based on national average costs with adjustments for geographic and facility specific factors. In addition, billed claims are subject to clinical coding edits Medicare has developed.

In setting the payment rates in the Outpatient Payment Prospective System (OPPS), CMS covers hospitals' operating and capital costs for services they furnish. Within the OPPS Ambulatory Payment Classifications (APCs) were adopted by CMS in August 2000. There are more than 800 APCs based on clinically similar items and services requiring similar amounts of resources. An outpatient visit may include multiple APCs, each APC having a predetermined rate. CMS determines the payment rate for each service by multiplying the APC relative weight for the service by a conversion factor. The relative weight for an APC measures the resource requirements of the service and is based on the median cost of the services in that APC. There are numerous other factors that comprise a reimbursement for a hospital outpatient setting.

On August 2, 2007, CMS published a final rule establishing a revised Medicare payment system for ASCs that applies to services provided on or after January 1, 2008 and expanded access to procedures in the ASC setting by allowing ASC payment to approximately 790 additional procedures in calendar year (CY) 2008. This compares to the nine specific reimbursement categories or ASC groups that were the previous Medicare ASC reimbursement groups. Also, on November 27, 2007, CMS published a final rule containing CY 2008 payment rates for ASCs based in part on the rates Medicare pays hospital outpatient departments (HOPDs). CMS changed the ASC payment system beginning January 1, 2008 because the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 also called Medicare Modernization Act (MMA) (Pub. L. 108-173, 117 Stat. 2066) required CMS to revise the ASC payment system no later than January 1, 2008.

The Government Accountability Office Report

CMS based the revised ASC payment system on the OPPS after the Government Accountability Office (GAO) studied ASC costs and found that the relativity of costs among ASC procedures was comparable to their relativity of

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costs in HOPDs. According to the statutorily mandated GAO report entitled, "Medicare: Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System" (GAO-07-86) released in November 2006, ASCs experience greater efficiencies in providing surgical services than HOPDs, resulting in surgical procedures being less costly when performed in an ASC The GAO determined that the APC groups in the OPPS facility setting. accurately reflect the relative costs of the procedures performed in ASCs. The GAO's analysis of the cost ratios showed that the ASC-to-APC cost ratios were more tightly distributed around their median cost ratio than were the OPPS-to-APC ratios. The report's analysis demonstrated that the APC groups reflect the relative costs of procedures performed by ASCs as they do for procedures performed in HOPDs and, therefore, that the APC groups could be used as the basis for an ASC payment. The GAO report concluded that, as a group, the costs of procedures performed in ASCs have a relatively consistent relationship with the costs of the APC groups to which they are assigned under the OPPS. The GAO's analysis also found that the procedures in the ASC setting have lower costs than those same procedures in HOPDs. The GAO reported that the median cost ratio among all ASC procedures was 0.39, whereas the median cost ratio among all OPPS procedures was 1.04. When the ASC median cost ratio is weighted according to Medicare ASC utilization, the ASC median cost increases to 0.84. This weighted ratio may be more indicative of the relationship between ASC and HOPD costs than a direct one-to-one comparison of APCs.

Based on its findings from the study, the GAO recommended that CMS implement a payment system for procedures performed in ASCs based on the OPPS, taking into account the lower relative costs of procedures performed in ASCs compared to HOPDs in determining ASC payment rates. CMS followed the GAO's recommendations.

CMS CY 2008 Revised ASC Payment System Under the OPPS-based revised ASC payment system, CMS pays for hospital outpatient services on a rate-per-service basis that varies according to APC group to which the service is assigned. CMS uses the Healthcare Common Procedure Coding System (HCPCS) Level I and Level II codes and descriptors to identify and group the services within each APC group. The OPPS includes payment for most hospital outpatient services except those identified in the CMS CY 2008 OPPS/ASC final rule published on November 27, 2007 that updated the OPPS for CY 2008 and provided the CY 2008 ASC conversion factor and payment rates. Medicare now uses the same APCs for ASCs as are used for HOPDs. Because ASCs provide only surgical services and hospitals provide many other types of outpatient procedures, such as emergency room services, HOPDs will utilize more APCs than ASCs.

In accordance with the MMA, the revised Medicare ASC payment system must be "budget neutral" which means that in CY 2008 Medicare expenditures under the revised Medicare ASC payment system must approximate the expenditures that would have occurred in the absence of the revised Medicare ASC payment system. In the CY 2008 OPPS/ASC final rule, CMS estimates that ASCs should be paid about 65 percent of the OPPS payment rates for the same surgical procedures in a HOPD.

The standard Medicare ASC payment for most ASC covered surgical procedures is calculated by multiplying the ASC conversion factor (\$41.401 for CY 2008) by the ASC relative payment weight set (based on the OPPS relative payment weight) for each separately payable procedure.

The complete lists of ASC covered surgical procedures and ASC covered ancillary services, the applicable payment indicators, payment rates for each covered surgical procedure and ancillary service before adjustment for regional wage variations, the wage adjusted payment rates, and wage indices are available on the CMS web site at <u>http://www.cms.hhs.gov/ascpayment/</u>.

CMS is providing a four-year transition to the fully implemented revised ASC rates. Payments during the four-year transition to the fully implemented revised ASC payment rates will be based on a blend of the CY 2007 ASC payment rates and the revised ASC payment rates at 75/25 in CY 2008, 50/50 in CY 2009, and 25/75 in CY 2010 with payment at 100 percent of the revised ASC

payment rates in 2011. Payment for covered surgical procedures added for ASC payment in CY 2008 or later and payment for covered ancillary services that are not paid separately under the existing ASC payment system will not be subject to a transition. For additional explanation, see

http://www.cms.hhs.gov/ascpayment/.

Implantable Devices

Prior to implementation of the revised Medicare ASC payment system, ASCs received separate payment for implantable devices. Under the revised system, CMS uses a modified payment methodology to establish the ASC payment rates for procedures that are designated as "device intensive." Device intensive procedures are specified ASC covered surgical procedures that, under the OPPS, are assigned to certain device dependent APCs. Device dependent APCs are groups of procedures that require the insertion or implantation of expensive devices. Payment for the high cost devices is packaged into the procedure payments under the OPPS. For the device dependent APCs, CMS develops estimates of the "device offset percentage," the proportion of the procedures' costs that are attributable to the cost of the device. CMS identifies the covered surgical procedures for which the device offset percentage of the APC under the OPPS is greater than 50 percent of the APCs median cost and designates those surgical procedures as device intensive. CMS pays the same

amount for the device-related portion of the procedure under the revised ASC payment system as under the OPPS for HOPDs. However, in the Medicare system payment for the service portion of the ASC rate will be adjusted by the ASC conversion factor.

For example: If the OPPS payment for a device intensive procedure is \$7,000 and the device offset percentage is 75 percent, the device portion is 5,250 (\$7,000 x 0.75 = \$5,250). The remaining \$1,750 (\$7,000 - \$5,250 = \$1,750) is the service portion of the procedure, the non-device cost that the facility incurs when the device is implanted. Under the revised ASC payment system, CMS will pay the same amount for the device portion of the procedure (\$5,250) as under the OPPS, but will adjust the service portion to approximately 65 percent of \$1,750, or \$1,137 (\$1,750 x 0.65 = \$1,137). This is consistent with other OPPS surgical procedures when ASCs are reimbursed for performance of these procedures. Thus, the Medicare ASC rate will be calculated by adjusting the OPPS service portion by the Medicare ASC conversion factor and that will be added to the full device portion of the OPPS rate to establish the full Medicare ASC payment rate for the procedure. Using the example, the resulting ASC reimbursement would be \$6,387 (\$5,250 + \$1,137 = \$6,387).

Because payment for procedures is based on the OPPS, which packages payment for implantable devices in the payment for the surgical procedures to implant them, in the Medicare system ASCs will no longer bill separately under the Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) fee schedule for any implantable devices.

Procedure payments, into which payment for devices is packaged, including those for device intensive procedures, are subject to the adjustment for geographic differences in wage. Because the labor-related share is 50 percent under the revised ASC payment system, the local wage index adjustment is applied to 50 percent of the national payment rate for the procedure involving the device. Payment rates for each covered surgical procedure before adjustment for regional wage variations, the wage adjusted payment rates, and wage indices are available on the CMS web site at http://www.cms.hhs.gov/ascpayment/.

Pass-through status under the OPPS is granted to new implantable devices that meet explicit OPPS criteria, including demonstrated substantial clinical improvement for patients. Under the OPPS, devices with pass-through status are paid separately for two to three years at hospital charges adjusted to cost. CMS provides separate payment to ASCs at contractor-priced rates for devices that are included in device categories with pass-through status under the OPPS when the devices are an integral part of a covered surgical procedure. Payment for these devices is not subject to the wage adjustment, while payment for procedures used to implant pass-through devices is subject to the wage adjustment.

In the Medicare system, ASCs will bill separately for devices that have pass-through status under the OPPS when provided integral to covered surgical procedures and will be paid separately under the revised ASC payment system. CMS has instructed ASCs in the Medicare system to use the appropriate Level II HCPCS codes to report the devices.

Division Data

In maintaining a medical billing database, the Division requires insurance carriers to submit billing and reimbursement information to the Division on a regular basis. The Division implemented a new reporting format in late 2006 to facilitate collection of medical billing and reimbursement data from insurance carriers in conjunction with new electronic billing reporting requirements. The new electronic reporting format is the International Association of Industrial Accident Boards and Commission's 837 format. Insurance carriers submitted CY 2005 and 2006 charged and paid data in this new format, and the Division has based the primary components of its analysis on CY 2006 information. In developing an analysis of the data for the amendment of §134.402 of this title, CY 2006 data was determined to be the most complete set of mature claims data available. The Division reviewed the CY 2006 claims data to have an improved understanding of the types of ASC facility services provided to injured employees and to understand the billing and reimbursement calculations associated with

those services. The Division was also able to review charge and payment activity for specific types of services.

Although an important component of the Texas workers' compensation system, ASC facility services account for a proportionally smaller portion of the medical benefits paid in the Texas workers' compensation system than hospital or doctor services. For example, based on a Deloitte Consulting, LLP (Deloitte) analysis of division data payments to ASCs for CY 2006 services totaled approximately \$21.4 million. Based on this observation, the Division estimated ASC reimbursement at less than three percent of total medical payments. Data used in the recent adoption of §134.403 of this title (relating to Hospital Facility Fee Guideline – Outpatient) and §134.404 of this title (relating to Hospital Facility Fee Guideline – Inpatient) (hospital fee guidelines) estimated payments to hospitals for CY 2006 services totaled approximately \$205 million, which represents approximately 21 percent of total medical payments. These hospital payments were split relatively evenly between inpatient services (\$93 million) and outpatient services (\$111 million). A similar Division review of reimbursement data for CY 2006 doctor services estimated payments at approximately \$625 million, or nearly 65 percent of total medical payments.

In CY 2006, 338 ASCs had approximately 13,700 Texas workers' compensation admissions, whereas 177 ASCs had ten or fewer admissions. Forty-one ASCs had more than 100 admissions each, representing 64 percent of

ASC charges and 62 percent of ASC reimbursements. Seventy-six ASCs had almost 80 percent of the admissions. This concentration is also evident in the services provided in the ASC facility setting. Ninety-five percent of all Texas workers' compensation ASC services were grouped to only 40 APCs. Further, the five most utilized APCs accounted for approximately 70 percent of the Texas workers' compensation system ASC encounters.

Deloitte Consulting, LLP

In March 2008, the Division entered into a professional services agreement with Deloitte, a subsidiary of Deloitte Touche Tohmatsu. Deloitte is one of the leading providers of complex consulting services, with a long history of service to most of the state governments across the country. Deloitte provides technology integration services, supporting the implementation of new legislation, designing operations to support refined business processes, and developing tools to support management decisions, and is often an advisor to some of the largest government agencies in the United States. Deloitte is experienced in deploying ASC and APC fee schedule reimbursement methodologies and is experienced in the workers' compensation area. Deloitte has access to industry and national normative databases that allows it to develop comparative analyses and assess differentials with the Division's internal data.

Specifically, the agreement sought Deloitte's expertise to perform actuarial services that indexed the Texas workers' compensation ASC facility

reimbursement to Medicare's 2008 ASC facility reimbursement. Additionally,

Deloitte was to index other health care systems' ASC reimbursement with Medicare reimbursement for ASC services.

Texas Workers' Compensation ASC Reimbursement Comparison to Medicare

The Division provided Deloitte detailed ASC utilization, charge, and payment data for CY 2005 and 2006 from the Division medical billing data base. The data set included over 29,000 bills attributable to more than 20,000 injured employees. Deloitte found the data set to be credibly populated and appropriate for use in the analysis. Data for the two calendar years were reviewed at a high level and determined to be consistent. The final analysis focused on the services provided during CY 2006.

As a preliminary review, Deloitte grouped and repriced the CY 2006 according to the CY 2006 Medicare and the §134.402 reimbursement methodologies. Analysis indicated that overall claims were paid at a rate of 213.6 percent of the Medicare ASC rate. This figure is consistent with the Division's previously stated reimbursement rate of 213.3 percent of Medicare and indicated a high level of data confidence for the majority of 2006 claims.

Almost 98 percent of the Texas workers' compensation claims are for ASC services that are not classified by Medicare as device intensive. Deloitte grouped and repriced these claims according to the new Medicare ASC reimbursement methodology. The resulting analysis estimates that CY 2006

ASC services provided and reimbursed in the Texas workers' compensation system were paid at approximately 189 percent of CY 2008 Medicare ASC reimbursement. This ratio establishes a reference point for the Division in establishing appropriate ASC reimbursement.

The remaining two percent of Texas workers' compensation claims involved services that Medicare identifies as device intensive. Device intensive procedures are identified as procedures including an implantable device where the device costs are on average more than 50 percent of the total Medicare procedure reimbursement. Deloitte estimated that these claims were reimbursed at approximately 112 percent of the CY 2008 Medicare ASC rate. Deloitte noted that the low figure for reimbursement of device intensive procedures may be related to the high proportion of these claims' overall costs associated with the implantable device rather than the procedure.

Comparison of Commercial and Medicare ASC Payment Rates

Deloitte also provided detailed information regarding reimbursement of ASC services by commercial payors outside the Texas workers' compensation system. The source of the commercial data for this analysis was the 2006 Medstat Market Scan Databases (Medstat). Medstat captures person-specific clinical utilization, expenditures and enrollment across patient types from large employers, health plans, government and public organizations, Blue Cross Blue Shield plans, and third party administrators. Medstat links paid claims and encounter data to detailed patient information across sites and types of providers and over time. This data represents a broad spectrum of insured employees and their dependents. Texas Medstat data for CY 2006 includes claim information for over one million members.

Deloitte analyzed the Medstat data in a similar fashion to the Texas workers' compensation data set. ASC services were identified and the data set processed to eliminate non-groupable claims, claims with negative allowed amounts, and claims where the patient age was less than 18. After applying Medicare grouping and pricing methodologies, Deloitte estimated the average commercial reimbursement for ASC services to be approximately 236 percent of Medicare reimbursement. Deloitte estimated the average ASC reimbursement for Preferred Provider Organizations (PPO) to be 265 percent of Medicare reimbursement. Various other payor types such as traditional indemnity, high deductible, basic medical and major medical coverage payment rates were estimated at approximately 217 percent of Medicare ASC reimbursement.

Setting Payment Adjustment Factors

In adopting amended payment adjustment factors (PAFs) for use in §134.402 of this title, the Division conducted extensive research to understand ASC facility reimbursement in the current Texas workers' compensation system, including: reimbursement rates, the reimbursement rates as compared to Medicare reimbursement, and the reimbursement rates as compared to non-workers' compensation reimbursement for ASC facility services, all of which are

requirements of the Labor Code at §413.011.

The Division also considered economic indicators for hospitals that are particularly relevant to the analysis process. Medicare margins and market basket information reflect the general increasing costs of care over time.

Deloitte reviewed Texas workers' compensation facility utilization and reimbursement. The reports prepared by Deloitte did not recommend a PAF, however, Deloitte did estimate that for CY 2006 ASC facility services were paid in the Texas workers' compensation system on average 189 percent of CY 2008 Medicare ASC facility services. In reviewing the estimated reimbursement rate, the Division considered the rate and the failure of CMS to adjust its reimbursement method for ASCs for an extended period of time. Although the Division adjusted for this situation when adopting the rate included in the initial §134.402, neither the previous §134.402 of this title nor the Medicare methodology actively considered medical inflation on an annual basis. CMS will utilize the Consumer Price Index for all Urban Consumers (CPI-U) (U.S. city average) to adjust its ASC reimbursement rates in CY 2010 and going forward. The CPI-U has increased approximately 15 percent since the adoption of the

current rule in May of 2004. If the Texas workers' compensation rate of 189 percent of 2008 Medicare reimbursement had been adjusted to reflect the change in the CPI-U since the original adoption of the rule in 2004, the equivalent rate would currently be approximately 217 percent of the 2008 Medicare ASC rate.

The Division, however, considered additional factors in setting the PAFs. The ratio of Medicare reimbursement to reimbursement made by other payors is an important comparison. Using commercially available data, Deloitte estimated commercial payor reimbursement for ASC services at approximately 236 percent of Medicare. The disparity between Texas workers' compensation system and commercial market is particularly evident in the five most frequently used APCs for musculoskeletal surgeries. These five APCs account for nearly 30 percent of all Texas workers' compensation system ASC encounters. Commercial reimbursement for the same APCs is approximately 290 percent of Medicare, compared to 172 percent of Medicare in the Texas workers' compensation system. Although Texas workers' compensation system payments exceed the Medicare payment, the existing payments have not been competitive with the commercial market.

In adopting a revised PAF, the Division noted and considered the recommendations made by system participants. Those recommendations

ranged from approximately 110 percent to 262 percent of the Medicare ASC facility services rate.

The Division also recognized the importance of surgically implanted devices to Texas injured employees. In establishing hospital facility reimbursement rates (see §134.403 and §134.404 of this title), the Division established methodologies to allow separate reimbursement of implantables to insulate facilities from potential losses directly related to the high costs of surgically implanted devices. This concept is replicated in the adopted amended ASC reimbursement methodologies to assure that costs of implantable devices are not a barrier to injured employee's access to services in an ASC facility setting.

The Division is adopting minimal modifications Medicare's to reimbursement methodology to reflect use of separate reimbursement for surgically implanted devices in non-device intensive procedures to ensure injured employees have access to care, including surgery where surgically implanted devices are medically necessary. The modification establishes two PAFs for the adopted amended rule, which are 235 percent and 153 percent of Medicare ASC reimbursement rate. The lower PAF maintains the offset ratio the Division used in establishing the lower PAF adopted in the hospital outpatient facility reimbursement methodology (see §134.403 of this title).

Additionally, the Division is adopting a specific reimbursement methodology for device intensive procedures that utilizes the higher PAF and allows separate reimbursement for the surgically implanted device either at the Medicare estimated cost, or the actual cost of the item plus an administrative fee. These device intensive procedures are specifically identified by Medicare and have device costs that are at least 50 percent of the Medicare APC reimbursement. In certain APCs, the device portion of the APC may be as high as approximately 88 percent of the Medicare APC rate. This methodology impacts a small number of APCs that warrant special consideration due to the disproportionate allocation of the device payment relative to other APCs.

The adopted amendments not only comply with the requirements of Labor Code §413.011, they also provide the Texas workers' compensation system with a rate that:

* is within the commercial market range;

* is less than the current preferred provider organization rate, but more than the current health maintenance organization rate;

* accounts for inflation based on the CPI-U since the initial adoption of §134.402 of this title;

* provides an increase over current reimbursement, improving the availability of ASC services to injured employees; and

maintains injured employee access to surgical implanted devices through separate reimbursement when appropriate for those devices.

The adopted amendments additionally comport with the Commissioner's authority under the Labor Code to audit and investigate both health care providers and insurance carriers as might be used in auditing implantable devices. Considering the value of implantable devices in returning the injured employee to work, the Commissioner may pursue audits to monitor, review, and study the utilization, billing, and reimbursement of implantable devices.

Upon consideration of all these factors and statutory requirements, the Division determines that adopted amended rates of 235 and 153 percent of the Medicare ASC reimbursement are the appropriate PAFs to be utilized in the Texas workers' compensation system along with the other identified adopted amendments for reimbursement of ASC facility services.

In response to comments from interested parties, and in consultation with the Medical Advisor, the Commissioner has adopted this section with a change to the proposal as published.

Language in subsection (g)(1)(B) of this section that required a facility or surgical implant provider, when requesting separate reimbursement for a surgically implanted device, to attach a copy of the invoice that supports actual cost to the facility or surgical implant provider is deleted in its entirety. This change from proposal is made as a result of public comment and to clarify the requirements that providers are required to provide documentation of the cost of the implantable through §133.210 of this title (relating to Medical Documentation). Section 133.210(c)(4) of this title establishes that a provider should include with its bill any supporting documentation for procedures which do not have an established Division maximum allowable reimbursement (MAR) and the exact description of the health care provided. Since surgically implanted devices do not have an established MAR, §133.210(c)(4) of this title applies. Stating the proposed subparagraph (B) in the rule is duplicative of the requirements of §133.210 of this title. Additionally, the deleted language created a perceived conflict or inconsistency with the implantable billing requirements in §134.403 and §134.404 of this title. It is the Division's intent to maintain consistency in all facility settings for the billing and reimbursement processes concerning separate reimbursement of surgically implanted devices.

3. HOW THE SECTION WILL FUNCTION.

Adopted amended §134.402(a) describes the applicability of the section. Adopted amended §134.402(a)(1) states that the section applies to facility services provided on or after September 1, 2008 by an ASC, other than professional medical services. Adopted amended §134.402(a)(2) notes that the section does not apply to professional medical services billed by a health care provider not employed by the ASC, except for a surgical implant provider as described in the section; and, that it is not applicable to services provided through a workers' compensation health care network certified pursuant to Insurance Code Chapter 1305, except as provided in Insurance Code Chapter 1305.

Adopted amended §134.402(b) provides definitions for words and terms that are used in the section. Adopted new §134.402(b)(1) defines the term "Ambulatory Surgical Center" to mean a health care facility appropriately licensed by the Texas Department of State Health Services. Adopted new §134.402(b)(2) defines the term "ASC device portion" to mean the portion of the ASC payment rate that represents the cost of the implantable device, and says that it is calculated by applying the CMS OPPS device offset percentage to the OPPS payment rate. Adopted new §134.402(b)(3) defines the term "ASC service portion" to mean the Medicare ASC payment rate less the device portion. Adopted new §134.402(b)(4) defines the term "Device intensive procedure" to mean an ASC covered surgical procedure that has been designated by CMS as device intensive in TABLE 56 – ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE INTENSIVE FOR CY 2008, as published in the November 27, 2007 publication of the Federal Register, or its successor. Adopted amended §134.402(b)(5) defines the term "Implantable" to mean an object or device that is surgically implanted, embedded, inserted, or otherwise applied, and related equipment necessary to operate, program, and recharge the implantable. Adopted new §134.402(b)(6) defines the term "Medicare payment policy" to mean reimbursement methodologies, models, and values or weights including its coding, billing, and reporting payment policies as set forth in the CMS payment policies specific to Medicare. Adopted new §134.402(b)(7) defines the term "Surgical implant provider" to mean a person that arranges for the provision of implantable devices to a health care facility and that seeks reimbursement for the implantable devices provided directly from an insurance carrier.

Adopted amended §134.402(c) clarifies that a surgical implant provider is subject to Chapter 133 and is considered a health care provider for purposes of the section and the sections in Chapter 133 of this title.

Adopted amended §134.402(d) requires that for coding, billing, and reporting of facility services covered in the section, Texas workers' compensation system participants shall apply Medicare payment policies in effect on the date a service is provided with any additions or exceptions specified in this section. Adopted amended §134.402(d)(1) provides for the inclusion of specific provisions contained in the Labor Code or Division rules, including Chapter 134, as taking precedence over any conflicting provision adopted or utilized by the CMS in administering the Medicare program. Adopted amended §134.402(d)(2) provides for the inclusion of Independent Review Organization decisions regarding medical necessity made in accordance with Labor Code §413.031 and §133.308

of this title (relating to MDR by Independent Review Organizations), which are made on a case-by-case basis, as taking precedence in that case only, over any Division rules and Medicare payment policies. Adopted new §134.402(d)(3) provides for the stated inclusion that whenever a component of the Medicare program is revised and effective, use of the revised component shall be required for compliance with Division rules, decisions, and orders for services rendered on and after the effective date, or after the effective date or the adoption date of the revised Medicare component, whichever is later.

Adopted amended §134.402(e) establishes that regardless of billed amount, reimbursement methods shall be determined in the following order. The first method is in adopted §134.402(e)(1), which states that reimbursement is the amount for the service that is included in a specific fee schedule in a contract that complies with the requirements of Labor Code §413.011. The second method is provided in adopted §134.402(e)(2), which states that if no contracted fee schedule exists that complies with Labor Code §413.011, the MAR amount is as described under subsection (f) of the section, including reimbursements for implantables. The last method is addressed in adopted §134.402(e)(3) and provides that if no contracted fee schedule exists that complies with Labor Code §413.011, and an amount cannot be determined by application of the formula to calculate the MAR as outlined in subsection (f) of the section, then reimbursement shall be determined in accordance with §134.1 of this title. Adopted amended §134.402(f) requires that the reimbursement calculation used for establishing the MAR shall be the Medicare ASC reimbursement amount determined by applying the most recently adopted and effective Medicare Payment System Policies for Services Furnished in Ambulatory Surgical Centers and Outpatient Prospective Payment System reimbursement formula and factors as published annually in the *Federal Register*. Reimbursement shall be based on the fully implemented payment amount as in ADDENDUM AA, ASC COVERED SURGICAL PROCEDURES FOR CY 2008, as published in the November 27, 2007 publication of the *Federal Register*, or its successor.

Adopted new §134.402(f)(1) allows two payment structures. The first reimbursement for non-device intensive procedures is to be the Medicare ASC facility reimbursement amount multiplied by 235 percent. In the alternative, if an ASC facility or surgical implant provider requests separate reimbursement for an implantable, reimbursement for a non-device intensive procedure is the sum of two parts. The first part is the lesser of the manufacturer's invoice amount or the net amount (exclusive of rebates and discounts) plus 10 percent or \$1,000 per billed item add-on, whichever is less, but not to exceed \$2,000 in add-on's per admission. The second part is the Medicare ASC facility reimbursement amount multiplied by 153 percent.

Adopted new §134.402(f)(2) allows a reimbursement for device intensive procedures to be the sum of the ASC device portion, and the ASC service portion multiplied by 235 percent. It also provides that if an ASC facility or surgical implant provider requests separate reimbursement for an implantable, reimbursement for the device intensive procedure shall be the sum of the lesser of the manufacturer's invoice amount or the net amount (exclusive of rebates and discounts) plus 10 percent or \$1,000 per billed item add-on, whichever is less, but not to exceed in \$2,000 in add-on's per admission and the ASC service portion multiplied by 235 percent.

Adopted amended §134.402(g) states that a facility, or surgical implant provider with written agreement of the facility, may request separate reimbursement for an implantable used in a device intensive procedure. Adopted amended §134.402(g)(1) provides that the facility or surgical implant provider requesting reimbursement for the implantable shall bill for the implantable on the Medicare-specific billing form for ASCs, and include with the billing a certification that the amount billed represents the actual cost as specified in the text. Adopted new §134.402(g)(2) states that an insurance carrier may use the audit process under §133.230 of this title (relating to Insurance Carrier Audit of a Medical Bill) to seek verification that the amount certified under paragraph (1) properly reflects the requirements of this subsection. Such verification may also take place in the Medical Dispute Resolution process under §133.307 of this title (relating to MDR of Fee Disputes), if that process is properly requested, notwithstanding §133.307(d)(2)(B). Adopted new §134.402(g)(3) provides that nothing in the rule precludes an ASC or insurance carrier from utilizing a surgical implant provider to arrange for the provision of implantable devices and that implantables provided by such a surgical implant provider shall be reimbursed

according to the subsection.

Adopted new §134.402(h) establishes that for medical services provided in an ASC, but not addressed in the Medicare payment policies as outlined in subsection (f) of the section, and for which Medicare reimburses using other Medicare fee schedules, reimbursement shall be made using the applicable Division Fee Guideline in effect for that service on the date the service was provided.

Adopted new §134.402(i) provides that if Medicare prohibits a service from being performed in an ASC setting, the insurance carrier, health care provider, and ASC may agree, on a voluntary basis, to an ASC facility setting. Adopted new §134.402(i)(1) states that the agreement may occur before or during preauthorization. Adopted amended subsection (i)(2) also sets forth that a preauthorization request may be submitted for an ASC setting only if an agreement has already been reached and a copy of the signed agreement is filed as a part of the preauthorization request. Adopted amended subsection (i)(3) provides that the agreement between the insurance carrier and the ASC must be in writing and include the reimbursement amount; any other provisions of the agreement; and names, titles, and signatures of both parties, with dates. Adopted amended subsection (i)(4) states that copies of the agreement are to be kept by both parties and that the agreement does not constitute a voluntary network established in accordance with Labor Code §413.011(d-1). Adopted amended (i)(5) provides that copies of the agreement are to be kept by both parties and that prevent agreement are to be kept by both parties and that copies of the agreement are to be kept by both parties that copies of the agreement are to be kept by both parties and that copies of the agreement are to be kept by both parties and that upon request of the Division, the agreement information shall be submitted in the form and manner prescribed by the Division.

Adopted new §134.402(j) establishes the severability of this section and states, if a court of competent jurisdiction holds that any provision of the section is inconsistent with any statutes of this state, are unconstitutional, or are invalid for any reason, the remaining provisions of the section shall remain in full effect.

4. SUMMARY OF COMMENTS AND AGENCY'S RESPONSE TO COMMENTS.

§134.402: Some commenters support the proposed rule.

Agency Response: The Division appreciates the supportive comments.

§134.402: Some commenters commend the Division for allowing stakeholders the opportunity to be involved in this beneficial rulemaking process, for looking at the big picture, and understanding where ASCs fit into the delivery of health care

and the benefits ASCs can provide to injured employees, employers, insurance carriers and other providers.

Agency Response: The Division appreciates the supportive comments and agrees that system participant input is an important component in exploring and understanding options for the development and operation of the Texas workers' compensation system.

§134.402: A commenter opines that the rule proposal will increase competition. The commenter suggests it may bring some doctors back into the workers' compensation system due to scheduling efficiencies appreciated in ASCs, which are less evident in hospital outpatient surgical departments. With surgery that can be accomplished sooner, an injured employee should be eligible for either rehabilitation services, or to return to work sooner, all of which are advantages to using the ASC site of service.

Agency Response: The Division acknowledges that the rule enhances access to surgical venue choices for injured employees. These choices may lead to increased competition with the potential for quality and outcome improvements.

§134.402(a)(1): A commenter asks if there will be a grace period applied to the new rule since such a short time frame from adoption to applicability date is extremely difficult.

Agency Response: The Division clarifies that previous §134.402(a)(2) contained a provision that prevents an extension beyond August 31, 2008, necessitating the implementation of these amendments by September 1, 2008.

§134.402(b)(5): A commenter supports the definition of "surgical implant provider."

Agency Response: The Division appreciates the supportive comments.

§134.402(b)(5): A commenter believes the definition of "surgical implant provider" is overly broad and could lead to overpayment and abuses, but the commenter also recognizes this definition is consistent with other Division fee guidelines.

Agency Response: The Division disagrees the definition is overly broad and could lead to overpayment and abuses. However, the Division agrees that the definition is consistent with Division definitions relating to implantable devices. The Division is concerned with any potential abuse and will monitor the use of surgically implanted devices throughout the workers' compensation system. The Division will closely monitor implant costs. This may include a data call to capture specific implantable information, such as the invoice cost and facility charge. In addition, the Division may request other specific implantable information, such as the lot number, model number, or serial number of the

device or other identifier used by a manufacturer. The latter identifiers are consistent with medical device tracking requirements imposed on a manufacturer when tracking is ordered by the Food and Drug Administration for a class II or class III medical device pursuant to 21 U.S.C. §360i (e) and 21 C.F.R. § 821.1 *et. seq.* Additionally, insurance carriers have the ability to audit health care providers and surgical implant providers in part under the authority of §133.230

and §133.307 of this title.

§134.402(b)(5): Some commenters believe the definition of "surgical implant provider" invites billing abuse and suggest it is so broad as it could be used to apply to all forms of durable medical equipment that is in any way applied to the body, when often such type of equipment is potentially reusable by the facility for many other patients. The commenters are opposed to the insurance carrier being forced to pay up to \$1,000 of a mark-up up each time the facility uses the equipment for a workers' compensation claim, and state this violates Labor Code §413.011(f) since it fails to achieve effective medical cost control.

Agency Response: The Division clarifies the components of an implantable device are generally tailored for the use by a specific patient and are not maintained or reused by a facility. The insurance carrier, through the bill review and audit processes, may address any potential insurance carrier uncertainty about the billing of an implantable. Reimbursement for the implantable and the

appropriate add-on amount will be made to the entity that submitted the CMS-1500 form with the required documentation and certification. Additionally, a cap of \$2,000 is identified in the rule to discourage unbundling of items that exceed the \$1,000 per billed item cap. This definition and the associated processes are consistent with adopted §134.403 and §134.404 of this title.

§134.402(b)(7) and (c): Some commenters state the Division lacks the statutory authority to recognize implant providers as health care providers, and state that it is inaccurate and unlawful. A "surgical implant provider" does not meet the definition of "health care provider" found in Labor Code §401.011, and the Texas Legislature has not recognized "surgical implant provider" as a stakeholder in the Texas workers' compensation system as it has with pharmaceutical processing agents under Labor Code §413.0111.

Agency Response: The Division disagrees with the comment. The Division clarifies that the definition for "surgical implant provider" does not expressly define such an entity as being a health care provider. Rather, §134.402(c) states that a surgical implant provider is subject to Chapter 133 of this title (relating to Benefits – Medical Benefits) and is considered a health care provider for purposes of §§134.402, 134.403 and 134.404 and Chapter 133. It has been the Division's position in the past that a company that supplies medical equipment is a facility that provides "health care," and thus can meet the definition of "health

care provider" under the Labor Code for purposes of Chapter 133. This interpretation was expressed in the adoption order for §133.1 (concerning Definitions for Chapter 133, Benefits - Medical Benefits) published in the *Texas Register* on March 10, 2000. (25 TexReg 2115 at 2118.) Subsequently, the statute changed to include surgical supplies as a form of health care pursuant to Labor Code §401.011(19)(F).

§134.402(b)(7): Some commenters recommend that the rule clarify in the definition of surgical implant provider that the definition does not pertain to or include an implant manufacturer.

Agency Response: The Division declines to make the change. The Division determines the definition for surgical implant provider is appropriate and that it maintains consistency with provisions contained in the Division's recently adopted hospital fee guidelines. This consistency is necessary to prevent confusion as to its application between fee guidelines.

§134.402(b)(7): Some commenters are concerned about the lack of rule language prohibiting device manufacturers from direct billing, and reference similarly stated concerns in response to the hospital outpatient and inpatient facility fee guideline proposals. One commenter states device manufacturers have no reason to work with insurance carriers in the discussion of what is

reasonable and what should be paid, and suggests such activity could even cause abuse of that process.

Agency Response: The Division disagrees and believes that removing or restricting manufacturers from billing insurance carriers directly may inadvertently restrict business decisions available to facilities. This restriction could hinder injured employees' access to implantable devices. Additionally, the Division disagrees there is no incentive for any implantable supplier to refuse to negotiate with insurance carriers in respect to what is reasonable and should be paid for Providers and insurance carriers are free to negotiate implantables. reimbursement above or below fee guidelines in the Texas workers' compensation system. As with any negotiation, it is assumed that negotiating parties must find mutually beneficial common ground based on their particular business needs. Although contracting does not appear to be a common occurrence in the current system, as the system matures, opportunities for negotiations and agreements may evolve. The consistent definitions and concepts included in all of the facility fee guidelines concerning implantables may facilitate those contracting opportunities. The Division sees no need to hinder the potential for innovative arrangements between system participants.

§134.402(d)(3): A commenter recommends clarification be provided as to how Medicare program changes occur, when and how they become effective in the workers' compensation system.

Agency Response: The Division clarifies that use of updated or revised Medicare components in the Texas workers' compensation system is not a new concept and §134.402(d)(3) requires use of the most recent payment policies adopted by the Medicare program for compliance with Division rules, decisions and orders for services rendered on or after the effective date, or after the effective date or the adoption date of the revised Medicare component, whichever is later. Further, the Division clarifies this is a standard provision that has been applied to other recently amended Division fee guideline rules in order to prevent the Texas workers' compensation system from falling out of synchronization with Medicare. Texas worker's compensation system participants have been supportive of this in previous rule efforts stating that without the provision, retrospective payments and refunds would make payment within the Texas workers' compensation system uncertain and unmanageable and would result in insurance carriers and hospitals incurring costs associated with making additional payments or refunding payments.

§134.402(d)(3): Some commenters encourage the Division to allow for a CPI-U increase even if Medicare should freeze this provision at some point in time. The commenters further indicate it may be difficult to address this by rule, and suggest a PAF adjustment in future years may be the solution. One commenter further states such CPI-U adjustment could be accomplished in a manner similar to the current conversion factor annual adjustment for professional services as outlined in §134.203 of this title (relating to Medical Fee Guideline for Professional Services).

Agency Response: The Division declines to make the change. The proposed and adopted rule automatically includes the CMS provisions for increases in ASC reimbursement based on the CPI-U that will begin in 2010. CMS utilizes different reimbursement methodologies and benchmarks for establishing inflation factors for outpatient hospital and ASC facility services. The Division adopts the CMS methodologies for updating reimbursement and consequently maintains a parallel relationship between both the CMS and the Texas workers' compensation system and the hospital outpatient and ASC facility reimbursements.

§134.402(d)(3): A commenter opposes any automatic annual inflation adjustment outside the Medicare methodology, as it is inconsistent with the Division's hospital outpatient fee guideline. The commenter advises that the Division review of fee guidelines is required every two years, and such review

and revision, if necessary, can take into account whether an inflation adjustment is necessary considering all other relevant factors.

Agency Response: The Division agrees and no changes to the rule are necessary. Inflation adjustments are currently included in the CMS methodologies and the Division has incorporated these annual revisions into the adopted rule by adopting the Medicare reimbursement structure. Future rule review and, if necessary, revision will consider all the requirements of the Labor Code including those related to reimbursement and annual adjustments.

§134.402(e)(2): Some commenters request clarification as to whether the reimbursement methodology related to the fee schedule and MAR is mandatory or discretionary and whether the statements made in an agency appellate brief contradict the methodology.

Agency Response: The Division clarifies §134.402 is mandatory for payment purposes. Labor Code §408.027(f) provides that "Any payment made by an insurance carrier under this section shall be in accordance with the fee guidelines authorized under this subtitle."

The issues raised by the commenters regarding an agency brief are currently before the Third Texas Court of Appeals where the Division is an appellee. The issues will be presented, and argued, before the Third Texas Court of Appeals at a hearing currently scheduled for September 10, 2008, and a ruling on these issues from the Third Texas Court of Appeals is expected after the hearing. As such, statements made in an agency appellate brief concerning medical fee dispute resolution are outside the scope of comments on this rule.

§134.402(f): A commenter states the rule's proposed rates are adequate to reimburse ASCs in a manner that their costs are covered and may make a profit on the treatments and services provided to injured employees.

Agency Response: The Division appreciates the supportive comment and the Division believes the adopted rule reflects appropriate reimbursement to ASCs in the Texas workers' compensation system.

§134.402(f): A commenter supports use of the current Medicare methodology.

Agency Response: The Division is appreciative of the supportive comment and is confident, based on the Division's internal and external analyses, that the adopted rule reflects appropriate reimbursement of ASCs and the Texas workers' compensation system, and that the adopted rule complies with the requirements of Labor Code §413.011.

§134.402(f): Some commenters support the rule's inference that there is no inclusion of a geographic wage adjustment, a component of the Medicare fee schedule, and state that such geographic wage adjustment would cause more payment problems than would be beneficial to system participants.

Agency Response: The Division clarifies that the most current Medicare reimbursement methodologies are included in the adopted rule. Although the wage adjustments and other specific components of the CMS calculation are not specifically mentioned within §134.402, the wage index adjustments and the other components of the calculation are necessary to maintain consistency with the CMS system. Additionally, the wage index adjustments attempt to recognize a portion of the geographic cost variations. These geographic variations are also included in other Division fee guideline rules through the use of CMS methodologies specific to those rules.

§134.402(f): A commenter recommends that this rule be reviewed in calendar years 2010 and 2011 to ensure the intent of *Federal Register* publications regarding the "fully implemented" reimbursement rates for ASCs.

Agency Response: The Division clarifies that the fully implemented rates are included in adopted §134.402(f). Also, future rule review and, if necessary,

revision will consider all the requirements of the Labor Code including those related to reimbursement and annual adjustments.

TITLE 28. INSURANCE

§134.402(f): A commenter recommends adoption of a conversion factor in the final rule in lieu of a Medicare percentage.

Agency Response: The Division declines to make the change. Use of the adopted payment adjustment factors is consistent with the reimbursement methodologies included in the hospital outpatient reimbursement guidelines.

§134.402(f): A commenter recommends the establishment of a specific reimbursement, such as 60 percent of billed charges, in situations when no contracted fee schedule exists that complies with Labor Code §413.011.

Agency Response: The Division declines to make the change. The majority of services provided in ASCs are addressed by the adopted fee guidelines. In any instance where a reimbursement amount cannot be calculated through the use of adopted Division fee guidelines, then §134.1 of this title is to be applied. Section 134.1 establishes reimbursement parameters consistent with Labor Code §413.011.

§134.402(f): A commenter states that the proposed PAFs and implant provisions in proposed §134.402 violates Labor Code §413.011(a), which requires that the Division adopt the most current reimbursement methodologies, models, and values or weights used by CMS with "minimal modifications." Such PAFs and separate payments for implants are much more than a minimal modification and there is no data to justify such a major modification to ensure the quality of medical care and to achieve effective medical cost control as required by Labor Code 413.011(d). The commenter additionally asserts that the Legislature has expressly prohibited the Division from changing CMS methodology with regard to reimbursement of implantables and states the Division shall recommend to the Legislature any statutory changes necessary to ensure injured employees have appropriate access to surgically implanted devices.

Agency Response: The Division disagrees with the commenter's assertions. Section 413.011(b) states "...this section does not adopt the Medicare fee schedule, and the commissioner may not adopt conversion factors or other payment adjustment factors based solely on those factors as developed by the federal Centers for Medicare and Medicaid Services." However, the Commissioner adopts the most current Medicare reimbursement methodologies as required by the Labor Code. In accordance with Labor Code §413.011(b), it is also clearly within the authority of the Commissioner to develop one or more conversion factors or other payment adjustment factors in determining the appropriate fees. The Commissioner adopts payment adjustment factors that provide appropriate reimbursement for facilities in order to provide reasonable injured employee access to procedures requiring surgically implanted devices. Further, the rule reflects minimal modifications to reimbursement methodologies to meet the occupational injury requirements as noted in Labor Code §413.011(a). Although Labor Code §413.011(i) states the Division shall recommend to the Legislature any statutory changes necessary to ensure appropriate access to surgically implanted devices, the Commissioner's current authority under the Labor Code allows the Commissioner to appropriately address access and reimbursement issues through the rulemaking process.

§134.402(f) and (g): Some commenters support the rule proposal in following the same basic structure as the Division's recently implemented rules for hospital outpatient and inpatient facility fee guidelines which allow providers a choice for separate reimbursement when implantables are involved in a surgical procedure. **Agency Response:** The Division appreciates the supportive comments and acknowledgement of the consistency between this and other rules in respect to the provider's choice for reimbursement of implantable devices.

§134.402(f)(1) and (2): Some commenters recommend alternate PAFs of 246 percent of Medicare when implants are not paid separately, and 160 percent of Medicare when implants are paid separately. The commenters indicate that with a 24 percent discount noted by the proposed PAFs, three percent of the

procedures may still be done at a higher cost location; whereas adjusting it to a 20 percent discount might eliminate that three percent completely and maximize the use of surgery centers. The commenters state that parity in reimbursement between ASCs and hospital outpatient departments when performing the same procedures for injured employees is supported by workers' compensation jurisdictions in California and Tennessee.

Agency Response: The Division declines to make the changes. In proposing and adopting PAFs for use in §134.402, the Division conducted extensive research to understand ASC facility reimbursement in the current Texas workers' compensation system, including: reimbursement rates, the reimbursement rates as compared to Medicare reimbursement, and the reimbursement rates as compared to non-workers' compensation reimbursement for ASC facility services, all of which are requirements of the Labor Code at §413.011. Upon consideration of the statutory requirements, the Division determines that adopted rates of 235 and 153 percent of the Medicare ASC reimbursement are the appropriate PAFs to be utilized in the Texas workers' compensation system, as explained earlier in the preamble. The adopted reimbursement may result in a more competitive relationship between the hospital outpatient and ASC facility settings for surgical services. **§134.402(f):** A commenter recommends rule language be amended to address the payment of ancillary services (Addendum BB), and specifically provide that ancillary services may only be reimbursed when provided in connection with a primary procedure (Addendum AA).

Agency Response: The Division declines to make the change. The Division has adopted the most current CMS payment policies and structures for reimbursement of ASC services. In an effort to maintain synchronization with the most current payment policies and also to avoid micromanaging the reimbursement process, the rule relies on the most recently adopted and effective Medicare payment system policies including the necessary direction provided through any addenda or tables included in the CMS payment policies. Although Addendum AA is cited in subsection (f) of the rule, its purpose is to note the fully implemented payment amount. Consequently, any additional references to specific addenda or tables are unnecessary.

§134.402(f)(1): A commenter supports the proposed payment adjustment factors, believing they will encourage more ASCs and medical providers associated with ASCs to participate in the Texas workers' compensation system. The commenter believes it is appropriate for the ASCs to receive payment that is less than in a hospital outpatient setting, but that a lower range such as that adopted by CMS is not appropriate for ASCs in the Texas workers' compensation

setting. ASC could potentially play a more critical role in helping employers control workers' compensation costs and helping workers become whole again.. The proposed PAFs should encourage more frequent use of ASCs, which should offset any increased costs to the system and increase market penetration of ASCs in the Texas workers' compensation system.

Agency Response: The Division agrees and appreciates the supportive comment.

§134.402(f)(1): Some commenters are opposed to any PAF increase beyond what the Division proposed by rule.

Agency Response: The Division agrees that the adopted PAFs are the appropriate reimbursement levels for the Texas workers' compensation system.

§134.402(f)(1) and (f)(2): A commenter supports the provisions in (f)(1)(B) and (2)(B) of the proposed rule that appropriately deviates from Medicare policies that will allow ASCs to elect to be separately reimbursed for implants since a bundled payment in many cases would not be adequate to cover the cost of certain implantables. The commenter references Labor Code §413.011(i) that establishes a public policy priority to ensure appropriate access to implantable devices. To ensure appropriate patient access is maintained, the commenter

believes the Division is well within these statutory provisions to adopt rules that deviate from strict Medicare policy.

Agency Response: The Division agrees that §413.011 provides the Commissioner with authority to adopt rules which comply with the statutory framework of §413.011.

§134.402(f)(1) and (f)(2): A commenter supports the separate reimbursement for implants at cost plus ten percent capped at \$1,000 per billed item, which allows a facility to be reimbursed for both the invoice and "acquisition" costs. However, the commenter recommends a higher limit than \$2,000 per admission add-on cap as this may not be at a high enough level to cover full acquisition and other costs for more expensive devices. The commenter notes these additional facility absorbed expenses include obtaining the medical devices, ordering, processing, storage, accounting, collections, cost of capital, depreciation, and amortization.

Agency Response: The Division appreciates the supportive comments regarding the add-on provisions. However, the Division disagrees that a higher limit than \$2,000 per admission is necessary. The adopted add-on provisions for implantables is consistent with the provisions adopted for implantable reimbursement in a hospital outpatient setting. The reimbursement amount recognizes that there are administrative costs associated with acquisition of an

item and that the entity (facility or surgical implant provider) responsible for these administrative tasks and billing for the item should be reimbursed. There is no reason to believe, however, that the administrative burdens extend to more than \$1,000 per item. The acquisition activities of ordering, receiving, stocking, and billing for a \$5,000, \$10,000, or \$50,000 item are similar. Consequently, in order to recognize costs of the acquisition and purchasing process, yet maintain cost control related to these administrative costs, the adopted rule limits add-ons to 10 percent of an item's cost up to \$1,000 per item. Additionally, a limit of \$2,000 in add-ons per admission is also adopted to discourage unbundling of expensive

implantable items.

§134.402(f)(2): A commenter recommends subparagraph (B) should apply in all cases when the provider would want to bill separately for implants, and consequently recommends deletion of subparagraph (A).

Agency Response: The Division disagrees and declines to make the change . The option for separate billing and reimbursement of implantables is made at the election of the facility. If the facility should choose not to bill separately for implantables, then subparagraph (A) is necessary to assure appropriate reimbursement to the facility. **§134.402(f)(2):** Regarding separate reimbursement of implantables, a commenter states that commonly, contracts for implantable devices are reimbursed on average at cost plus 10 percent. The commenter estimated that in 2007, approximately 24.2 percent of workers' compensation cases in ASCs involved implants and one percent of the cases involved device intensive procedures.

Agency Response: The Division appreciates the comment and notes that the adopted rule allows for separate reimbursement at cost plus 10 percent with an add-on limit of \$1,000 per item with a limit of \$2,000 in add-ons per admission.

§134.402(f)(2) and (g): A commenter asks if a uniform rule will be developed specifically addressing separate reimbursement for implantables, and suggests there are no rules, just suggestions as to how hospitals and ASCs may or may not indicate on a bill that a separate reimbursement for implantables is being sought. The commenter recommends the use of a modifier as an indicator of separate reimbursement request.

Agency Response: The Division agrees that identifying reimbursement methodologies is important to the successful implementation of the adopted rule. The Division is currently investigating the possibility of following the National Uniform Claim Committee's Instructions, which direct supplemental information to be placed in the shaded area above the applicable service line in Section 24 of

the CMS-1500 form. This allows up to 61 characters to be printed in this space. In the eBilling structure this translates to a claim/line note in the 837(P). The Division anticipates providing additional instruction in the ASC rule implementation process similar to that offered with the hospital fee guidelines.

§134.402(f)(2): A commenter supports paying the higher PAF for the facility portion only, and paying implants separately. The commenter also supports the provision that allows implants to be reimbursed at cost plus 10 percent with a cap of \$1,000 per billed item, or \$2,000 per admission.

Agency Response: The Division appreciates the supportive comments.

§134.402(g): Some commenters support the provision that allows a surgical implant provider to bill insurance carriers directly. One commenter supports the ability of surgical implant providers to bill insurance carriers directly for implants because facilities often do not have the infrastructure to acquire, prior authorize, and secure payment for implantable devices.

Agency Response: The Division appreciates the supportive comments.

§134.402(g)(1)(B): A commenter recommends rule amendment to clarify that a surgical implant provider or facility requesting separate reimbursement must always submit the original manufacturer's invoice, which may be in addition to

the vendor's invoice, so that an insurance carrier can calculate any add-on payments pursuant to (f)(2) of the rule. Transparency in implant billing from the manufacturer all the way to the payer has become increasingly important in light of recent implant billing trends and investigations by Medicare and other

agencies.

Agency Response: The Division declines to make the change and notes that subparagraph B and its requirements have been deleted. The Division clarifies that providers are required to provide documentation of the cost of the implantable through §133.210 of this title (relating to Medical Documentation). Section 133.210(c)(4) of this title establishes insurance that a provider should include with its bill any supporting documentation for procedures which do not have an established Division MAR and the exact description of the health care provided. Since surgically implanted devices do not have an established MAR, §133.210(c)(4) of this title applies.

§134.402(g)(1)(B): A commenter recommends the deletion of the requirement to submit an invoice, and emphasizes the need for parity between ASCs and hospital outpatient departments, as well as maintaining consistency with other Division fee guidelines that do not require a submitted invoice. This proposed requirement in addition to the billing certification in this rule is redundant and

could hamper timely claims submission and payment when there is no factual justification for this required difference.

Agency Response: The Division agrees and subparagraph (B) is deleted from subsection (g)(1) of this section. The Division recognizes that inclusion of the deleted language would create a potential perceived conflict and inconsistency with the implantable billing requirements in §134.403 and §134.404 of this title. It is the Division's intent to maintain consistency in all facility settings for the billing and reimbursement processes concerning separate reimbursement of surgically implanted devices. Providers are required to provide documentation of the cost of the implantable through §133.210 of this title.

§134.402(g)(1)(C): A commenter states that it is a common business practice in commercial contracts to provide a certification of the cost of the implant, and that contractual agreements include billing a standard mark-up of, generally, two times the cost of the implant.

Agency Response: The Division appreciates the comment and notes that the adopted rule requires that the facility or surgical implant provider submit with the billing a certification regarding the actual cost (net amount, exclusive of rebates and discounts) for the implantable.

§134.402(i)(1): A commenter recommends the rule language be amended to provide that the agreement may occur only before preauthorization to ensure that preauthorization is utilized to determine medical necessity and is not delayed while the amount of reimbursement is negotiated.

Agency Response: The Division declines to make the change. The Division believes the parties to the agreement are best suited to determine how and when a negotiation could take place. The requirements of subsection (i), including the specific agreement, are adequate to facilitate the process without micromanagement by the Division.

5. NAMES OF THOSE COMMENTING FOR AND AGAINST THE SECTION.

For: Insurance Council of Texas, Medtronic, and Texas Association of Business. For, with changes: Stratacare Inc., Texas Ambulatory Surgery Center Society, Texas Mutual Insurance Company, United Surgical Partners International, and Zenith Insurance Company.

6. STATUTORY AUTHORITY.

The amendments to the rule are adopted under the Texas Labor Code §§408.021, 408.027, 408.031, 413.002, 413.007, 413.011, 413.012, 413.013, 413.014, 413.015, 413.016, 413.017, 413.019, 413.031; 413.041, 413.0511, 413.053, 402.0111, and 402.061.

Section 408.021 entitles injured employees to all health care reasonably required by the nature of the injury as and when needed. Section 408.027 sets out the process for payment of health care providers. Section 408.031 provides that an injured employee may receive benefits under a workers' compensation network established under Chapter 1305 of the Insurance Code. Section 413.002 requires the Division to monitor health care providers, insurance carriers and claimants to ensure compliance with rules adopted by the Commissioner of workers' compensation, including fee guidelines. Section 413.007 sets out information to be maintained by the Division. Section 413.011 mandates that the Division establish medical policies and guidelines by rule. Section 413.012 requires the Division to review and revise the medical policies and fee guidelines at least every two years to reflect fair and reasonable fees. Section 413.013 requires the Division by rule to establish programs related to health care treatments and services for dispute resolution, monitoring, and review. Section 413.014 requires preauthorization by the insurance carrier for health care treatments and services. Section 413.015 requires insurance carriers to pay charges for medical services as provided in the statute and requires that the Division ensure compliance with the medical policies and fee guidelines through audit and review. Section 413.016 provides for refund of payments made in violation of the medical policies and fee guidelines. Section 413.017 provides a presumption of reasonableness for medical services fees that are consistent with the medical policies and fee guidelines. Section 413.019 provides for payment of interest on delayed payments refunds or overpayments. Section 413.031 provides a procedure for medical dispute resolution. Section 413.041 requires health care practitioners and health care providers to submit certain financial disclosure information to the Division. Section 413.0511 requires the Medical Advisor to make recommendations regarding the adoption of rules and policies to develop, maintain, and review guidelines as provided by Section 413.011. Section 413.053 establishes the standards of reporting and billing. Section 402.00111 provides that the Commissioner of workers' compensation shall exercise all executive authority, including rulemaking authority, under the Labor Code and other laws of this state. Section 402.061 provides that the Commissioner of workers' to adopt rules as necessary to implement and enforce the Texas Workers' Compensation Act.

7. TEXT.

Subchapter E. Health Facility Services

§134.402. Ambulatory Surgical Center Fee Guideline.

(a) Applicability of this rule is as follows:

(1) This section applies to facility services provided on or after September 1, 2008 by an ambulatory surgical center (ASC), other than professional medical services. (2) This section does not apply to:

(A) professional medical services billed by a health care provider not employed by the ASC, except for a surgical implant provider as described in this section; or

(B) medical services provided through a workers' compensation health care network certified pursuant to Insurance Code Chapter 1305, except as provided in Insurance Code Chapter 1305.

(b) Definitions for words and terms, when used in this section, shall have the following meanings, unless clearly indicated otherwise.

(1) "Ambulatory Surgical Center" means a health care facility appropriately licensed by the Texas Department of State Health Services.

(2) "ASC device portion" means the portion of the ASC payment rate that represents the cost of the implantable device, and is calculated by applying the Centers for Medicare and Medicaid Services (CMS) Outpatient Prospective Payment System (OPPS) device offset percentage to the OPPS payment rate.

(3) "ASC service portion" means the Medicare ASC payment rate less the device portion.

(4) "Device intensive procedure" means an ASC covered surgical procedure that has been designated by CMS as device intensive in TABLE 56 –

ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE INTENSIVE FOR CY 2008 or its successor.

(5) "Implantable" means an object or device that is surgically:

- (A) implanted,
- (B) embedded,
- (C) inserted,
- (D) or otherwise applied, and

(E) related equipment necessary to operate, program, and recharge the implantable.

(6) "Medicare policy" payment means reimbursement methodologies, models, and values or weights including its coding, billing, and reporting payment policies as set forth in the Centers for Medicare and Medicaid Services (CMS) payment policies specific to Medicare.

(7) "Surgical implant provider" means a person that arranges for the provision of implantable devices to a health care facility and that then seeks reimbursement for the implantable devices provided directly from an insurance carrier.

(c) A surgical implant provider is subject to Chapter 133 of this title and is considered a health care provider for purposes of this section and the sections in Chapter 133.

(d) For coding, billing, and reporting, of facility services covered in this rule, Texas workers' compensation system participants shall apply the Medicare payment policies in effect on the date a service is provided with any additions or exceptions specified in this section, including the following paragraphs.

(1) Specific provisions contained in the Labor Code or the Texas Department of Insurance, Division of Workers' Compensation (Division) rules, including this chapter, shall take precedence over any conflicting provision adopted or utilized by the CMS in administering the Medicare program.

(2) Independent Review Organization decisions regarding medical necessity made in accordance with Labor Code §413.031 and §133.308 of this title (relating to MDR by Independent Review Organizations), which are made on a case-by-case basis, take precedence in that case only, over any Division rules and Medicare payment policies.

(3) Whenever a component of the Medicare program is revised and effective, use of the revised component shall be required for compliance with Division rules, decisions, and orders for services rendered on and after the effective date, or after the effective date or the adoption date of the revised Medicare component, whichever is later.

(e) Regardless of billed amount, reimbursement shall be:

 (1) the amount for the service that is included in a specific fee schedule set in a contract that complies with the requirements of Labor Code §413.011; or

(2) if no contracted fee schedule exists that complies with Labor Code §413.011, the maximum allowable reimbursement (MAR) amount under subsection (f) of this section, including any reimbursement for implantables.

(3) If no contracted fee schedule exists that complies with Labor Code §413.011, and an amount cannot be determined by application of the formula to calculate the MAR as outlined in subsection (f) of this section, reimbursement shall be determined in accordance with §134.1 of this title (relating to Medical Reimbursement).

(f) The reimbursement calculation used for establishing the MAR shall be the Medicare ASC reimbursement amount determined by applying the most recently adopted and effective Medicare Payment System Policies for Services Furnished in Ambulatory Surgical Centers and Outpatient Prospective Payment System reimbursement formula and factors as published annually in the *Federal Register*. Reimbursement shall be based on the fully implemented payment amount as in ADDENDUM AA, ASC COVERED SURGICAL PROCEDURES FOR CY 2008, published in the November 27, 2007 publication of the *Federal Register*, or its successor. The following minimal modifications apply:

(1) Reimbursement for non-device intensive procedures shall be:

(A) The Medicare ASC facility reimbursement amount multiplied by 235 percent; or

(B) if an ASC facility or surgical implant provider requests separate reimbursement for an implantable, reimbursement for the non-device intensive procedure shall be the sum of:

(i) the lesser of the manufacturer's invoice amount or

the net amount (exclusive of rebates and discounts) plus 10 percent or \$1,000 per billed item add-on, whichever is less, but not to exceed \$2,000 in add-on's per admission; and

(ii) the Medicare ASC facility reimbursement amount

multiplied by 153 percent.

(2) Reimbursement for device intensive procedures shall be:

(A) the sum of:

(i) the ASC device portion; and

(ii) the ASC service portion multiplied by 235 percent;

or

(B) If an ASC facility or surgical implant provider requests separate reimbursement for an implantable, reimbursement for the device intensive procedure shall be the sum of:

(i) the lesser of the manufacturer's invoice amount or the net amount (exclusive of rebates and discounts) plus 10 percent or \$1,000 per billed item add-on, whichever is less, but not to exceed \$2,000 in add-on's per admission; and

(ii) the ASC service portion multiplied by 235 percent.

(g) A facility, or surgical implant provider with written agreement of the facility, may request separate reimbursement for an implantable.

(1) The facility or surgical implant provider requesting reimbursement for the implantable shall:

(A) bill for the implantable on the Medicare-specific billing form for ASCs;

(B) include with the billing a certification that the amount billed represents the actual cost (net amount, exclusive of rebates and discounts) for the implantable. The certification shall include the following sentence: "I hereby certify under penalty of law that the following is the true and correct actual cost to the best of my knowledge," and shall be signed by an authorized representative of the facility or surgical implant provider who has personal knowledge of the cost of the implantable and any rebates or discounts to which the facility or surgical implant provider may be entitled.

(2) An insurance carrier may use the audit process under §133.230 of this title (relating to Insurance Carrier Audit of a Medical Bill) to seek verification that the amount certified under paragraph (1) of this subsection properly reflects the requirements of this subsection. Such verification may also take place in the Medical Dispute Resolution process under §133.307 of this title (relating to MDR of Fee Dispute), if that process is properly requested, notwithstanding §133.307(d)(2)(B) of this title.

(3) Nothing in this rule precludes an ASC or insurance carrier from utilizing a surgical implant provider to arrange for the provision of implantable devices. Implantables provided by a surgical implant provider shall be reimbursed according to this subsection.

(h) For medical services provided in an ASC, but not addressed in the Medicare payment policies as outlined in subsection (f) of this section, and for which Medicare reimburses using other Medicare fee schedules, reimbursement shall be made using the applicable Division Fee Guideline in effect for that service on the date the service was provided.

(i) If Medicare prohibits a service from being performed in an ASC setting, the insurance carrier, health care provider, and ASC may agree, on a voluntary basis, to an ASC setting as follows:

(1) The agreement may occur before, or during, preauthorization.

(2) A preauthorization request may be submitted for an ASC facility setting only if an agreement has already been reached and a copy of the signed agreement is filed as a part of the preauthorization request.

(3) The agreement between the insurance carrier and the ASC must be in writing, in clearly stated terms, and include:

- (B) any other provisions of the agreement; and
- (C) names, titles and signatures of both parties with dates.
- (4) Copies of the agreement are to be kept by both parties. This

agreement does not constitute a voluntary network established in accordance with Labor Code §413.011(d-1).

(5) Upon request of the Division, the agreement information shall be submitted in the form and manner prescribed by the Division.

(j) Where any terms or parts of this section or its application to any person or circumstance are determined by a court of competent jurisdiction to be invalid, the invalidity does not affect other provisions or applications of this section that can be given effect without the invalidated provision or application. reviewed by legal counsel and found to be a valid exercise of the agency's legal

authority.

Issued at Austin, Texas, on _____, 2008.

Stanton K. Strickland, Deputy Commissioner Legal Services Texas Department of Insurance, Division of Workers' Compensation

IT IS THEREFORE THE ORDER of the Commissioner of Workers' Compensation that amended §134.402 concerning Ambulatory Surgical Center Fee Guideline is adopted.

AND IT IS SO ORDERED.

ALBERT BETTS COMMISSIONER OF WORKERS' COMPENSATION

ATTEST:

Stanton K. Strickland, Deputy Commissioner Legal Services

COMMISSIONER'S ORDER NO.