

**STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF WORKERS' COMPENSATION**

**FINAL STATEMENT OF REASONS AND
UPDATED INFORMATIVE DIGEST**

**Subject Matter of Regulations: Workers' Compensation - Official Medical Fee
Schedule: Inpatient Hospital Fee Schedule**

**TITLE 8, CALIFORNIA CODE OF REGULATIONS
Sections 9789.20, 9789.21, 9789.22, and 9789.25**

AN IMPORTANT PROCEDURAL NOTE ABOUT THIS RULEMAKING:

The Inpatient Hospital Fee Schedule component of the Official Medical Fee Schedule "establish(es) or fix(es) rates, prices, or tariffs" within the meaning of Government Code section 11340.9(g) and is therefore not subject to Chapter 3.5 of the Administrative Procedure Act (commencing at Government Code section 11340) relating to administrative regulations and rulemaking.

This rulemaking proceeding to amend the Inpatient Hospital Fee Schedule is being conducted under the Administrative Director's rulemaking power under Labor Code sections 133, 4603.5, 5307.1 and 5307.3. This regulatory proceeding is subject to the procedural requirements of Labor Code sections 5307.1 and 5307.4.

CONSIDERATION OF RELEVANT MATTER PRESENTED

After Notice of the Proposed Rulemaking published pursuant to Labor Code section 5307.4, a public hearing was held on January 25, 2011 at which interested persons could participate through the submission of written data, views, and arguments, including oral presentations. A 1st 15-day comment period ending on November 2, 2012, and a 2nd 15-day comment period ending on November 28, 2012, invited interested persons to submit written comments relative to the proposed modifications to the regulation or to the added documents for each comment period. The Acting Administrative Director has subsequently considered all of the data, views, statements, and arguments presented or submitted.

The Acting Administrative Director of the Division of Workers' Compensation, pursuant to the authority vested in her, has amended or adopted the following sections of Division 1, Chapter 4.5, Subchapter 1, of title 8, California Code of Regulations, relating to the Inpatient Hospital Fee Schedule component of the Official Medical Fee Schedule:

**Section 9789.20 General Information for Inpatient Hospital Fee Schedule –
Discharge On or After July 1, 2004 [Amend]**

Section 9789.21	Definitions for Inpatient Hospital Fee Schedule [Amend]
Section 9789.22	Payment of Inpatient Hospital Services [Amend]
Section 9789.25	Federal Regulations, Federal Register Notices, and Payment Impact File by Date of Discharge [Adopt]

BACKGROUND TO REGULATORY PROCEEDING

In 2003, the Legislature enacted Senate Bill 228 (Alarcon, Chapter 639, Statutes of 2003; SB 228) as part of workers' compensation reform legislation intended to reduce unnecessary medical and litigation expenses, among other things, in workers' compensation cases in California.

As one of its provisions, the bill substantially amended Labor Code section 5307.1, which provided for the Administrative Director to adopt a medical fee schedule for workers' compensation claims which would establish maximum reasonable fees. Labor Code section 5307.1, as amended by SB 228, provides that, commencing January 1, 2004, all fees shall be paid in accordance with the fee-related structure and rules of the relevant Medicare payment systems and that the maximum reasonable fees shall be 120 percent of the estimated aggregate fees prescribed in the Medicare payment system before the application of the inflation factor set forth in the statute.

SB 228 further provided for a separate reimbursement for implantable medical devices, hardware, and instrumentation for six different Diagnostic Related Groups (DRGs). (Lab. Code, § 5318(a).) In 2007, Medicare refined and revised its DRG system known as the Medicare Severity DRG system (MS-DRG) resulting in fourteen different MS-DRGs subject to Labor Code section 5318. The MS-DRG system was incorporated into the OMFS Inpatient Hospital Fee Schedule effective December 1, 2007. SB 228 also provided that the pass-through section would only be operative until the Administrative Director adopts a regulation specifying separate reimbursement, if any, for implantable medical hardware or instrumentation for complex spinal surgeries. (Lab. Code, § 5318(b).)

On January 2, 2004, to comply with the requirements of Labor Code sections 5307.1 and 5318, through emergency rulemaking, the Administrative Director adopted an Inpatient Hospital Fee Schedule section of the Official Medical Fee (OMF) Schedule (set forth in 8 C.C.R sections 9789.20-24) for fees in accordance with the Medicare payment system. A Certificate of Compliance was filed on April 30, 2004, and the Inpatient Hospital Fee Schedule regulations became effective on June 15, 2004. The Labor Code section 5318 pass-through methodology was incorporated as part of this fee schedule.

In 2012, the Legislature enacted Senate Bill 863, (De León, CHAPTER 363, Statutes of 2012; SB 863) as part of workers' compensation reform legislation intended to reduce unnecessary medical and litigation expenses, among other things, in workers' compensation cases in California. As one of its provisions, SB 863 added subsection (m) to Labor Code section 5307.1, which provided that on or before July 1, 2013, the

Administrative Director shall adopt a regulation specifying an additional reimbursement for Medicare Severity Diagnostic Groups (MS-DRGs) 028, 029, 030, 453, 454, 455, and 456 to ensure that the aggregate reimbursement is sufficient to cover costs, including the implantable medical device, hardware, and instrumentation. This regulation shall be repealed as of January 1, 2014, unless extended by the Administrative Director.

SB 863 also repealed Labor Code section 5318, as of January 1, 2013. As stated earlier, Labor Code section 5318 required separate reimbursement for implantable medical devices, hardware, and instrumentation (spinal devices) for fourteen specific complex spinal surgeries (pass-through payment). Labor Code section 5318 provided this section would only remain operative until the Administrative Director adopted a regulation specifying separate reimbursement, if any, for spinal devices for specific complex spinal surgeries. When the Administrative Director adopted the Inpatient Hospital Fee Schedule section of the Official Medical Fee Schedule (OMFS) on January 2, 2004, for fees in accordance with the Medicare payment system, the Labor Code section 5318 pass-through payment methodology was incorporated as part of this fee schedule. When the regulation was adopted, Labor Code 5318, by self-execution, became inoperative, and no longer had any force or effect.

Labor Code section 5307.1 further provides that the Administrative Director shall adjust the Inpatient Hospital Fee Schedule to conform to any relevant changes in the Medicare payment system by issuing an order, exempt from Labor Code sections 5307.3 and 5307.4 and the rulemaking provisions of the Administrative Procedure Act (Chapter 3.2 (commencing with section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), informing the public of the changes and their effective date.

Sections 9789.20 through 9789.24 set forth the general information, definitions and payment schedule for the Inpatient Hospital Fee Schedule section of the Official Medical Fee schedule. The amendments to the Inpatient Hospital Fee Schedule section of the Official Medical Fee Schedule regulations address only sections 9792.20, 9792.21, and 9792.22, which are intended to implement SB 863, by revising the methodology for reimbursement of implantable spinal devices used in complex spinal surgeries specified in SB 863, and make minor revisions to conform to the proposed changes in reimbursement, and to update or clarify sections of the Inpatient Hospital Fee Schedule. The Administrative Director is also adopting section 9789.25 which provides for the updates to the federal regulation, federal register, and payment impact file references made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, in order to conform to changes in the Medicare payment system as required by Labor Code section 5307.1. (Lab. Code, §§5307.1(g)(1), 5307.1(g)(2).)

UPDATED INFORMATIVE DIGEST

The Acting Administrative Director incorporates the Informative Digest prepared in this matter. Since the Notice of Proposed Regulatory Action, the Legislature enacted SB 863 (De León, Chapter 363, Statutes of 2012) as part of workers' compensation reform legislation intended to reduce unnecessary medical and litigation expenses, among other

things, in workers' compensation cases in California. SB 863 impacts on the Inpatient Hospital Fee Schedule regulations are as follows:

- Repeals Labor Code section 5318 as of January 1, 2013, and adds subsection (m) to Labor Code section 5307.1.
- As stated earlier, Labor Code section 5318 required separate reimbursement for implantable medical devices, hardware, and instrumentation (spinal devices) for fourteen specific complex spinal surgeries (pass-through payment). Labor Code section 5318 provided this section would only remain operative until the Administrative Director adopted a regulation specifying separate reimbursement, if any, for spinal devices for specific complex spinal surgeries. When the Administrative Director adopted the Inpatient Hospital Fee Schedule section of the Official Medical Fee Schedule (OMFS) on January 2, 2004, for fees in accordance with the Medicare payment system, the Labor Code section 5318 pass-through payment methodology was incorporated as part of this fee schedule. When the regulation was adopted, Labor Code 5318, by self-execution, became inoperative, and no longer had any force or effect.
- Effective January 1, 2013, eliminates additional reimbursement to 7 of the 14 complex spinal surgery MS-DRGs, currently receiving pass-through payments. (MS-DRGs 457-460 and 471-473)
- Provides additional reimbursement for the other 7 of the 14 complex spinal surgery MS-DRGs, during a transition period ending 1/1/2014. (028-030 and 453-456)
- The add-on amount for the 7 specified complex spinal surgery MS-DRGs (028-030 and 453-456) shall ensure the aggregate reimbursement is sufficient to cover costs, including spinal device costs.
- The transition period ends as of 1/1/2014, after which, no additional reimbursement will be given, unless extended by the administrative director.

In response, the regulation was amended to:

- Eliminate additional reimbursement for 7 complex spinal surgery MS-DRGs (MS-DRGs 457-460 and 471-473) originally addressed in the Initial Statement of Reasons.
- Remove an alternative pass-through payment method for complex spinal surgery procedures.
- Provide for a fixed additional allowance reimbursement methodology for the complex spinal surgery MS-DRGs specified in SB 863 (028-030 and 453-456).

UPDATE OF INITIAL STATEMENT OF REASONS

The Acting Administrative Director incorporates the Initial Statement of Reasons prepared in this matter. The purposes and rationales for the regulations as set forth in the Initial Statement of Reasons continue to apply, unless otherwise noted in the Final Statement of Reasons.

THE FOLLOWING SECTIONS WERE ADOPTED OR AMENDED FOLLOWING THE PUBLIC HEARING AND WERE CIRCULATED FOR A 15-DAY COMMENT PERIOD (There were two 15-day comment periods as follows: first 15-day comment period: October 18, 2012 - November 2, 2012; second 15-day comment period: November 13, 2012 – November 28, 2012)

Modifications to Section 9789.21 Definitions for Inpatient Hospital Fee Schedule

Subdivision (b)(1) is amended to move references to capital wage index as specified in the federal register covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(b), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (b)(2) is amended to read, “For discharges occurring before January 1, 2008...” instead of “For discharges occurring on or before January 1, 2008...”.

Specific Purpose of Change: This change is required to correct the effective date of discharge.

Subdivision (b)(3) is amended to move references to fixed loss cost outlier threshold as specified in the Federal Register covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(b), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (d) is amended to specify a time frame for when this definition is applicable, and to amend the term “spinal hardware” to “spinal devices”. The subdivision is amended to read, “For discharges before January 1, 2014, “Complex spinal surgery” is defined...”; and is amended to read “spinal devices” instead of “spinal hardware”.

Specific Purpose of Change: The purpose of adding a date is to specify the time frame for when this definition is applicable. The term “spinal hardware” was changed to “spinal devices” to conform to the terminology used consistently throughout the inpatient hospital fee schedule regulations.

Subdivision (e) is amended to read, “spinal devices” instead of “spinal hardware”.

Specific Purpose of Change: The term “spinal hardware” was changed to “spinal devices” to conform to the terminology used consistently throughout the inpatient hospital fee schedule regulations.

Subdivision (e)(1)(C) is amended to move references to capital standard federal payment rate covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(b), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(1)(D) is amended to move references to capital geographic adjustment factor covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(1)(E) is amended to read, “For discharges occurring before January 1, 2008...” instead of “For discharges occurring on or before to January 1, 2008...”.

Specific Purpose of Change: This change is required to correct the effective date of discharge.

Subdivision (e)(1)(F) is amended to move references to capital disproportionate share adjustment factor covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(1)(G) is amended to move references to capital indirect medical education adjustment factor covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(2)(A) is amended to move references to hospital-adjusted rate for prospective operating costs formula as specified in the federal regulations to section 9789.25(a), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(2)(B) is amended to move references to labor-related national standard operating rate covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(b), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(2)(C) is amended to move references to operating wage index covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(2)(D) is amended to move references to the nonlabor-related portion as specified in the federal regulations to section 9789.25(a), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(2)(E) is amended to move references to operating disproportionate share adjustment factor covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(2)(F) is amended to move references to operating indirect medical education adjustment covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (e)(2)(G) is amended to move references to hospital specific rate covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (f) is amended to reinstate the codified regulatory text that was deleted for the initial comment period ending on January 25, 2011. Subdivision (f) is also amended to add the following language to the end of the definition of costs, "...and except for cases reimbursed under section 9789.22(g)(1), plus documented paid spinal device costs, net of discounts and rebates, plus any sales tax and/or shipping and handling charges actually paid."

Specific Purpose of Change: The proposed regulations for the initial comment period proposed rescinding this subsection because proposed amended section 9789.22(f) provided formulas used to determine costs. When SB 863 was enacted, it was necessary to reinstate the definition of "costs", because section 9789.22(f) was amended after the initial comment period in reaction to SB 863. The language added to the end of the definition is a non-substantive change adopted after the second 15-day comment period, which is necessary to make the definition consistent with the changes made in section 9789.22(f).

Subdivision (f now g) is amended to change the numbering within the subdivision; and to move references to hospital specific operating cost-to-charge ratio and hospital specific capital cost-to-charge ratio covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (g now h) is amended to change the numbering within the subdivision; and to restore the codified regulatory reference to subdivision (f) definition of costs.

Specific Purpose of Change: The proposed regulations for the initial comment period proposed removing reference to subdivision (e now f) because the proposed regulations rescinded subdivision (e now f). When SB 863 was enacted, subdivision (f) was reinstated. Therefore, the codified regulatory reference to subdivision (f) is reinstated in the text of this subdivision.

Subdivision (h now i) is amended to change the numbering within the subdivision; and to change references to other sections of the inpatient hospital fee schedule.

Specific Purpose of Change: These amendments are necessary to conform to amendments to sections 9789.22(g) and removal of proposed section 9789.22(h).

Subdivision (i now j) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (j now k) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (k now l) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (l now m) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (m now n) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (n now o) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (o now p) is amended to change the numbering within the subdivision; and is amended to move references to labor related portion covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(b), and are deleted from this section.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions, and to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (p now q) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (q now r) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (r now s) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (r now s)(1) is amended to change the numbering within the subdivision; and is amended to move references to wage index covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c) for the variable name on the Payment Impact file and section 9789.25(b) for the Federal Register reference that defines the wage index, and are deleted from this section.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions, and to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (r now s)(2) is amended to move references to the nonlabor-related portion formula as specified in the federal regulations to section 9789.25(a), and are deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (s now t) is amended to change the numbering within the subdivision.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions.

Subdivision (t now u) is amended to change the numbering within the subdivision; and to move references to payment impact file covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(c), and are deleted from this section.

Specific Purpose of Change: These amendments are necessary to reflect proper numbering of the subdivisions, and to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (u) is amended to delete the proposed text defining price adjustment.

Specific Purpose of Change: As a result of SB 863, the pass-through payment methodology for reimbursement of spinal devices used in complex spinal surgery MS-DRGs is eliminated for discharges occurring on or after 1/1/2013, and the proposed addition of the definition of “price adjustment” is removed as well.

Subdivision (w) is amended to delete the proposed text defining spinal hardware.

Specific Purpose of Change: As a result of SB 863, the pass-through payment methodology for reimbursement of spinal devices used in complex spinal surgery MS-DRGs is eliminated for discharges occurring on or after 1/1/2013, and the definition of “spinal hardware” is reinstated in section 9789.22(g), and removed from this subsection.

Modifications to Section 9789.22 – Payment of Inpatient Hospital Services

Subdivision (b) is amended to move references to the federal regulations to section 9789.25(a), and is deleted from this section.

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (c) is amended to move references cost items specified in the federal regulations to section 9789.25(a).

Specific Purpose of Change: This format change is necessary to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (d) is amended to add “-physicians fee schedule” after “Official Medical Fee Schedule”, and to delete reference to deleted subdivision 9789.22(h).

Specific Purpose of Change: The term “physicians fee schedule” is added to clarify which fee schedule is being referred to. The proposed alternative pass-through payment methodology for spinal devices used in specified complex spinal surgery MS-DRGs set forth in the proposed subdivision (h) is deleted. Therefore, reference to subdivision (h) needs to be deleted from this subdivision.

Subdivision (e) is amended to require hospitals to bill according to the e-billing regulations or the standardized paper billing regulations.

Specific Purpose of Change: This subdivision is amended to conform hospital billing to the e-billing regulations beginning with Section 9792.5.0 or the standardized paper billing regulations beginning with Section 9792.5.2.

Subdivision (f)(1) is amended to:

Reinstate codified language, “Cost Outlier cases. Inpatient services for cost outlier cases, shall be reimbursed as follows:”

Modify the following:

Step 2 is to read, “Determine costs. $\text{Costs} = ((\text{total billed charges} - \text{charges for spinal devices}) \times \text{total cost-to-charge ratio}) + \text{documented paid spinal device costs, net of discounts and rebates, plus any sales tax and/or shipping and handling charges actually paid.}$ ”

Step 3 is to read, “Determine outlier threshold. $\text{Outlier threshold} = (\text{Inpatient Hospital Fee Schedule payment amount} + \text{hospital specific outlier factor} + \text{any new technology pass-through payment determined under Section 9789.22(h)} + \text{any additional allowance for spinal devices under Section 9789.22(g)(2)})$.”

Specific Purpose of Change: After the enactment of SB 863, the proposed alternative pass-through payment methodology for the cost of spinal devices used in specified complex spinal surgery MS-DRGs was deleted from the proposed regulations. As a result, the alternative methodology for determining whether a case qualifies as an outlier case was also deleted from the proposed regulations. So, the codified regulatory language was reinstated with modifications to address the issue of charge compression as discussed below.

Steps 2 and 3 were amended to address the issue of charge compression. The purpose of the outlier provision is to protect hospitals from financial losses attributable to atypically high cost cases. Device costs are part of the case costs. However, applying an overall cost-to-charge ratio to determine the hospital’s costs understates the hospital’s costs for the discharge because of the charge compression issue. The methodology that is being adopted addresses the hardware cost issue.

Subdivision (f)(2) is deleted. The proposed revisions would have provided a methodology for determining the additional allowance for cost outlier cases involving complex spinal surgery.

Specific Purpose of Change: After the enactment of SB 863, the proposed alternative pass-through payment methodology for the cost of spinal devices used in specified complex spinal surgery MS-DRGs was deleted from the proposed regulations. As a result, the alternative methodology for determining whether a case qualifies as an outlier case was also deleted from the proposed regulations.

Subdivision (f)(now 2) numbering within the subdivision is added to the paragraph which reads, “If costs exceed the outlier threshold, the case is a cost outlier case. The additional allowance for the outlier case equals 0.8 x (costs – cost outlier threshold).” Specific Purpose of Change: Numbering is added to this paragraph for clarity.

Subdivision (f)(3) numbering is added, the codified regulatory text for determining whether a case qualifies as a cost outlier case is restored, an effective date of January 1, 2013 for discharges is added, and reference is made to subsection (g)(1) instead of (g).

Specific Purpose of Change: Numbering is added for clarity. The codified regulatory text is restored to conform to the changes made to subdivision (f)(1), and is amended to clarify that this subsection applies to discharges occurring before January 1, 2013. Finally, this subdivision is amended to clarify the referenced charges pertain to spinal devices reimbursed under subsection 9789.22(g)(1) only.

Subdivision (g) is amended to read “spinal devices” instead of “spinal hardware”.

Specific Purpose of Change: The term “spinal hardware” was changed to “spinal devices” to conform to the terminology used consistently throughout the inpatient hospital fee schedule regulations.

Subdivision (g)(1) is amended to read “spinal devices” instead of “spinal hardware”; to change the dates of discharges from December 15, 2010 to January 1, 2013; to add the word “DRG” after “complex spinal surgery”; and to read “net of discounts and rebates” instead of “net price adjustments”.

Specific Purpose of Change: The term “spinal hardware” was changed to “spinal devices” to conform to the terminology used consistently throughout the inpatient hospital fee schedule regulations. The date of discharge was changed to reflect the correct effective date. The word “DRG” was added for consistency and clarity. The original codified regulatory text, “Net of discounts and rebates” is reinstated, to minimize changes to language that is already in use.

Subdivision (g)(2)(A) now (g)(2) is amended to change the numbering within the subdivision; to change the dates of discharges from December 15, 2010 to on or after January 1, 2013 but before January 1, 2014; to read “spinal devices used during complex spinal surgery MS-DRGs” instead of “discharges assigned to”; and to delete MS-DRGs 457, 458, 459, 460, 471, 472, and 473. Subdivision (g)(2) is also amended to change the additional allowance for spinal devices used in specified complex spinal surgery MS-DRGs. An additional allowance of \$9,140 shall be made for spinal devices used during complex spinal surgery MS-DRGs 453, 454, and 455. An additional allowance of \$3,170 shall be made for spinal devices used during complex spinal surgery MS-DRG 456, and an additional allowance of \$670 shall be made for spinal devices used during complex spinal surgery MS-DRGs 028, 029, and 030.

Specific Purpose of Change: The amendments to numbering are necessary to reflect proper numbering of the subdivisions. The dates of discharge were changed to reflect the correct effective dates. MS-DRGs 457-460 and 471-473 were deleted because SB 863 eliminated authority to give additional reimbursement for the cost of spinal devices used in these complex spinal surgery MS-DRGs. The additional allowance for spinal devices used during complex spinal surgery MS-DRGs 028, 029, 030, 453, 454, 455, and 456 were increased from the proposed additional allowance for the following reasons: The initial RAND analyses and the basis of comparing Medicare and workers' compensation patients is an underlying assumption that the Medicare rates are sufficient to cover the cost of caring for Medicare patients and provide a reasonable rate of return. Because of the charge compression issue, costs for complex spinal surgery cases are understated and raise concerns that the Medicare rates are insufficient. This changes the focus of an analysis from comparing the costs of Medicare and workers' compensation patients to comparing the amounts implicit in the OMFS allowances for device costs to estimated device cost. This comparison suggests that until Medicare addresses the charge compression issue, the current OMFS allowances may not be sufficient to cover the costs of the spinal devices. The add-on amounts were determined by comparing the average implant costs implicit in the allowances with the average costs reported in *Orthopedic News 2009* and updating for inflation. These add-on amounts are for lumbar and cervical spinal fusions and are not specific to the MS-DRGs that are eligible for the additional reimbursement. The regulations were amended to update the additional reimbursement amounts for inflation between 2010 and 2013. Based on data submitted by the hospital industry during the 1st 15-day comment period, the approach taken for MS-DRGs 453, 454, and 455 were reconsidered. The additional reimbursement amount for these three MS-DRGs take advantage of California Workers' Compensation Institute (CWCI) data published in their June 2012 paper, that are specific to these MS-DRGs, which are more costly than cervical or lumbar spinal fusions and have higher device costs. The CWCI analysis indicates that the average costs for these MS-DRGs were \$28,330 in 2010 compared to \$19,896 implicit in the OMFS allowance. An add-on of \$9,140 ($(\$28,330 - \$19,487 * 1.021) * 1.084$) is more accurate rather than the lumbar fusion add-on amount. The rationale for using a broader patient population is that the current pass-through system does not provide incentives for efficient hardware use and any price negotiation. The rationale for using workers' compensation-specific implant cost data is that it reflects the actual costs being incurred for complex spinal surgery. Broader patient data are not available for the MS-DRGs 453-455 and given the substantial difference between the average spinal implant for these MS-DRGs relative to MS-DRGs 459-060, it is more appropriate to use the CWCI data.

Subdivision (g)(2)(B) is deleted.

Specific Purpose of Change: This subdivision is deleted to conform to the modifications made to the proposed revisions.

Subdivision (g)(3) is added to read, "For discharges occurring on or after January 1, 2014, complex spinal surgery DRGs shall not receive any additional or separate

reimbursement for spinal devices, unless the Administrative Director extends section 9789.22(g)(2) to discharges occurring on or after January 1, 2014, in accordance with Labor Code section 5307.1(m) through a later enacted regulation.”

Specific Purpose of Change: This amendment is to conform to SB 863 which states the regulation adopted by the Administrative Director on or before July 1, 2013 specifying an additional reimbursement for specified complex spinal surgery MS-DRGs will be repealed as of January 1, 2014, unless extended by the Administrative Director.

Subdivision (g)(4) numbering is added as a non-substantive change after the 2nd 15-period ended. This subdivision is amended to restore the codified regulatory definition of a spinal device.

Specific Purpose of Change: Numbering is added for clarity, and the codified definition of spinal device is reinstated to minimize changes to language that is already in use.

Subdivision (h) is deleted. This proposed division would have provided an alternative payment methodology for discharges assigned to specified complex spinal surgery DRGs, which allowed a pass-through payment based on the hospital’s documented paid costs for the spinal devices.

Specific Purpose of Change: As part of implementation of SB 863, which states the Administrative Director shall specify an additional reimbursement for specified complex spinal surgery MS-DRGs, this proposed subdivision is deleted.

Subdivision (i) is deleted. This subdivision would have set forth the procedures for annual election of the alternative payment methodology for discharges assigned to specified complex spinal surgery DRGs.

Specific Purpose of Change: This proposed subdivision is deleted to conform to the amendments made to the proposed regulations, which delete the alternative payment methodology. The alternative payment methodology would have required the hospital to make an annual election in order to get reimbursed under this methodology.

Subdivision (j now h) is amended to change the numbering within the subdivision; and the codified language, “which document is hereby incorporated by reference and will be made available upon request of the Administrative Director” is reinstated.

Specific Purpose of Change: Numbering is added for clarity, and incorporation by reference is reinstated as a technical correction.

Subdivision (k now i) is amended to change the numbering within the subdivision; and the codified language, “which document is hereby incorporated by reference and will be made available upon request of the Administrative Director” is reinstated.

Specific Purpose of Change: Numbering is added for clarity, and incorporation by reference is reinstated as a technical correction.

Subdivision (l now j)(1) is amended to change the numbering within the subdivision; to read, "...and the hospital shall receive the additional allowances under Sections 9789.22(g) and (h) when applicable", instead of "...and the hospital shall receive the additional allowances under either Sections 9789.22(g) or (h) and under Section 9789.22(j) when applicable"; to change reference from Section 9789.22(m) to Section 9789.22(k).

Specific Purpose of Change: Numbering is added for clarity, and to conform citations to the proper numbering of other subdivisions as amended.

Subdivision (l now j)(2)(A) is amended to change reference from Section 9789.22(l)(1) to Section 9789.22(j)(1); and to move references to payment to the transferring hospital for post-acute DRGs covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(b), and are deleted from this section.

Specific Purpose of Change: This subdivision is amended to conform citations to the proper numbering of other subdivisions as amended, and to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (l now j)(2)(B) is amended to: 1) clarify qualifying Medicare Severity DRGs are referred to as "special pay" DRGs; and to move references to payment to the transferring hospital for special pay DRGs covering discharges between March 1, 2011 and November 30, 2011, and for discharges on or after December 1, 2011, made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, to section 9789.25(b), and are deleted from this section.

Specific Purpose of Change: This subdivision is amended to clarify qualifying MS-DRGs are referred to as "special pay" DRGs, and to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (m now k) is amended to move references to Title 42, Code of Federal Regulations, Sections 412.23(e) to section 9789.25(a), and is deleted from this section.

Specific Purpose of Change: This subdivision is amended to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (m now k)(3) is amended to restore the codified language, "which document is hereby incorporated by reference and will be made available upon request of the Administrative Director".

Specific Purpose of Change: The incorporation by reference is reinstated as a technical correction.

Subdivision (m now k)(5) is amended to restore the codified language, “which document is hereby incorporated by reference and will be made available upon request of the Administrative Director”.

Specific Purpose of Change: The incorporation by reference is reinstated as a technical correction.

Subdivision (n now l) is amended to change the dates of discharges from before December 15, 2010, to before January 1, 2013; and from on or after December 15, 2010, to on or after January 1, 2013.

Specific Purpose of Change: The dates of discharge were changed to reflect the correct effective dates.

Subdivision (o now m) is amended to change the numbering within the subdivision.

Specific Purpose of Change: The amendments to numbering are necessary to reflect proper numbering of the subdivisions.

Modifications to Section 9789.25 - Federal Regulations, Federal Register Notices, and Payment Impact File by Date of Discharge.

This proposed section is revised to provide the updates to the federal regulation, federal register, and payment impact file references made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, in order to conform to changes in the Medicare payment system as required by Labor Code section 5307.1(g)(2).

Subdivision (a) is amended to add references to the federal regulations that are referenced in the Inpatient Hospital Fee Schedule Administrative Director Orders for discharges effective March 1, 2011 and effective December 1, 2011; and to add references to federal regulation Sections 412.2 and 412.64 for discharges occurring on or after January 1, 2004.

Specific Purpose of Change: This subdivision is amended to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (b) is amended to add references to the federal register notices that are referenced in the Inpatient Hospital Fee Schedule Administrative Director Orders for discharges effective March 1, 2011 and effective December 1, 2011; and to add references for discharges occurring on or after January 1, 2013 but before January 1, 2014.

Specific Purpose of Change: This subdivision is amended to make the Inpatient Hospital Fee Schedule regulations more readable and understandable.

Subdivision (c) is amended to add references to the payment impact file that are referenced in the Inpatient Hospital Fee Schedule Administrative Director Orders for discharges effective March 1, 2011 and effective December 1, 2011. For discharges occurring on or after 12/1/2009, “Sole Community Hospital – Hospital Specific Rate” is corrected to include the year 2006 in the hospital specific payment (HSP) rate updated to FY 2010 for SCH providers location.

Specific Purpose of Change: This subdivision is amended to make the Inpatient Hospital Fee Schedule regulations more readable and understandable, and to correct typographical errors.

UPDATE OF MATERIAL RELIED UPON

The following additional documents beyond those identified in the Initial Statement of Reasons were relied upon by the Acting Administrative Director and added to rulemaking file after close of the initial 30-day comment period. They were identified in the Notice of Modification to Text of Proposed Regulations and Notice of Addition of Documents to Rulemaking File for the first 15-day comment period and the second 15-day comment period. These additional documents were available for 15 day public review and comment from October 18 through November 2, 2012; and November 13 through November 28, 2012, respectively.

Additional documents relied upon by the Acting Administrative Director and added to the rulemaking file and made available for public inspection and comment during the first 15-day comment period (October 18 through November 2, 2012)

1. Swedlow, Alex and Ireland, John, *Preliminary Estimate of California Workers' Compensation System-Wide Costs for Surgical Instrumentation Pass-Through Payments for Back Surgeries*, California Workers' Compensation Institute, June 2012.
2. Wynn, Barbara, O., *Allowances for Spinal Hardware Under California's Official Medical Fee Schedule*, RAND, May 9, 2012.
3. Wynn, Barbara, O., Timbie, Justin William, and Sorbero, Melony, E., *Medical Care Provided Under California's Workers' Compensation Program: Effects of the Reforms and Additional Opportunities to Improve the Quality and Efficiency of Care*, RAND, 2011.
4. Carreyrou, John, McGinty, Tom, and Millman, Joel, *In Small California Hospitals, the Marketing of Back Surgery*, Wall Street Journal, February 9, 2012.
5. Miller, Laura, *ASCs vs. Hospitals: How Spine Surgery Reimbursement Compares*, Becker's ASC Review, June 17, 2012.

Additional documents relied upon by the Acting Administrative Director and added to the rulemaking file and made available for public inspection and comment during the second 15-day comment period (November 13 through November 28, 2012)

1. *Orthopedic Network News*, Volume 21, Number 4, October 2010.
2. *Lumbar Fusion Surgery in California: Volumes, Costs, Length of Stay, Surgical Complications, and Insurance Reimbursement*, Berkeley Center for Health Technology, Volume 2, Issue 4.
3. *Volumes, Costs, and Reimbursement for Cervical Fusion Surgery in California Hospitals, 2008*, Berkeley Center for Health Technology, Volume 2, Issue 5.
4. Wynn, Barbara, O., *Analysis of Add-On Allowances*.

LOCAL MANDATES DETERMINATION

- Local Mandate: None. The proposed regulations will not impose any new mandated programs or increased service levels on any local agency or school district.
- Cost to any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code: None. The proposed amendments do not apply to any local agency or school district.
- Other nondiscretionary costs/savings imposed upon local agencies: None.

CONSIDERATION OF ALTERNATIVES

The Division considered all comments submitted during the public comment periods, and made modifications based on those comments to the regulations as initially proposed. The Acting Administrative Director has now determined that no alternatives proposed by the regulated public or otherwise considered by the Division of Workers' Compensation would be more effective in carrying out the purpose for which these regulations were proposed, nor would they be as effective as and less burdensome to affected private persons and businesses than the regulations that were adopted.