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3

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What is a Lien, really?

LC 4903:

The appeals board may determine and allow as liens against any sum to be paid as compensation:

- > A reasonable attorney's fee
- > The reasonable value of living expenses
- > Reasonable burial expenses
- > Unemployment compensation disability benefits
- A reasonable expense incurred by or on behalf of the applicant

Who is a lien claimant? Any person or entity claiming payment under 4903



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5

OFFICIAL MEDICAL FEE SCHEDULE

- The Official Medical Fee Schedule (OMFS) is promulgated by the DWC administrative director under Labor Code section 5307.1 and can be found in sections 9789.10 et seq. of Title 8, California Code of Regulations. It is used for payment of medical services required to treat work related injuries and illnesses.
- Section 9789.111 provides the effective dates of fee schedule provisions. In addition, adjustments to the fee schedule, in the form of Administrative Director Orders, are posted on the fee schedule web pages to conform to relevant Medicare and Medi-Cal changes pursuant to Labor Code section 5307.1 subdivision (g) and Title 8, California Code of Regulations, section 9789.110.

http://www.dir.ca.gov/dwc/omfs9904.htm



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OMFS, Why do I care?

You're telling me that workers' compensation providers bill in excess of OMFS?

The first step once you receive a lien notice:

- Check for dates of service that were not previously reviewed.
- Have bill review double check Explanations of Review once you have notice of a lien. Frequently there have been improper reductions after the first review.

Per LC §4603.2(b)(2) 15% penalty plus interest due if *properly documented* bill not paid within 45 days of receipt.

PENALTY CORNER



7

L.C. 4603.2(b)(1)(B):

"Effective for services provided on or after January 1, 2017, the request for payment with an itemization of services provided and charge for each service shall be submitted to the employer within 12 months of the date of service (or date of discharge for inpatient facilities).

The rules shall define good cause for an exception to the 12 month period

The request is barred unless timely submitted.



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LC 4603.2(b)(5)(A)(B):

- a) An employer may defer objecting to or paying any bill submitted by, or on behalf of, a provider whose liens are stayed pursuant to LC 4615, and the time limits for taking any action prescribed by paragraph (2) and (3) shall not commence until the stay is lifted pursuant to LC 4615.
- b) An employer may object to any bill submitted by, or on behalf of, a provider who has been suspended pursuant to L.C. 139.21



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9

Before the lien is filed—BILL REVIEW

LC §4603.3 "SHALL"!!!

- > Submit invoice to bill review
- > Provider paid per OMFS
- > Explanation of Review (EOR) sent
- Statement of items/procedures bills, amount requested
- > Amount paid
- > Basis for adjustment, change or denial
- > Additional information required to make a decision
- > Reason for denial, if not a fee dispute
- > Contact information for dispute resolution

That's it...Right?







Second Review



LC §4603.2(e)(1):

If the provider disputes the amount paid, the provider may request a second review within 90 days of service of the explanation of review... The request for a second review shall be submitted to the employer on a form prescribed by the administrative director and shall include the following:

- a) The date of the EOR
- b) The item and amount in dispute
- c) The additional payment requested and why
- d) The additional information requested



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11

Second Review

LC §4603.2(e)(1):

- Applies to all dates of service January 1, 2013 later when the only dispute is the amount of payment
- ▶ Date of service, not date of injury Second Review Request Form:

http://www.dir.ca.gov/dwc/DWCPropRegs/IBR/FormSBR_1.pdf





More on the Second Review

LC §4603.2(e)(2):

"If the only dispute is the amount of payment and the provider does not request a second review within 90 days, the bill shall be deemed satisfied and neither the employer nor the employee shall be liable for any further payment."

End of the story? Please let that be it....



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13

Independent Bill Review

L.C. §4603.6

Like Second Review, Independent Bill Review only applies to fee schedule disputes.

SR process must have been completed to get to IBR!



Independent Bill Review

LC §4603.6

(A) If the only dispute is the amount of payment and the provider has received a second review that did not resolve the dispute, the provider may request an independent bill review within thirty calendar days of service of the second review. If the provider fails to request an independent review within thirty days the bill shall be deemed satisfied.

OUTSOURCE



15

IBR Procedure (from the top)



- 1. Provider submits request for payment (RFP)
- 2. Payment, along with explanation of review issues w/in 45 days.
- 3. If provider disputes amount paid, request second review w/in 90 days of service of
 - 1. EOR
 - 2. WCAB order resolving threshold issues such as AOE/COE



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IBR Procedure



- 4. If second review is not requested w/in 90 days, the bill is deemed satisfied
- 5. If second review is requested:
 - A written determination is due w/in 14 days of review request
 - 2. The undisputed amount is due w/in 21 days of request
- 6. If the provider disputes the amount paid after the second review, independent bill review must be requested w/in 30 calendar days of service of the second review.
 - 1. If not, bill deemed satisfied



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17

IBR Procedure



- 7. If liability is contested for reasons other than appropriate fee (eg MPN, AOE/COE, etc), issues to be resolved <u>prior</u> to request for **Independent Bill Review.** Thirty days to request starts 30 days after other issues are resolved.
- 8. Independent Bill Reviewer assigned w/in 30 days of request. When notified of assignment, requested documents must be submitted within ten days
- 9. IB Reviewer may request additional documents of ER or Provider. "The employer shall have no obligation to serve medical reports on the provider unless the reports are requested by the IB Reviewer" (30 days to provide) [4603.6]



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IBR Procedure



- 10. Provider to pay \$250 independent bill review fee (reduced from \$335). If review finds that more money is owed, then fee is reimbursed to provider.
- independent bill reviewer shall make written determination of amounts to be paid, if any, and reasoning. [4603.6]



19



IBR Procedure



Duplicate Claims

"Duplicate submissions of medical services itemizations, for which an explanation of review was previously provided, shall require *no further or additional notification or objection* by the employer to the medical provider and *shall not subject the employer to additional penalties or interest...* for failing to respond to the duplicate submission."

LC 4603.2(b)(4)

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IBR Procedure



- As such it is final and binding unless a verified appeal is filed with the WCAB w/in twenty days of service
- The determination is presume correct



21

IBR Procedure



PROCEDURE (

To set aside an Order of the Administrator Director, the petitioner must show by clear & convincing evidence:

- AD acted without or in excess of her powers
- Fraud
- Material conflict interest
- Determination was result of bias (race, national origin, sex, sexual orientation, etc.)
- Determination is result of a "plainly erroneous express or implied finding of fact, provided that the mistake of fact is a matter of ordinary knowledge based on the information submitted for review and not a matter that is subject to expert opinion."

[LC4603.6]

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"Medical Legal" Billling

Lien claimant call: "You have to pay what I say because I am a 'medical legal' provider."

Does this happen?

ALL THE TIME!

But why?

- Additional/increased charges
- End run around UR and IMR



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23

"Medical Legal" Billing

NOT SO FAST! Let's back up a minute

Per CCR §9793(h) a Medical-Legal Expense means: "Any cost or expenses incurred...for x-rays, laboratory fees, other diagnostic tests, medical reports, medical records, medical testimony, and as needed, interpreter fees, for the purpose of proving or disproving a contested claim."

OK, I'm with you so far. So what is a contested claim?

B

"MEDICAL LEGAL" Billing



CCR §9793(b) defines a Contested Claim:

- 1. Where the administrator <u>has rejected liability</u> for a claim benefit.
- 2. Where the claims administrator has failed to accept liability for a claim and the claim has become presumptively compensable under Section 5402 of the Labor Code.
- 3. Where the claims administrator has failed to respond to a demand for payment.
- 4. Where the claims administrator has accepted liability for a claim and a <u>disputed medical fact</u> exists.



25

"MEDICAL LEGAL" Billing

CCR §9793(e) defines a Disputed Medical Fact as an issue in dispute concerning:

- 1. The employee's medical condition
- 2. The cause of the employee's medical condition
- 3. For dates of injury before January 1, 2013* on or before June 30, 2013, treatment for the employee's medical condition
- 4. The existence, nature, duration, or extent of temporary or permanent disability caused by the employees medical condition.
- 5. The employee's eligibility for rehabilitation services.

*Concerning a dispute over a utilization review decision if the decision is communicated to the requesting physician.



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"MEDICAL LEGAL" Billing

OK, so how do I resolve a contested claim?

Disputed Claim?

 LC 4060: This section shall apply to all disputes over the compensability of an injury.

Disputed Fact?

- LC 4061: Objection to a PD determination
- LC 4062: Objection to a medical determination not covered by 4060 or 4061 and not subject to 4610

What do these sections have in common?

 They both initiate the medical-legal process under 4062.1 or 4062.2



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27

"MEDICAL LEGAL" Billing

So, while there is a provision for a treating physician evaluation to be medical-legal:

CCR§9793(c): An evaluation of an employee which results in the preparation of a narrative medical...and is performed by a QME or AME, or the primary treating physician for purposes of proving or disproving a contested claim.

It's almost *always* going to be a PQME or AME after completion of the 4062.1 or 4062.2 process.



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Diagnostic Testing, Med Legal?

All MRIs and EMG/NCV studies are med legal. Right?

Actually, there are rarely med legal. Your lien claimant is just trying to catch you asleep at the wheel.

Diagnostics may be ordered by an AME or/QME under CCR §9793(a)(4)(c), however they are much more likely to be part of a treatment plan. All relevant defenses apply: MPN control, denied claim, Utilization Review, IMR, and no "special" charges or codes.

- 1. Look at the name of the requesting physician, is it your OME?
- Does the QME request the diagnostic in order to complete the medical legal evaluation?



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DURABLE MEDICAL EQUIPMENT

Your Honor, clearly the applicant needed \$25,000 in TENS units, batteries, electrodes, tape, and 'supplies'. In fact, he may have even received some of this stuff!



DURABLE MEDICAL EQUIPMENT

Practice pointers:



- 1. Demand prescriptions by the treating physician
- 2. Demand verification applicant received equipment and was given an explanation in how to use it.
- 3. Did the referring doctor say why the DME was prescribed?
- 4. Did he comment on whether it helped?
- 5. Demand invoices!
- 6. Is the applicant actually using the DME?
 - 1. Comment in follow up reports
 - 2. Is the DME helping
 - 3. Deposition testimony



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31

MORE ON DME



Has your lien claimant faxed you "proof" that *other carriers* pay their absurd prices?

Per *Tapia v Liberty Mutual* (73 CCC 1338) all lien claimants have the burden of proving their charges are reasonable.

- The lien claimant's billing, by itself, does not establish that the claimed fee is "reasonable" and the lien need not be allowed in full if it is unreasonable on its face.
- Evidence is not limited to the same geographic area.
- "The board may take into consideration a number of factors, including but not limited to the fee usually accepted by the lien claimant and other inpatient and outpatient providers."

So if we pay \$200 for a TENS unit in Sacramento, we don't care if some asleep at the wheel carrier paid \$1000 for one last week and we don't care if the lien claimant says he gets \$2000 in Beverly Hills, we still pay \$200.



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EVEN MORE DME

A DME provider must have a license to dispense equipment.

You mean I can't hand this stuff out of my garage?



Demand copy of the license to dispense DME as required by Health & Safety Code 111656. A DME distributor's license status may be requested by the CA Department of Public Health:

http://www.cdph.ca.gov/pubsforms/forms/CtrldForms/cdph8707.pdf

JAM Medical & Orthogear are two of our *favorite* DME providers familiar to those of you with cases in southern California who for some dates of service do not have the licensure required by the Department of Public Health.



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33

Pharmaceuticals

Red pill or blue pill? Just call me when you need a refill...

- 1. Identify the Prescribing Doctor
 - 1. Request must come from treating physician per CCR 9785.
- Compare medical reports. Is there an explanation of why the medication is reasonably required to treat the injury?
 - LC4600: Employer is only responsible for reasonable and necessary treatment.
- 3. Confirm receipt of the medications.
 - 1. Signature for deliveries.
 - 2. Deposition testimony.
- 4. Any confirmation that the medication was actually used?
 - 1. Periodic drug testing. Especially when you have a pain management specialist involved.



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Repackaged Pharmaceuticals

Mendoza v. Buckbinder Industry, Inc. (2010 Panel Decision)

- 1. Physician must prove usual and customary charge.
- If change is disputed, defendants must show that OMFS provides for lesser reimbursement.
- 3. In this case there are no evidence as to what the treating physician paid for pharmaceuticals dispensed to the applicant.
- 4. If samples that are given to the doctor are dispensed, there can be no charge.
- 5. Charges cannot be higher than a brand name equivalent drug.

Lessons:

- 6. Submit to bill review for reduction per OMFS.
- 7. Demand proof of physician's cost.
- 8. Compare with cost of brand name equivalent.





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35

Compound Medications

Effective January 1, 2012: LC5307.1(e)(2)

- Billing at the ingredient level with National Drug Code Indicated.
- 2. Ingredients without NDC are *not* reimbursable.
- 3. Reimbursement 100% of Medi-Cal plus a "dispensing fee."
- 4. If dispensed by a doctor, reimbursement shall not exceed 300% of the documented paid cost but in no case more than \$20 above documented paid costs.

Don't forget! LC §4600.1 requires prescribing physician to prescribe generic medications unless they are unavailable or an explanation is provided as to why the generics are not prescribed.



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Compound Medications

Demand the quantity of compounds. It's a recipe, so what are the ingredients?!

Once you have the recipe, check the current price http://www.dir.ca.gov/dwc/pharmfeesched/PFS.asp



37

Secondary Physicians

PTP, orthopedist Dr. Brown refers applicant to psychiatrist Dr. Bummed, because?

The PTP is allowed to refer applicant to secondary physicians where appropriate, CCR §9785(a)(2).

Per §9785(e)(3) the secondary physician *shall* (emphasis added) report to the PTP and the PTP is responsible to obtain those reports and incorporate them into the PTP's reports per §9785(e)(4). PTP must put request on a *Request for Authorization*.

PTPs routinely fail to comply.



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AME/QME can be your friend!

When preparing the cover letter to AME/QME, ask whether the medical treatment received to date has been medically necessary.

For example, Dr. QME, in your expert opinion was it medically necessary for the applicant to have been prescribed \$18,000 worth of TENS units? If so, please explain why. Did the applicant obtain any benefit?

Was it medically necessary for the applicant to be prescribed 300 tablets of OxyContin over a 2 year period for an ankle contusion?

This can also be addressed by way of deposition.



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39

AME/QME can be your friend!

- ▶ HOWEVER....
 - Advocacy letters have become increasingly scrutinized by applicant attorneys since the "en banc" Maxham case. (Maxham v. California Department of Corrections and Rehabilitation)
 - Essentially limits the amount of information which is provided to a med/legal evaluator.
 - AA's have recently increased objections to advocacy letters based on this case.



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Interpreters



L.C. §4600(g) Applicant entitled to a QUALIFIED INTERPRETER during medical TREATMENT APPOINTMENTS.

What exactly is a qualified interpreter?

Reg 9795.1.5 & 9795.1.6 defines a qualified interpreter as one who is certified or provisionally certified.

In California, ask for the certification number. Your interpreter should have one.



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41

Qualified Interpreters Continued



9795.1(a)(1) defines a certified interpreter. Basically an interpreter who has passed an examination administered by the state. A provisional interpreter per 9795.1(a)(2) is OK when a certified interpreter isn't available

- a. if other parties agree
- b. or WCJ based on a finding

9795.3(b) is the fee schedule for interpreters



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MORE ON INTERPRETERS



Guitron v. Santa Fe Extruders 76 Cal. Comp. Cases 228

The board held that to recover charges for interpreting services, the interpreter lien claimant has the burden of proving that:

- ▶ The services were *reasonably* required.
- ▶ The services were *actually* provided.
- ► The interpreter was *qualified* to provide the services, and
- The fees charged were reasonable.



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43

Interpreter Loophole?

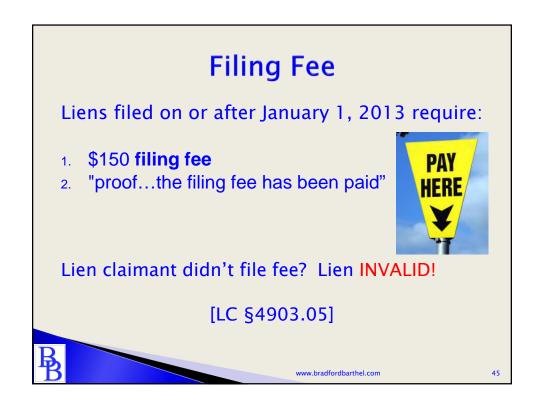


LC 5811(b)(2) deals with reimbursement for costs.

- Interpreter fees that are reasonably and necessarily incurred shall be paid by the employer under this section.
- A qualified interpreter may render services during the following.
 - A deposition
 - An appeals board hearing
 - A medical treatment appointment or medical-legal examination
 - During those settings which the administrative director determines are necessary to ascertain the applicant's proficiency in English



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BE NICE, EVEN TO LIEN CLAIMANTS!

Reg 10109(e) mandates defendants deal in good faith. Yes, even with lien claimants!

Reg 10250(b) requires stating under penalty of perjury when filing a DOR that moving party has made good faith attempts to resolve disputes requiring WCAB intervention.



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47

Medical Expense Lien Filing Statutes of Limitation

- ▶ Date of Service before July 1, 2013:
 - 3 years from date of service.
- ▶ Date of Service after July 1, 2013:
 - 18 months from date of service.



Don't Jump The Gun!

LC 4903.6(a)(1)

- 1. Lien claimants must wait to file!
- 2. No filing/serving:
 - 1. Until 60 days after claim has been accepted or denied, or
 - 2. 60 days after the 90-day investigation period...

...whichever is earlier AND...



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49

Don't Jump The Gun!



4903.6(a)(2)

 No filing/serving until 45 days to pay for treatment [4603.2(b)(1)] have elapsed.

OR

 No filing/serving until the 60 days to pay for Med Legal have elapsed.



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Assignment of Liens

CIGA pushed for "anti assignment" legislation.

Why?

- Lien claimants generate income by selling "paper."
- By lien conference time, tough to determine who provided
- WCJs hate this, and so do we!



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Assignment of Lien

Assignment now prohibited! (unless provider no longer performs services billed)

NOTE: most compound med liens *were* assigned by pharmacy before IW leaves shop!

[4903.8(a)-(b)]



Assignment of Lien

If lien assigned after filed...

...copy of assignment must be served w/in 20 days

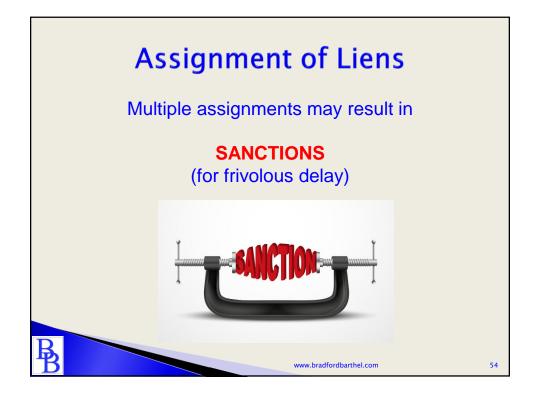
NOTE: critical to determine who actually performed the services. Compound pharmacies list assignee in very small print & hire collection agent.

- tough to assess who performed services
- great way to potentially knock out a lien with an unprepared lien rep!

[4903.8(b)(2)]



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Settlement of Case-in-Chief & Liens

Concerns regarding "hold harmless" language. *Barajas v. F&H Cold Storage*:

- WCAB allowed full recovery for medical service lien outside of
- Order Approving indicated that defendant held applicant harmles's.

What's the difference?

Some judges will interpret "hold harmless" language to place defendants in the applicant's shoes, thereby assuming liability the applicant might have. The problem? The applicant doesn't have an MPN defense applicant in the applicant is the problem. an MPN defense. If we're in the applicant's shoes, neither can we!

The lesson: If liens are to be deferred at the time the case in chief is settled, agree to "pay, adjust, or litigate," but never "hold harmless.'



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55

Copy Service Fees



- Copy Services fee schedule went into effect July 1, 2015 and was recently modified in 2022.
 - Regulations §9980 through §9994.
 - Includes a "flat rate" pricing system with limited add-on items allowable.
 - Amended in 2022 to include new scheduled fees for dates of service "on or after July 15, 2022"
- A flat rate pricing system with only a few "add-on items" allowed.
- A flat fee of \$180 covers everything that has to do with requesting, obtaining, and copying one set of records, regardless of format or media, up to 500 pages. Payment is limited to "copy and related"
 - If it's not directly related to copying records, you don't pay for it. No vague items can be added to the bill; the flat fee covers everything.
 - The fee schedule goes even further and specifically disallows payment for certain non-copy-related items: Summaries, tabulations, and indexing of documents.



- ▶ Regulation §9983, for Dates of Service prior to 07/15/22:
- (1) A \$180.00 flat rate,

Includes "an initial set of records, from a single custodian of records, which includes, but is not limited to, mileage, postage, pickup and delivery, phone calls, repeat visits to the record source and records locators, page numbering, witness costs for delivery of records, check costs, costs charged by a third party for the retrieval and return of records held offsite by the third party, service of the subpoena, shipping and handling, and subpoena preparation."

(A) Release of information services of witness costs for retrieval and return of physical records held offsite by a third party are governed by Evidence Code section 1563.



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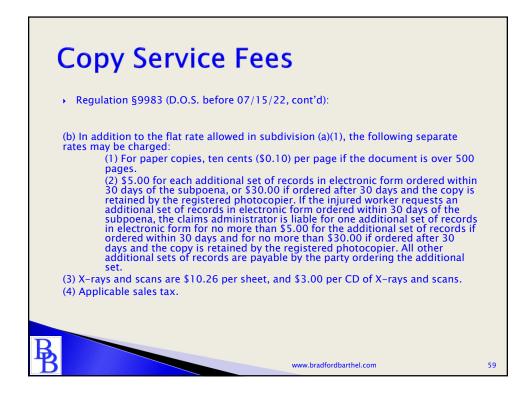
57

Copy Service Fees

- Regulation §9983 (D.O.S. before 07/15/22, cont'd):
- (2) \$75.00 in the event of cancellation after a subpoena or request for records by authorization has been issued but before records are produced, or for a Certificate of No Records (CNR).
- (3) \$20.00 for records obtained from the Employment Development Department.
- (4) \$30.00 for records obtained from the Workers' Compensation Insurance Rating Bureau.



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- Regulation §9984 for Dates of Service on or after 07/15/22:
- (1) A \$230.00 flat rate,

 For an initial set of records (with same limitations from §9983(a)(1)

B

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▶ Regulation §9984 for Dates of Service on or after 07/15/22:

(2) \$75.00 in the event of cancellation after a subpoena or request for records by authorization has been issued but before records are produced, or for a Certificate of No Record (CNR). The claims administrator will not be liable for bills submitted under this subdivision unless:

(A) The bill submitted for cancellation includes a copy of the request for records containing the date of the request and identity of the requesting party, and a copy of the cancellation order containing the date of cancellation and identity of the cancelling party.

(B) The bill submitted for CNR includes a copy of the request for records containing the date of the request and identity of the requesting party, and a copy of the CNR containing the date of the certificate.



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61

Copy Service Fees

Regulation §9984, (for D.O.S. on or after 07/15/22, cont'd):

(c) In addition to the flat rate allowed in subdivision (a)(1), the following separate rates may be charged:

- (1) For paper copies, ten cents (\$0.10) per page if the document is over 500 pages.
- (2) \$10.00 for each additional set of records. If the injured worker requests an additional set of records, the claims administrator is liable for one additional set of records. All other additional sets of records are payable by the party ordering the additional set.
- (3) X-rays and scans are \$10.26 per sheet, and \$3.00 for electronic storage media of X-rays and scans.
- (4) Applicable sales tax.



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▶ Warning: New Penalty Subsection Regulation §9981(e):

"Bills must be paid *or contested* within thirty days of receipt by the claims administrator. If a bill is not paid within this period, then the unpaid portion of the billed sum will be increased by 25 percent."

So make sure to issue objection!!!!!



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63

More on Copy Services



Do we have to pay for non-approved vendors?

Per evidence Code 1560, applicant's and their representative shall have full access to all medical evidence for review and can request via subpoena.

However, are automatic subpoenas reasonable and necessary?

No! *Taylor v. WCAB* 63 CCC 350 (W/D 1998). When applicant's attorney has access to all records served by defense counsel in its possession and employee authorization, subpoena costs shall not be awarded.

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Fighting Subpoenas!



L.C. 5307.9

Call applicant's attorney and advise you will provide all non privileged documents such as benefit notices, payment printout, medical records. In other words, you'll turn over everything you are required to.

File motion to quash. Subpoenas for claim files are notoriously overbroad. Failure to object may result in having to turn over everything in your file.

The subpoena filed by AA is also very likely duplicative of subpoenas that we have already issued. Failure to object and quash may result in you having to pay twice!



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65

Quashing a Subpoena

California Code of Civil Procedure 1985(b): Subpoenas must be specific. The items desired must be indicated such as medical reports & payroll records.

Often the subpoena is not copied on defense counsel so it's defective on its face.

If an ADJ number has not issued the WCAB has no jurisdiction, so no power to enforce a SDT.



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Changes in 2018 (SB 1160)

LC 4615 Stayed Liens (All coincides with LC 139.21):

Lien on behalf of physician, practitioner, or provider of medical services; stay pending criminal charges for fraud against workers' compensation system, medical billing, insurance; posting of information on Internet Web site.

SB 1160 added 5 new subsections to LC 4615:

- Filing of criminal charges per 139.21 (A)(1)(a) the following shall occur:

 - Automatic Stay
 Stay shall be in effect until the disposition of the criminal proceedings.
- Stay shall remain in effect until the commencement of lien consolidation procedures.
- Can request for dismissal and forfeiture of sums by physician, practitioner, or provider,
- The AD shall promptly post on Internet Web of stayed liens.
- Shall not preclude the appeals board the appeals board from inquiring into and determining within a workers compensation proceeding whether a lien is stayed.
- The AD may adopt rules for the implementation of this section.
- The filing of new or additional criminal charges.



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67

LC 139.21 (a)(1)(D) and (E) and (3) -(6) (as of January 1, 2018):

Suspension of physicians, practitioner, or provider from practicing workers' compensation for cause; notice and hearing; adjudication of liens.

- (D) The entity is controlled by an individual who has been convicted of a felony or misdemeanor.
- (E) changes made to clauses (i) and (iii) of Subparagraph (A) and (B) do not constitute a change in, but are declaratory of, the existing law. (added Medicaid)

- (3) An entity is controlled by an individual if the individual is an officer or director of the entity, or a shareholder with a 10 percent or greater interest.

 (4) For purposes of this section and LC 4615, an individual or entity is considered to have been convicted of a crime if any of the following:

 (A) A judgement of conviction has been entered by a federal, state, or local court, regardless of whether there is an appeal pending or whether the judgement of conviction or other record relating to criminal conduct has been expunged.

 (B) There has been a verdict or finding of guilt.

 (C) A plea of quilty has been accepted.
- (C) A plea of guilty has been accepted.
- (5) The AD may amend an existing suspension or commence a subsequent suspension proceeding pursuant to paragraph (1).
 (6) The AD may adopt regulations specifying any exemptions that shall not serve as the basis for exclusion under paragraph (1).





