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HOOPs West 2014

Managed Care Litigation

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Topics

- Medical Necessity Challenges
- Class Action Developments
- Waiver of Copays / The Surgicenter Cases
- UCR & NonPar Reimbursement
- Plan Liability for Failed IPAs
- ERISA Litigation Developments

Medical Necessity Challenges

Medical Necessity

- ***Sarchett v. Blue Shield of Cal.*, 43 Cal. 3d 1 (1987)**
  - **"The problem of retrospective denial of coverage can be reduced through the growing practice of preadmission screening of nonemergency hospital admissions. When such screening is not feasible, as in the present case, we think the best the courts can do is give the policy every reasonable interpretation in favor of coverage. We trust that, with doubts respecting coverage resolved in favor of the subscriber, there will be few cases in which the physician's judgment is so plainly unreasonable, or contrary to good medical practice, that coverage will be refused."**

- ***Hughes v. Blue Cross of Northern Cal.*, 215 Cal. App. 3d 832 (1989)**
  - **"The presence of good faith implies 'consistency with the justified expectations of the other party.' … But good faith demands a construction of medical necessity consistent with community medical standards that will minimize the patient's uncertainty of coverage in accepting his physician's recommended treatment. "**

Medical Necessity

- ***Simmons v. California Physicians' Service*, 2013 WL 794377 (Cal. App. 2 Dist. March 3, 2013)**

- ***Mendoza v. Health Net, Inc.* BC491954 (Cal. Super. Ct. July 26, 2013)**

- ***Dennis F. v. Aetna Life Ins. Co.*, 12-CV-02819-SC, 2013 WL 5377144 (N.D. Cal. Sept. 25, 2013)**

Medical Necessity

- ***Simmons v. California Physicians' Service***
  - **Blue Shield denied coverage for IVIG treatment and Fentora related to CIDP**
    - **IVIG = Intravenous Immunoglobin Treatment**
    - **CIDP = Chronic Inflammatory Demyelinating Polyneuropathy**
    - **Fentora = mediation to treat breakthrough pain associated with cancer**

Medical Necessity

Simmons v. California Physicians' Service

- **Blue Shield's medical review finds the treatment is not medically necessary because (1) IVIG is appropriate only if begun at an earlier stage of CIDP, and (2) Fentora is appropriate only for cancer**
- **Blue Shield defines "medically necessary" as consistent with Blue Shield medical policy**
- **DMHC's IMR for Fentora upholds denial of coverage as not medically necessary**
- **Simmons sues, and Blue Shield moves for summary judgment**

Medical Necessity

Simmons v. California Physicians' Service

- **Upholds Summary Judgment for Blue Shield:**
  - **Claim for denial of coverage for IVIG is time-barred under the PPO's limitations period**
  - **On the Fentora denial, *Sarchett v. Blue Shield of Cal.,* 43 Cal. 3d 1 (1987) and *Hughes v. Blue Cross of Northern Cal*., 215 Cal. App. 3d 832 (1989) do not mandate any particular definition of "medically necessary"**
  - **Those cases stand for the proposition that the plain language of a plan controls**
  - **Blue Shield's definition of "medically necessary" – that it is consistent with Blue Shield medical policy – unambiguously means some kind of internal procedure**
- **Blue Shield's definition of "medical necessity" complies with the law because California precedent mandates no particular definition**

Medical Necessity

Mendoza v. Health Net, Inc.

- **Mendoza's physician recommends robotic surgery to treat prostate cancer**
  - **Mendoza gets second opinion, and the second physician recommends open radical prostatectomy**
  - **Mendoza chooses the latter**
  - **Health Net says it will pay only for the former**
  - **Mendoza pays out of pocket and sues, arguing Health Net's "medical necessity" definition violates the *Sarchett and Hughes* line of cases**

Medical Necessity

Mendoza v. Health Net, Inc.

- **Cross-motions for summary adjudication under CCP § 437c(s) of the following issue:**
  - **Does Health Net's definition of "medical necessity" (in the plan at issue) comply with California law?**
- **Court rules for Health Net and against Plaintiff**

Medical Necessity

Mendoza v. Health Net, Inc.

- The Court characterized *Sarchett* as focusing on the procedural fairness of "medical necessity" determinations, which was not at issue here
- It characterized *Hughes* as holding that the implied covenant of good faith and fair dealing is breached when the decision to deny coverage is "sloppy, cursory, callous, concocted, AND deceptive"
  - "Add these five bad features together and they are bad faith."
  - *Hughes* is inapposite on its facts

Medical Necessity

Mendoza v. Health Net, Inc.

- **Because California precedent mandates no particular definition of "medical necessity," Health Net's motion is granted and Mendoza's is denied**
- **Trial court certifies the issue for appeal**
- **But Court of Appeal denies Mendoza's writ petition**

Class Action Developments

Class Action Overview

- (1) The Risks: Trends in Managed Care Class Actions
  - Coverage, Medical Necessity, Out-of-Network
  - PPACA Issues (Essential Health Benefits, MLR)
- (2) How to Win: Newest Tools to Defeat Managed Care Class Actions

Major Trends in Managed Care Class Action Litigation

- Coverage for Types of Conditions
  - Autism
  - Mental Health
- Medical Necessity
- Provider Class Actions
- Potential Issues under the PPACA

Coverage for Types of Conditions

- **Autism Spectrum Disorder (ASD)**
  - **"Medical Services" for ASD are covered, but certain therapies typically are excluded.**
  - **Applied Behavioral Analysis (ABA) are often excluded as:**
    - **Experimental**
    - **Habilitative/non-restorative**
    - **Non-health care (educational)**
    - **Not provided by licensed providers**
  - **Occupational Therapy / Speech-language Therapy often excluded as:**
    - **Habilitative/non-restorative**
    - **Non health care (educational)**

Coverages for Types of Conditions: Case Examples

- ***Johns v. Blue Cross Blue Shield of Michigan*, 2009 WL 910785 (E.D. Mich., March 31, 2009)**
  - **Proposed class of BCBS of Michigan plan members who were denied coverage for ABA treatment**
  - **Provisionally denied certification due to no evidence that the experimental coverage exclusions were the same across differing plans**
- ***Potter v. Blue Cross Blue Shield*, 2011 WL 9378789 (E.D. Mich., July 14, 2011) and 2013 WL 4413310 (E.D. Mich., March 30, 2013)**
  - **Proposed class of BCBS of Michigan plan members who (a) were denied claims on ground that ABA was investigative or experimental, or (b) who did not make a claim for ABA due to BCBS' policy not to cover ABA**
  - **Court certified both classes due to fact that across-the-board policy on experimental ABA was the central issue in the case, and administrative review would have been futile**
  - **Court then found on administrative record that experimental determination was "arbitrary and capricious"**

Coverages for Types of Conditions: Case Examples

- ***Churchill v. Cigna Corp.*, 2011 WL 3563489 E.D. Pa., Aug. 12, 2011)**
  - **Proposed class of Cigna plan members who (a) were denied claims on ground that ABA was experimental, or (b) who did not make a claim for ABA due to Cigna's policy not to cover ABA**
  - **Court certified class (a) because policy that ABA was experimental was applied uniformly**
  - **Court denied class (b) because class members failed to exhaust administrative remedies, and reasons for doing so were not uniform; contrary to *Potter***

Coverage for Types of Conditions

- **Mental Health Parity**
  - **Federal MHPA**
  - **State MHPA**
  - **Examples: Preauthorization/concurrent review requirements for mental health services; medical necessity reviews of routine, outpatient, out-of-network mental health; rate disparities**

Medical Necessity

- **Denial of coverage for medically "unnecessary" services**
  - ***i.e.*, *LACMA vs. Health Net* – plaintiffs claim Health Net denied payments for technologically advanced, lifesaving procedures under "community standard" definition of medical necessity.**
  - **Trial court agreed with insurers' definition; case on appeal**
- **Fed MHPA and State MHPA implicated**
  - **E.g. Class action lawsuit filed against Kaiser over mental health care wait times**

Medical Necessity

Dennis F. v. Aetna Life Ins. Co. , 2013 WL 5377144 (N.D. Cal., Sept. 25, 2013)

- Lawsuit on behalf of children with mental health conditions challenging denial of coverage
- Plaintiffs argue that Aetna uses its Level of Care Assessment Tool ("LOCAT") score to make determinations of medical necessity, and that Aetna fails to properly score subscribers
- Plaintiffs move for class certification

Medical Necessity

Dennis F. v. Aetna Life Ins. Co.

- **Class certification denied.**
  - **Court recognizes that LOCAT scores are "strongly correlated" with coverage decisions and are "probative" of medical necessity determinations**
  - **But individualized clinical judgment could still trump LOCAT scores**
  - **Aetna offers a number of examples where LOCAT scores would have denied coverage, yet coverage was provided due to overriding, individualized clinical judgment**
  - **Medical necessity determinations are individually unique and cannot be litigated on a class basis**

Out-of-Network Reimbursement Class Actions

- Moving beyond "flawed data" allegations and cases (see Ingenix litigation)
- Recent ERISA class action filed against Aetna and 300 employers
  - Six ambulatory surgery centers that provided services to self-funded plan participants who had portions of claims denied because above UCR claim that (1) underpriced or underpaid; (2) breached fiduciary duties; and (3) failed to followed ERISA-mandated procedures
  - NOTE: This is likely a response to Aetna's offensive against these nonpar surgery centers.

Litigation Risks from the ACA

- Essential Health Benefits
  - Feb. 25, 2013 HHS Final Rule (45 CFR §§ 147, 155-56)
  - Provider Non-Discrimination in EHB benefits
  - States may mandate beyond EHB categories
- Provider Exclusion from Networks

Litigation Risks from the ACA (cont'd)

- **Medical Loss Ratio Requirements (45 CFR §§ 158.110-606)**
  - **Filed rate doctrine?**
  - **No private right of action**
  - **However, will State Attorney Generals take up the baton? *See Mississippi ex. Rel. Hood v. AU Optronics Corp.***

Supreme Court on Class Certification

- **Tougher Class Certification Standards**
  - **The "rigorous analysis" requirement (*Comcast*)**
  - **The "overlap exception" & embrace of merits disputes (*Comcast*)**
  - **New 23(a)(2) "commonality" standard: "common answers" (*Dukes*)**
  - **Individualized damages may preclude 23(b)(3) predominance (*Comcast*)**
  - **But "no license" to engage in "free-ranging merits inquiries" at class certification *(Amgen)***

Supreme Court on Class Action Waivers

- **Enforceability of Class Action Waivers**
  - **Rejection of class arbitration (unless explicitly agreed) (*Stolt-Nielsen*)**
  - **State law cannot override enforceability of class action waiver (*Concepcion*)**
  - **"Effective vindication" attack on class action waivers not available (*Italian Colors*)**
  - **But arbitrator may decide the contract authorizes class arbitration, and if arguably construing the contract will not be overturned (*Oxford Health*)**

How These Tools Are Being Used

- **Lack of commonality/predominance (*Dukes*)**
  - ***Windisch v. Hometown Health Plan*, 2011 WL 4758715 (D. Nev., October 7, 2011) – denied certification of class of in-network providers alleging denial and delay of payment through down coding, bundling and use of modifiers**
  - ***Penn. Chiro. Ass'n v. Blue Cross*, 2011 WL 6819081 (N.D. Ill., December 28, 2011) and 286 F.R.D. 355 - (N.D. Ill. 2012) – denied certification of ERISA provider class due to individualized and uncommon issues of standing and compliance with ERISA requirements.**

How These Tools Are Being Used (cont'd)

- **Attack damages on class-wide basis/force early expert determination (*Comcast*)**
  - ***Halvorson v. Auto-Owners Insurance Co*., 718 F.3d 773 (8th Cir. 2013)**
  - ***In re Rail Freight Fuel Surcharge Antitrust Litigation*, 725 F.3d 244 (D.C. Cir. 2013)**
- **Use arbitration clauses, but with some caution (*Concepcion / Stott-Nielson/Oxford Health*)**
  - **Rarely (if ever) has AAA arbitrator denied request for class-wide arbitration**

Waiver of Copays / The Surgicenter Cases

Waiver of Copayments/Deductibles

- **Deductibles, copays & co-insurance increasingly important**
  - ***"Copayments sensitize employees to the costs of health care, leading them not only to use less but also to seek out providers with lower fees . . . which makes medical insurance less expensive and enables employers to furnish broader coverage (or to pay higher wages coupled with the same level of coverage)."***

    ***Kennedy v. CIGNA*, 924 F.2d 698 (7th Cir. 1991, Easterbrook).**

Waivers Prohibited By Medicare

"Routine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare."

HHS, Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372 (Dec. 19, 1994).

State Laws Are Mixed

- Minority of states: prohibit routine waiver as deceptive
  - Colorado, Florida Georgia, Iowa, South Dakota, others
- Others states - must rely on other theories:
  - Contract Exclusions
  - Fraud/Unfair business practices
  - Interference

Contract Exclusions

- ***Kennedy v. CIGNA*** **(7th Cir. 1991)**
  - **Facts:**
    - **Plan exclusion where member was not legally required to pay 20% coinsurance**
    - **Provider waived coinsurance in written agreement**
  - **Holding: "If [the provider] wishes to receive payment under a plan that requires co-payments, then he must collect those co-payments – or at least leave the patient legally responsible for them."**

The Surgicenter Cases: Referrals with Waiver of Copayments

- ***Aetna v. Bay Area Surgical Management LLC*** **(Santa Clara Superior Court, filed Feb. 2, 2012)**
  - **Defendants are 7 nonpar surgicenters and related individuals**
  - **Allegations:**
    - **Defendant surgicenters offer physicians illegal inducements to refer**
    - **Induce Participating Physicians to refer patients out of network to surgicenters where the physicians have a financial interest**
    - **Cherry pick patients for referral based on high insurance coverage**
    - **Surgicenter seeks nonpar reimbursement from insurer at inflated rates that are much higher charges than contracted facility rates**
    - **Surgicenter waives copayment so that patient does not pay more than an in-network copayment**
    - **Surgicenter kicks back profits to the referring physician**
    - **Physicians do not adequately disclose their financial interest**

The Surgicenter Cases: Referrals with Waiver of Copayments

- **Examples from complaint:**
  - **Physician received an annual bonus of $980,000**
  - **Physicians were promised 805% annualized return on investment**
  - **Surgicenter charge for "correction of bunion": $66,100**
  - **Aetna paid $23 million for 1900 procedures that should have cost only $3 million – a 771% increase**
- **Waiver of Copayment:**
  - **$66,100 charge for "correction of bunion"**
  - **Submits claim for $66,100 (misrepresentation of reasonable charge) with intent that Aetna would remit 80% of $66,100**
  - **Aetna pays $52,880 based on the misrepresentation**
  - **Surgicenter never collects coinsurance of $10,576 (20% of $52,880) (total allowed amount)**

The Surgicenter Cases: Referrals with Waiver of Copayments

- **The Court Overrules the Surgicenters' Demurrer:**
  - **The complaint "sufficiently alleges an unethical and substantially injurious business practice that involves fraudulent billing for the purposes of the UCL's unfair and fraudulent prongs."**

The Surgicenter Cases: Referrals with Waiver of Copayments

- **Court's Ruling on the Surgicenters' Demurrer:**
  - **Aetna adequately pleads a UCL violation based on illegal referrals (B&P Code 650) where remuneration is based on value or volume of referrals, not proportional to investment or ownership**
  - **UCL is also supported by alleged fraudulent waiver of copayments (distinguishing 1981 AG Opinion and the Duz-Mor Case)**
  - **Failure to disclose waiver of copayment to insurer can be fraudulent**
  - **Aetna has standing to allege illegal corporate practice of medicine based on surgicenters "cherrypicking" the patients for referral**
  - **Aetna pleads the alleged fraud with sufficient specificity**
  - **Aetna adequately pleads a cause of action for unjust enrichment**
  - **Demurrer to claim for "interference with contract" sustained with leave to amend to clarify how member's or provider's contracts were affected**

UCR & NonPar Provider Reimbursement

Legal Basis of Recovery

- In the absence of a contract express or implied in fact through the conduct of the parties, the cause of action is generally for *quantum meruit* or the reasonable amount for the services in question. The action is equitable in nature to prevent unjust enrichment.
- Little guidance about how the reasonable value determination is to be made.

Non-Contracted Providers: Legal Theories

- ***Quantum Meruit*** **as articulated in** ***Bell v. Blue Cross*** **is the prevailing legal theory**
- **B&P Code 17200**
- **Direct cause of action under H&S Code 1371.4 –** ***Enloe Medical Center v Principal Life Ins. Co.*****, 2011 WL 6396517 (E.D. Cal., 2011) (denial of MSJ) relying on** ***Prospect Medical Group, Inc. v. Northridge Emergency Medical Group*****, 45 Cal. 4th 497, 509, 87 (2009); compare to** ***Ochs v PacifiCare of California*****, 115 Cal. App. 4th 782 (2004)**

Other Possible Legal Claims

- **Unfair business practices under Cal. Business and Professions Code § 17200. Injunctive relief, restitution and attorney's fees possibly available.**
- **The basis of the claim is that the plan acted unlawfully by failing to comply with its payment obligations under the Knox-Keene Act.**

Argument: Reasonable Value ≠ Billed Charges

- Charges are arbitrarily set and bear no relationship to cost.
- Charges are inconsistent across facilities in the same geographic area.
- In the non-contracted setting, patients and payers have no control over the amounts charged.
- Providers almost never receive full billed charges as payment.

Argument: "Reasonable Billed Charges" Should Be The Default Payment Rate

- **Silent PPO law requires "active encouragement" to access PPO discounts.**
- **Aggregate charge information is publically available, so charge comparison is possible.**
- **Amounts paid are confidential.**
- **Discounts should only be available for network providers.**

Court Decisions On Reasonable Value

- ***Temple Univ. Hosp. v. Healthcare Mgmt. Alternatives, Inc.*, 832 A.2d 501 (Pa. Super. Ct 2003) "With respect to a Medicaid plan, "services are worth what people ordinarily pay for them . . ."**
- ***Kunz v. Patterson Floor*, 67 Cal. Comp. Cases 1588 (2002) "[T]he 'usual fee' to which we refer is the fee usually accepted, not the fee usually charged, because that is an aspect of the economics of a medical provider's practice in the current market."**
- ***Howell v. Hamilton Meats,* 52 Cal. 4th 541 (2011) "As we have seen, a medical care provider's billed price for particular services is not necessarily representative of either the cost of providing those services or their market value."**

Jury Verdict Awarding Hospital Billed Charges

- ***Children's Hospital Central California v. Blue Cross of California*, Case No. MCV 048512 (Madera County Sup. Ct.) (2011).**
  - **Trial court denied discovery regarding contracted payment information because "the court finds that 'fees usually charged' does not mean payments accepted."**
  - **Jury verdict of $10.7m finding hospital's billed charges were the reasonable value for post-stabilization services rendered to plan's Medi-Cal managed care beneficiaries.**
  - **Notice of Appeal filed by Blue Cross (8/3/12); oral argument set for tomorrow (5/14/14).**

Regulatory Considerations On Reasonable Value

- **Health & Safety Code § (HS)1317.2a(d) requires payers to pay "reasonable charges" for emergency services.**
- **HS 1395.6 requiring "active encouragement" to make unlawful "silent PPOs" or the improper leasing of discounted rates.**
- **HS 1262.8: Plans are required to pay charges for authorized post-stabilization services.**

The "Gould" Standard

- Based on *Gould v. Workers' Comp. Appeals Board* (1992) 4 Cal. App. 4th 1059, a workers compensation appellate decision.
- Cal. Code Regs., tit. 28, § 1300.71(a)(3)(B)
  - Provider's training, qualifications, length of time in practice;
  - nature of services;
  - geographic prevailing provider rates;
  - other relevant aspects of the medical provider's practice; and
  - any unusual circumstances.

PPACA: Payments to NonPar Emergency Providers

- Nothing is in the statute
- But new regulations create rules to "prevent payment of unreasonably low amounts"
- Payments must be at least the greater of:
  - the median "in-network" amount payable by the plan for the service;
  - an amount calculated in the manner usually used by the plan to calculate UCR rate; or
  - the Medicare rate.
- Neither the statute nor regs prohibit balance billing.

Update on Ingenix Litigation

- In numerous cases, plaintiffs have specifically targeted Ingenix and its role in the establishment of UCR reimbursement rates.
- Complaints related to Ingenix include the following:
  - Plans improperly deflate levels of reimbursement paid to non-participating providers
  - Plans conspire with third-party vendors that provide data necessary to establish UCR charges
  - Plan under-report claims experience when attempting to establish UCR charges

Update on Ingenix Litigation

- In 2009, UnitedHealth Group entered a $350 million class action settlement concerning out-of-network reimbursements by UHG using the Ingenix database.
- Also shut down Ingenix database, and funded establishment of Fair Health, an independent nonprofit that administers database of "usual and customary" rates.
- In 2012, Aetna entered into a similar class action settlement to settle claims relating to its use of the Ingenix database.
- In March 2014, however, Aetna provided notice that it was canceling the settlement, due to the fact that too many claimants had opted out.
- What's next?

Plan Liability for Failed IPAs

Health Plan Liability for Failed IPAs

- Recent litigation sparked by financial collapse of Capitated/Delegated Providers
  - La Vida
  - Bellflower
  - MaxiMed
- Issue is whether the health plan is liable for physician or hospital claims left unpaid when the IPA fails.

Health Plan Liability for Failed IPAs

- **Health & Safety Code § 1371:**

  "The obligation of the plan to comply with this section [timely claims payment] shall not be deemed to be waived when the plan requires its medical groups, independent practice associations, or other contracting entities to pay claims for covered services."

- **Health & Safety Code § 1371.4 (Regarding the obligation to pay for emergency services):**

  "(e) A health care service plan may delegate the responsibilities enumerated in this section to the plan's contracting medical providers."

Health Plan Liability for Failed IPAs

- **Previous Caselaw:**
  - ***CMA v Aetna* (2001): Health plans not liable to IPA contracted physicians who signed contracts to "look solely to" the IPA for payment**
  - ***Desert Healthcare v Pacificare* (2001): Court abstained from this complex economic issue, defers to DMHC regulation.**
  - ***Cal. Emergency Phys v. Pacificare* (2003): Health plans not liable to non-contracted emergency physicians; rejects "negligent delegation" theory**
  - ***Ochs v Pacificare* (2004): Same, but suggests possibility of a "negligent delegation" theory**

Health Plan Liability for Failed IPAs

- ***Centinela Freeman Emergency Medical Associates v. Health Net, et al.*, Ct of Appeals, 2nd Dist., April 2, 2014)**
  - **Plaintiffs are non-contracted ER physicians whose claims were left unpaid by LaVida**
  - **Court allows the case to proceed on the "negligent delegation" theory suggested in *Ochs***
  - **Health plans would be liable for La Vida's unpaid claims if they "knew or should have known that the RBO was financially unable" to pay its claims**
  - **Theory applies to the decision to delegate initially to the RBO, or to continue delegation after financial difficulties arise**

Health Plan Liability for Failed IPAs

"HMO's which would shirk their statutory obligation to reimburse emergency physicians by delegating that obligation to an IPA they know or have reason to know is financially unable to meet that obligation would, in effect, have the emergency physicians treat their enrollees for free. This is morally blameworthy."

Health Plan Liability for Failed IPAs

- **Limitations in the Court's Opinion**
  - **Limited to Emergency Providers only**
    - **Case is premised on the EMTALA obligations of emergency providers.**
    - **Court rejects a similar theory asserted by radiologists on the basis that radiologists provide elective services not subject to EMTALA.**
  - **Limited to NonPar Providers only.**
    - **Contracted providers are still bound by their "look solely" clause under *CMA v Aetna.***
  - **Court is careful to say it is not advocating complete de-delegation – only that the plan may be liable for the narrow segment of unpaid claims of nonpar emergency providers.**

Health Plan Liability for Failed IPAs

- **Other issues**
  - **Medi-Cal may be different**
  - **DMHC may be watching this case to firm up its own position on Medi-Cal claims**
  - **Need to increase monitoring and supervision of RBOs' nonpar emergency claims**
  - **Unclear whether the same theory could apply to underpaid claims versus unpaid claims**
  - **For Corrective Action Plans, health plans need to maintain clear, official documentation of DMHC participation and oversight**

ERISA Litigation Developments

Preemption/Removal of Provider Cases

- ***Melamed v. Blue Cross*, 9th Cir. 2014**
- **Completely Preempted**
  - **"Implied Contract"**
  - **"Third party beneficiary" of subscriber contracts**
  - **"Melamed seeks reimbursement for benefits that exist 'only because of [defendant's] administration of ERISA-regulated benefit plans," citing *Cleghorn v. Blue Shield, 9th Cir. 2005***

Preemption/Removal of Provider Cases

- ***Marin General Hospital v. Modesto & Empire Traction Co.*, 9th Cir. 2009**
  - **Not Preempted**
    - **"Oral Contract" (Prior Authorization)**
    - **Because the root of the claim depends on a separate obligation, regardless of whether the Plan otherwise covers it**
    - **But prior authorization still arises "only because of the defendant's administration of ERISA-regulated benefit plans."**

Preemption/Removal of Provider Cases

- What about other "Implied Contracts"
  - Quantum meruit?
  - "Implied in law" contract that nonpar Emergency Providers will be paid
    - Based on H & S Code §1371.4
    - *Cleghorn v. Blue Shield of California (9th Cir. 2005)* (A beneficiary's claim premised on 1371.4 is completely preempted and therefore removable. Court does not reach the "savings clause" issue for 1371.4.)
  - "Implied in fact" contracts
  - Third Party Beneficiary theory

Iqbal/Twombly -- Pleading ERISA with Specificity

- ***Sanctuary Surgical Centre v. Aetna et al*** **(11th Cir. 2013)(unpublished), *cert.denied, 3/24/14.***
  - **Providers sued under ERISA for benefits, breach of fiduciary duty, failure to provide plan documents and equitable estoppel.**
  - **Based on "manipulation under anesthesia" for 1,857 different patients, under many different group plans, denied as experimental or not medically necessary**
  - **Court dismissed complaint under the *Iqbal/Twombley* pleading standard: must plead "a claim to relief that is plausible on its face."**
  - **Dismissal upheld on appeal.**

Overpayment Recovery from Providers

- ***Pa. Chiropractic Assn. v. Blue Cross Blue Shield Assn*, N.D.Ill (3/28/2014)**
  - **Overpayment recovery from a provider constitutes an "adverse benefit determination"**
  - **Plan must issue a revised EOB and offer full ERISA appeals rights**
  - **Applies to set-offs and to overpayment demands**
  - **Permanent injunction issued**

Reminder: No Attorney Client Privilege

- ***Stephan v. Unum*** **(9th Cir. 2012)**
  - **"Fiduciary Exception" to AC Privilege**
  - **Insurer is a claims fiduciary under ERISA**
  - **Attorney's duty extends to beneficiaries of the ERISA plan**
  - **Therefore beneficiaries can discover attorney client communications of the plan (insurer)**

Reminder: No Attorney Client Privilege

- The AC Privilege applies only after the insurer and beneficiary are sufficiently "adverse"
- At the least this means after the completion of all internal appeals
- Receipt of a demand letter from the beneficiary's attorney does NOT make the situation sufficiently adverse to protect the insurer's AC privilege

Reminder: Work-Life Balance!

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Emerging Fraud and Abuse and Antitrust Risks under the ACA

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Roadmap

- Background
- Fraud & Abuse & False Claims Act (FCA)
- Antitrust
- Questions

FCA BASICS

FCA – Origin and History

- **Federal Civil False Claims Act ("FCA") 31 U.S.C. §3729 *et seq*.**
  - Enacted in 1863 to punish contractors who defrauded the Union Army
  - Major amendments in 1986, 2009 and 2010
  - Since 1986, has become Government's primary enforcement weapon for combating fraud, waste, and abuse
  - Record setting recoveries in just past two years

FCA - Common Theories of Liability

1. **False Claim –** ***knowing submission*** of or causing another to submit a false claim to the Government or a recipient of Government funds.
2. **False Record or Statement –*knowingly making or using*** a false record or statement material to a false claim.
3. **Reverse False Claim** –***knowingly making*** a false record or statement material to an obligation to pay money to the Government, or ***knowingly and improperly avoiding*** an obligation to pay money to the Government.
4. **Conspiracy** – when a contractor ***conspires to do*** *any of the above.*

FCA – Damages, Penalties & Relator's Claims

- **Damages:** Difference between what the government actually paid and what it should have paid absent the alleged FCA violation – ***TREBLED!***
- **Penalties:** $5,500 to $11,000 ***per claim*** and may be applied even in the absence of actual damages
- **"Whistleblower" Share & Retaliation Claims**

RECENT FCA AMENDMENTS

2010: ACA

Anti-Kickback Statute ("AKS")

- Establishes that a violation of the AKS can be the basis for FCA liability
- Changes the intent-and-knowledge requirements under the AKS. Now, a "person need not have actual knowledge or specific intent to commit a violation"
- Affects the "*Hanlester*" defense, which interpreted the AKS to require proof the defendant (1) had specific knowledge of the law, and (2) had specific intent to disobey the law. *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995)

ACA's Changes to the FCA

- Creates *Per Se* FCA Violation for Failure to Report and Return Overpayments:
  - Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.
- Does not add a new liability provision to the FCA, but stipulates with only limited detail the procedural steps and time period to report and return an identified overpayment obligation in order to avoid potential FCA liability.

ACA's Changes to the FCA

- ACA provides a 60-day deadline for **reporting and returning** overpayments.
- The deadline is the later of:
  - (A) the date which is 60 days after the date on which the overpayment was identified; or
  - (B) the date any corresponding cost report is due, if applicable.
- Effective for overpayments "identified" as of the March 23, 2010 PPACA enactment date

NEW RISKS FOR HEALTH PLANS

New Flows of Government Dollars

- A whole new “commercially insured" population is subject to the False Claims Act and federal enforcement arena if an insurer makes a false statement in connection with:
  - **Its medical loss ratio data**
  - **Its reinsurance submissions**
  - **its justification for any rate increase**
  - **Its risk corridor calculations**
  - **Its risk adjustment submissions**
  - **In qualifying its products for participation in the Exchange …**

"The Three R's" and The False Claims Act

Risk Adjustment
- Premium adjustments to offset adverse selection
- Individual & Small Group Markets
- Both inside and outside the Exchange

Risk Corridors
- Government shares gains/losses beyond +/- 3% of Target
- Individual & Small Group Markets
- Inside the Exchange

Reinsurance
- Government provides "stop loss" style reinsurance
- Individual Market Only
- Both inside and outside the Exchange

Exchange Standards

- HHS set minimum standards that Exchanges must use in certifying QHPs for participation. Standards set for:
  - marketing;
  - network adequacy;
  - inclusion of "essential community providers" willing to accept the "generally applicable payment rates" of the plan;
  - accreditation;
  - quality improvement;
  - uniform enrollment forms; and
  - standardized benefit presentation format permitting consumer comparisons.

FCA Reaches Payments Via Exchange

- Under Sec. 1313 of PPACA, ***payments made by, through or in connection with an Exchange*** are subject to the FCA if the payments include any federal funds; AND

- "Compliance with the requirements of this Act concerning eligibility for a health insurance issuer to participate in the Exchange shall be a material condition of an issuer's entitlement to receive payments, including payments of premium tax credits and cost-sharing reductions, through the Exchange".

Payors, Plans, MCO Risk Areas

- Recent amendments to the FCA bring health plans further into the Government's FCA "cross-hairs"
- Any false claim, record, or statement resulting in the receipt of federal funds can expose a health plan to FCA liability. Such risk areas include the following:
  - **Federal Employees Health Benefits Program** (*e.g.*, certification of community rate or, starting in 2013, accuracy of MLR data submission);
  - **Medicare Advantage** (*e.g.*, plan rate bid certs);
  - **Contractor Performance** (*e.g.*, timeliness of claims payments, notices of claim denials, reconsiderations, and appeals, marketing, enrollment/disenrollment, under utilization, accessibility of services);

Payors, Plans, MCO Risk Areas

- **Falsification of Reports/Certifications** (*e.g.*, regarding encounter data, quality-of-care review, enrollee health status reports, or data required to be submitted to the government);
- **"Red-Lining"** (*e.g.*, insurance companies that provide Medicare Advantage insurance coverage and paid on a per patient basis, improperly discourage enrollment by persons they deem to be sicker or at higher risk for serious illness, to decrease risk and enhance revenue); and,
- **Medicare Part D Fraud**
- **Intermediary Services** (*e.g.*, failure to provide appropriate level of services and/or to ferret out issues and fraud)

COMPLIANCE TIPS AND BEST PRACTICES

Taking it to Your World

- Risks from submissions on rates and costs for commercially insured populations make fraud and abuse a more critical company compliance need outside of traditional "government program" arenas
- FCA risks created by false statements regarding qualification for Exchange participation
- Government attorneys will likely have greater access to approval to use compulsory process
- Broader whistleblower protections

Key Risk Areas

- Inaccurately reporting or certifying data in premiums, bids and rate proposals or annual reports, even if not financial.
- Using inaccurate or “mis-bucketed” data to support reported claims experience and loss ratios and risk corridor performance.
- Sloppy tracking or reporting of actuarial risk or member diagnoses used in risk adjustment scoring for government or commercial populations.
- Not promptly addressing possible “overpayments”
- Falsely certifying compliance with rate or bid requirements.

Key Risk Areas

- Falsely certifying compliance with marketing or other program requirements or restrictions on de facto “red-lining”.
- Inaccurately reporting enrollment or failing to correct inaccurate enrollment or other demographics.
- Manipulating provider or vendor dealings to distort reported claims or administrative expenses.
- Government concern about “paper” compliance programs fuels allegations that mistakes were “reckless” and therefore support False Claims allegations.

Antitrust risks for Payers under ACA

Risks?

Opportunity?

The future

Antitrust Risks

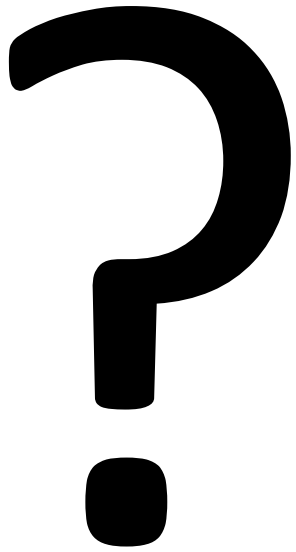
- Exchanges
- Provider consolidation:
  - ACOs/Clinical Integration
  - Mergers
- Efforts to maintain market position

Opportunities and Antitrust Risks

- Vertical Integration
  - How will provider/payer integration be viewed by FTC/DOJ?
    - Integrated care delivery models
    - Provider acquisitions
  - Lessons from St. Luke's case in Idaho.
- Horizontal Consolidation

Payers, ACA, Antitrust and the Future

Questions?



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HOOPS WEST 2014

Narrow Networks: Now or Never?

Kevin Kroeker

Peter Roan

Los Angeles, CA

May 13, 2014

Overview and Roadmap

1. Why the Move Toward Narrow Networks
2. State and Federal Developments
3. Provider Reactions
4. Impact of State Requirements Governing Treatment of Physicians
5. Litigation Challenging Network Termination/Exclusion

1. Current Business Environment and the Move Toward Narrow Networks

Why Narrow Network? Why Now?

- Narrow Networks are Not New
  - Initially a response to large employers that pushed for options to lower their health care costs
    - Blue Shield Net Value Plan for CaLPERS , 2005
    - Anthem Blue Cross exclusion of Cedars and UCLA, 2013
- ACA-Related Pressures for Narrow Networks
  - Exchange Products and pressure for low premiums
  - Medicare Advantage Plans
    - Response to lower CMS payments
    - Quality and cooperation of providers influences star ratings
  - Trends towards provider accountability for costs and quality (influenced by ACOs)

Benefits of Narrow Networks

- Narrow network → Cost-effective providers
- Narrow network → Lower payment rates in exchange for patient volume
- Narrow network → Lower consumer premiums
- Narrow network → Better Integration
- Narrow network → An opportunity for better quality

Concerns of Narrow Networks

- Narrow network → Lower cost at a price
- Narrow network → Longer waiting times for appointments
- Narrow network → Less choice for patients and less accessibility
- Narrow network → May be disruptive to some existing provider-patient relationships
- Narrow network → Insufficient access

2. State and Federal Developments

State Reactions

- Executive Action
- Legislation
- Regulatory Action (e.g., additional network adequacy requirements)

Executive Action: Mississippi Governor Executive Order 1327

- Governor Bryant intervened in dispute between BCBS Mississippi and 10 Health Management Associates hospitals
- EO 1327 required plan to rescind contract terminations
- Required DOI to conduct investigation and hold hearings on Plan's compliance with law
- Challenge by plan resulted in Amended EO 1327:
  - Rescinded requirement that plan and hospitals return to pre-contract termination status and proceed according to the contracts then in effect

Legislative Reaction

- Any willing provider proposals
  - N.H. House Bill 1294 (2014) - Insurer participating in the health exchange shall allow any willing provider in the state the opportunity to negotiate in good faith to participate in its exchange network.
  - MS Senate Bill 2709 (2014) - Health insurer shall not discriminate against any provider who is located within the geographic coverage area of the health benefit plan and who is willing to meet the terms and conditions for participation established by the health insurer.
  - PA House Bill 222 (2013) - A health care payer shall be required to contract with and to accept as a health care benefit plan participant any willing provider of health care services. A health care payer shall not discriminate against a provider of health care services who accepts payer's standard payment levels and meets and agrees to quality standards.

Regulatory Reaction

- Washington State's Insurance Commissioner sought to keep five insurers from narrowing networks for products offered on the Exchange, asserting inadequate networks.

- Maine's Insurance Superintendent prevented insurer from switching members to an Exchange plan that excluded six state hospitals. Switch was approved in counties where network was determined to be adequate.

DMHC Network Requirements

- At least one FTE MD required for every 1,200 enrollees, and at least one FTE primary care MD for every 2,000 enrollees
- All enrollees live or work within 30 minutes or 15 miles of a contracting or plan-operated primary care provider
- All enrollees live or work within 30 minutes or 15 miles of a contracting or plan-operated hospital
- Timely access regulations specify additional access requirements and require annual reporting of compliance.

CDI Network Requirements

- Similar requirements to those of DMHC, adopted based upon 2002 legislation and subsequently adopted timely access regulations.
- Commissioner Jones is planning new “start from scratch” accessibility regulations in 2014.

Covered California Network Requirements

- Qualified Health Plans (QHPs) required to meet network adequacy standards of applicable health insurance regulator (DMHC or CDI) as well as federal regulations.
- QHPs must maintain a network that includes sufficient geographic distribution of essential community providers ("ECPs") – providers that serve predominantly low-income and underserved individuals. ECPs must be available to provide reasonable and timely access to covered services to low-income populations in each geographic region where the QHP provides services to enrollees.

Covered California (cont.)

- Covered California is prepared intervene if access problems arise in narrow network plans, including enrollment freezes.
- Covered California is considering contracting with a "Secret Shopper" consultant to check on provider access and other potential mechanisms for reporting and measuring provider accessibility.

Big Issue for CDI and DMHC in 2014

- "Network adequacy will be a big issue in 2014.“ Dave Jones, California Insurance Commissioner (*LA Times*, February 4, 2014).
- 2014 Hot Issue No 1 - Network Adequacy/ Narrow Networks (Gary Baldwin, Deputy Director Plan and Provider Relations, ICE Annual Conference, November 14, 2013)

SB 964 (Hernandez)

- Requires DMHC to conduct annual reviews of plans for timely access and network adequacy and by line of business for Medi-Cal and Covered California.

Network Adequacy Under ACA § 1311(c)(1)(B)

- The Secretary shall, by regulation, establish criteria for the certification of health plans as qualified health plans. Such criteria shall require that, to be certified, a plan shall, at a minimum—
- …(B) ensure a sufficient choice of providers (in a manner consistent with applicable network adequacy provisions under section 2702(c) of the Public Health Service Act), and provide information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers….

Network Adequacy Rule for QHPs

45 C.F.R. § 156.230

- QHP issuer must ensure that the provider network of each QHP, is available to all enrollees:
  - Includes essential community providers;
  - Be sufficient in numbers and types of providers, including providers specializing in mental health and substance abuse services, to assure that all services will be accessible without unreasonable delay; and
  - Be consistent with the network adequacy provisions of section 2702(c) of the PHS Act

2014 Federal Network Adequacy Standards

- CMS reliance on:
  - Issuer accreditation status,
  - Identify states with review processes at least as stringent as those identified in 45 C.F.R. § 156.230(a), or
  - Collect network access plans as part of CMS' evaluation of plans' network adequacy.

Federal Network Adequacy Standards for 2015

Final 2015 Letter to Issuers in the Federally-facilitated Marketplaces

- CMS will assess provider networks using a "reasonable access" standard, and will identify networks that fail to provide access without unreasonable delay.
- CMS will focus most closely on those areas which have historically raised network adequacy concerns, e.g., hospitals, mental health providers, and PCPs.
- CMS will notify the issuer of the identified problem area(s) and will consider the issuer's response prior to making the certification or recertification determination.
- CMS will share information and analysis and coordinate with states that are conducting network adequacy reviews.

CMS Final 2015 Call Letter for Medicare Advantage Plans

- MA organizations required to notify CMS at least 90 days prior to network changes for any no cause termination that they deem "significant".
- CMS will determine whether terminations are substantial and require the granting of a Special Election Period. Criteria include:
  - Number of enrollees affected;
  - Size of affected service area;
  - Timing of the termination;
  - Whether adequate and timely notice is provided to enrollees; and
  - Any other information that may be relevant to the particular circumstance(s).

2015 Call Letter (cont'd)

- Additional SEP considerations:
  - Enrollee must demonstrate that he/she has been affected by the change.
  - SEPs will not be granted when MAOs make changes to their network that are effective on January 1 of the following contract year, as long as affected enrollees are notified of the changes prior to the start of the Annual Election Period.
- Best practice for MAOs is to provide enrollees more than the required 30 days advance notice of significant network changes for no cause.
- New required language in ANOC and EOC materials regarding MAOs' responsibilities to notify enrollees of network changes.

2015 Call Letter (cont'd)

- CMS expects MAOs to take a conservative approach in determining whether a network change is significant and notify CMS if there is any doubt as to whether planned contract termination represents significant change to the network.
- CMS encourages MAOs to provide more than 60 days prior notice to providers whose contracts are being terminated without cause to allow for a complete appeals process prior to beneficiaries being notified.

3. Provider Reactions

Provider Reactions

- Lawsuits challenging contract termination
  - Breach of contract
  - Violation of state law
  - Disruption of existing provider-patient relationships
  - Interference with existing physician referral networks
  - Undermine ER coverage in many hospitals
  - Impact on care by certain of sub-specialists
- Administrative appeals with state insurance departments

4. Impact of Laws Governing Treatment of Physicians

Consider Impact of State Laws on Provider Terminations

According to the *Survey of State Fair Procedure Rights Triggered by Excluding Providers from Health Care Networks* published November 2013 by the American Health Lawyers Association:

- 4 states allow termination or exclusion of physicians without either good cause or any fair procedure.
- 23 states require both good cause for exclusion or termination and fair procedure.
- 14 states and D.C. impose restrictions on grounds for termination/exclusion and require fair procedure.
- 9 states impose no specific requirements on MCOs concerning physician termination/exclusion.

States that Permit Termination/ Exclusion Without Cause or Fair Procedure

- Colorado: *Grossman v. Columbine Med. Grp.*, 12 P.2d 269, 271 (Colo. Ct. App. 1999)(MCOs with provider contracts permitting termination without cause with not less than 60 days' prior notice need not provide a fair hearing).
- Connecticut: *Ramirez v. Health Plan of the Northeast, Inc.*, 285 Conn. 1, 938 A.2d 576, 586-587 (Conn. 2008)(provider contract must provide at least 60 days' prior notice of termination).

States that Permit Termination/ Exclusion Without Cause or Fair Procedure

- South Dakota: S.D. Codified Laws § 58-17F-11 (60 day prior notice required, patients in active course of treatment can continue with existing provider up to 90 days following effective date of contract termination).
- Tennessee: Tenn. Ann. Code § 56-32-130 (physician cannot be terminated because of communications with patients concerning health status, treatment options or for assisting enrollee in attempting to obtain coverage); *see also City of Cookeville v. Humphrey*, 126 S.W.3d 897, 904-907 (Tenn. 2004)(public hospital authority permitted to enter into exclusive provider contract and decision to close the staff of the imaging department did not require that hearings be provided to terminated or excluded physicians).

23 States that Require Both Good Cause and Fair Procedure

- CA, ID, IL, KY, ME, MA, MS, MO, MT, NH, NJ, NM, NY, OH, OR, PA, RI, SC, TX, UT, VT, WA, and WV.
- CA: *Potvin v. Metropolitan Life Ins. Co.*, 22 Cal.4th 1060, 1066 (2000).
  - Fair procedure required.
  - Decision must be rational and based on fair procedure – not arbitrary, capricious, discriminatory, irrational or contrary to public policy.
  - Procedural fairness requires, at a minimum, notice and an opportunity to be heard.

23 States that Require Both Good Cause and Fair Procedure

- Illinois: *Dookerman v. County of Cook*, 920 N.E. 2d 633, 648-649 (Ill. App. Ct. 2009).
  - Termination cannot be arbitrary, capricious, or unreasonable.
  - Provider must be given a meaningful opportunity to be heard.
  - At least 60 days' prior notice of termination is required to both the physician and affected plan enrollees.
- Washington: *Jolly v. Regence Blueshield*, 220 P.3d 1264, 1270 (Wash. 2009)(contract providers must be given notice of the reasons for termination and an opportunity to be heard on the merits of the decision) *see also* Rev. Code Wash. § 48.43.055 (health insurers must file procedures for review of provider complaints with the State Insurance Commissioner).

The Middle Ground States

- AK, AR, DE, D.C., FL, GA, HI, IN, MD, MI, MN, NE, ND, OK, and VA
- Examples:
  - Delaware. 18 Del. Code § 3339 (permits terminations without cause, but requires that the provider receive 60 days' prior notice and may request written reasons for the termination).
  - Florida. Fla. Stat. Ann. § 440.134 (at least 60 days' notice required unless patient danger or government action affecting provider's practice); § 641.315(7) (HMO may not terminate contract without written reason for termination which may include business reasons).

States With Few or No Requirements

- No Requirements: AL, AZ, IA, KS, NC, and WY
- Few Requirements:
  - LA: La. Rev. Stat. § 22:1007 (only restriction is that MCO cannot terminate based on provider's communication with patient).
  - NV Nev. Rev. Stat. Ann. § 616B.5286 (MCO cannot terminate or refuse to contract with workers compensation provider for advocating for patients).
  - WI: Wis. Stat. § 609.30(HMO cannot terminate a provider for discussing treatment options or making referrals).

Medicare Advantage (MA) Requirements

42 C.F.R. § 422.202(d) requires MA plans to provide an appeals process through which physicians may challenge with or without cause terminations.

- Must provide notice to the physician of the reasons for the action, the standards and profiling data, if any, used to evaluate the physician and the numbers and mix of physicians needed by the MA organization, and the physician's right to appeal and the process and timing for appeal hearings.
- MA organization must ensure that the majority of hearing panel members are peers of the affected physician.
- If termination is for quality of care reasons, MA plan must give notice to licensing or disciplinary bodies.
  - Must give at least 60 days prior notice.

Any Willing Provider Laws

- AWP laws generally require insurers in the state to contract with licensed providers willing to accept the contract terms offered by the insurer.
- According to a survey published by Thomson/Reuters in 2012, 40 states have at least some form of AWP law. WL 0110 SURVEYS 23.
- Scope of these laws varies greatly by type of provider and plan type and requirements.
- At least 19 states have AWP laws covering physicians: DE, GA, ID, IL, IN, KY, LA, MA, MI, MN, NE, NM, NC, SD, UT, VA, WV, WI, WY.

Sample: IL St. Ch. 215 § 134/40(a)

"All health care plans that require each enrollee to select a health care provider for any purpose including coordination of care shall permit an enrollee to choose any available primary care physician licensed to practice medicine in all its branches participating in the health care plan for that purpose. The health care plan shall provide the enrollee with a choice of licensed health care providers who are accessible and qualified. Nothing in this Act shall be construed to prohibit a health care plan from requiring a health care provider to meet the health care plan's criteria in order to coordinate access to health care."

AWP Laws

- Providers must be qualified and meet credentialing requirements.
- MT and NE guarantee the right of providers to submit competitive bids.
- AWP laws in IN and VA specifically apply to hospitals.
- AWP laws are subject to the ERISA savings clause and are thus not preempted for insured business. *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003).
- But, AWP laws do not apply to self-insured plans. *E.g., Prudential Ins. Co. of America v. National Park Med. Cntr.*, 413 F.3d 897, 913 (8th Cir. 2005).

Medicare Advantage Preemption

- Any "State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations" are preempted. 42 U.S.C. § 1395w-26(b)(3).
- State physician fair hearing requirements and AWP laws are not State licensing or solvency requirements and thus appear to be preempted as applied to MA plans.

Provider Anti-Discrimination Under ACA § 2706

- "A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law."
- Not an any willing provider law.
- Nothing in this section prevents a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.

Provider Anti-Discrimination Under ACA § 2706 (cont.)

- The law is broadly worded – "shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification."
- The meaning of "participation" is more straightforward, but what did the drafters mean by "coverage"?
- May class litigation result when potential classes of licensed practitioners are denied participation?

5. Litigation Challenging Network Termination/Exclusion

Considerations

- Contract Requirements
- Plan Type
- All or Limited to Particular Networks
- Binding Arbitration Required for Contract Disputes?
- May Providers Seek a TRO or Preliminary Injunction in Court?

Potvin v. Metropolitan Life Ins. Co.

- 22 Cal.4th 1060 (2000). Individual physician brought action against insurer who terminated him from their PPO network based on a without cause termination provision in the provider contract.
- Trial court granted summary judgment, and the physician appealed contending the he had a common law right to a fair hearing prior to termination.
- California Supreme Court reversed holding that the "common law right to fair procedure does not apply to an insurer's removal of a physician from its preferred provider list unless the insurer possesses power so substantial that the removal significantly impairs the ability of an ordinary, competent physician to practice medicine or a medical specialty in a particular geographic area thereby affecting an important, substantial economic interest."

Nordella v. Anthem Blue Cross

- California Superior Court Case No. BC 444364 (filed Dec. 15, 2010)
- 2013 Los Angeles jury verdict awarding $3.8 million in compensatory damages to an urgent care physician who claimed Anthem Blue Cross denied his application to be a network provider in March 2010 because he was a patient advocate.
- The physician claimed he met all credentialing requirements but that the insurer had retaliated against him because he advocated for patients when he was a network provider between 1990-2003.

Nordella v. Anthem Blue Cross (cont.)

- Plaintiff asserted that the evidence presented by the insurer supporting the denial of his application was only prepared after the decision to deny his application was made.
- He also asserted that the argument advanced by the insurer that there was no network need was only a pretext and that the real reason for the denial of his application was his past patient advocacy.
- The case was settled after the compensatory damage verdict was rendered and before the punitive damage phase of the trial was to begin.

Palm Med. Grp., Inc. v. State Comp. Ins. Fund

- 161 Cal.App.3d 366 (2008). $1.1 million jury verdict in favor of an occupational clinic denied admission in workers compensation insurer's provider network. Jury found insurer have violated group's right to fair procedure. Trial court granted defendant judgment notwithstanding the verdict.
- Court of appeal reversed holding *Potvin* applied to contract applications and not only to terminations and that the trial court record supported the jury verdict.

Roger v. CorVel, Appeal No. G045935, Cal. Ct. App., 4th Dist. (May 16, 2013).

- Unpublished decision upholding trial court judgment after a bench trial that termination was justified because the provider consistently failed to comply with network treatment guidelines.
- Also upheld the trial court decision that the provider was not damaged by the networks' failure to comply with its own internal grievance and appeal processes because the record demonstrated the provider would not conform his practice to network guidelines.

Examples of Facilities Challenging Network Termination / Exclusion

In re Seattle Children's Hospital

- The Hospital filed a lawsuit against the State of Washington Office of Insurance Commissioner ("OIC"), challenging its exclusion from exchange networks. Superior Court, King County, Washington Case No. 13-2-34827-6.
- The Hospital also filed a Demand for Hearing with the OIC Hearings Unit, Docket No. 13-0293, to review the OIC's decision to permit the Hospital's exclusion from many plans sold through the state's insurance exchange alleging that the Commissioner abused his discretion by not adequately scrutinizing issues surrounding quality and access to services under State and Federal law.
- Insurers participating in the Washington exchange including Coordinated Care Corp., Premera Blue Cross and Bridgespan Health Company, a subsidiary of Regence BlueShield, intervened in the action.

In re Seattle Children's Hospital

- February 20, 2014 OIC Hearings Unit issued orders in favor of the Hospital in response to motions to dismiss brought by the OIC and the intervenors finding that the Hospital had standing to pursue its claims that the OIC had not followed federal or state law in approving the networks without including the Hospital.
- The OIC and the insurers also argued that the OIC had no jurisdiction to order the insurers to contract with any particular hospital, but the Hearings Unit rejected that argument finding that the Hospital was making no such demand.

In re Seattle Children's Hospital

- The Hospital filed a Motion for Partial Summary Judgment arguing, among other things, that the OIC was required to consider and comply with ACA standards including the each exchange plan include "essential health benefits" under 42 U.S.C. § 18022 and applicable State laws and regulations. RCW 48.43.715, WAC 284-43-849.
- The Hospital also argued that OIC must ensure that each exchange plan include in their networks "essential community providers" that serve predominately low-income, medically underserved individuals. 42 C.F.R. § 156.235.

In re Seattle Children's Hospital

- The Hearings Unit found that the OIC was required to consider and comply with the ACA and State standards on network adequacy, but ruled there were triable issues precluding partial summary judgment as to whether because of the unique services offered by the Hospital it must be included as a contracted provider by the exchange plans. Order Denying Motion for Partial SMJ, March 14, 2014.
- In denying the Motion, the Hearings Unit also ruled that there were triable issues of fact concerning whether the practice of using "single case agreements" by exchange plans when certain specialty services could only be obtained from the Hospital was consistent with the ACA.

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In re Seattle Children's Hospital

- With respect to the issue of whether the Hospital was an essential community provider, the Hearings Unit noted that exchange plans were not required to contract with an essential community provider if the provider refuses to accept the generally applicable payment rates of the plan. 42 C.F.R. § 156.235(d).
- The Hospital sought assistance from the federal Office of Personnel Management which has authority under the ACA to review and approve multi-state plans, but OPM declined to intervene. *BNA Health Law Reporter*, Vol. 23, No. 17 at pp. 589-590 (April 24, 2014).
- Further proceedings are pending.

In Re: Frisbie Memorial Hospital

- New Hampshire Insurance Department Case No. 13-038-AR New Hampshire Department of Insurance denied a complaint filed by the Hospital over its exclusion from Anthem's provider network.
- Frisbie complained that it did not have an opportunity to negotiate with Anthem and that exclusion will cause competitive disadvantage.
- The DOI noted that the Hospital did not challenge whether Anthem's exchange offering did not meet New Hampshire's network adequacy standards, and instead had challenged whether Anthem could exclude the Hospital.
- DOI ruled that it does not regulate competition and cannot order Anthem to contract with any particular provider.

In Re: Frisbie Memorial Hospital

- Anthem enrollee Margaret McCarthy filed a claim with the New Hampshire Insurance Commissioner that the N.H. Health Marketplace cannot be adequate without Frisbie.
- The Commissioner has permitted the claim to proceed and a public adjudicative hearing will take place on May 14.

Lessons

- Ensure contract terminations comply with provider contract requirements
- Document objective decision-making with respect to provider terminations and denials of applications for inclusion in provider networks
- Provide a fair hearing where the law may require it
- Evaluate potential political or regulatory reaction
- Keep applicable regulators informed
- Evaluate need for clarifications to provider contracts
- Review accuracy of member materials on scope of the provider network
- Monitor member complaints regarding provider availability and accessibility

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HOOPS WEST 2014

HEALTH CARE PRIVACY AND SECURITY DEVELOPMENTS

Jennifer Romano

and

Scott Moore

HIPAA - $4.8 Million Settlement

- New York and Presbyterian Hospital and Columbia University filed a joint breach report dated September 27, 2010
- Disclosure of ePHI of 6,800 individuals, including patient status, vital signs, medications and lab results
- HHS announced settlement on May 7, 2014
- Largest settlement so far under HIPAA

HIPAA

- Health Insurance Portability and Accountability Act
  - Passed in 1996
  - Privacy and Security Rules (regulations) issued by 2003
- 2009 HITECH Act
  - Added provisions requiring breach notification
  - Increased enforcement (penalty amount, State AGs)
  - Business Associate liability increased
- 2013 Final Rule
  - Modified “interim final rule” in place since 2009
  - Finalized enforcement changes
  - BA direct liability

HIPAA - A Brief Review

- What is Regulated?
  - Protected Health Information: information about health status, treatment or payment about a specific individual
    - Identifier (name, SSN, etc.) + health info
    - Does not apply to "de-identified data"

- Who is Regulated?
  - Covered Entities: health plans, providers, clearinghouses
  - Business Associates: anyone else that has access to PHI from a CE, including subcontractors
    - Includes vendors, cloud providers, contractors
    - "Conduit" exception very narrow

Selected California Privacy Laws

- Confidentiality of Medical Information Act (Civil Code §§ 56 et seq)
- Customer Records Act (Civil Code §§ 1798.80 et seq)
- Insurance Information and Privacy Protection Act (Insurance Code §§ 791 et seq)

Three Primary HIPAA Components

- Privacy Rule (45 C.F.R. §§ 164.500 et seq)
  - Limits uses and disclosures
- Security Rule (45 C.F.R. §§ 164.300 et seq)
  - Requires sufficient administrative, physical, technical, and organizational security safeguards
- Breach Notification Rule (45 C.F.R. § 164.400 et seq)
  - Must notify individuals (and OCR) if PHI is compromised
  - Media notice sometimes required

The Privacy Rule - Uses & Disclosures

- General Rule: No use/disclosure without authorization
  - Major Exceptions:
    - Treatment, Payment, Healthcare Operations
    - Required by Law
    - Health Oversight Activities / Safety
  - But:
    - Minimum Necessary Required

The Privacy Rule

- Compliance Issues (Many Detailed in Security Rule)
  - Policies and Procedures
  - Privacy Official
  - Training & Discipline
  - Safeguards
  - Mitigating Harm from noncompliance

- Notice of Privacy Practices (NPP)

The Security Rule – Overview

- Requires sufficient administrative, physical, technical, and organizational safeguards

- Intended to be technology-neutral & risk-based
  - Required level of security must be reasonable based on the size of the organization, type and amount of PHI, etc.

- Contains broad "Standards" and more detailed "Implementation Specifications." Two types:
  - Required – must do
  - Addressable – must do, or "reasonable and appropriate"

The Security Rule – Administrative Safeguards

- Risk Analysis (R)
- Training (A), Role-Based Access Controls (A), and Sanctions (R)
- Responding To/Documenting Security Incidents (R)
- Data Backup/Disaster Recovery (R)
- Periodic Audits (R)
- Business Associate Contracts (R)

The Security Rule – Physical Safeguards

- Facility Access Controls (A)
- Workstation Safeguards (R)
- Disposal & Device Controls (R)

The Security Rule – Technical Safeguards

- Access controls, such as unique user logins (R)
- Encrypting information (A)
- Auditing the use of hardware and software (R)
- Preventing improper modification of ePHI (A)

The Security Rule – Organizational Requirements

- Business Associate Agreements (the details)
  - Must be in writing (but direct liability regardless)
  - Must comply with security rule
  - Must notify of security incident
  - Applies down the line (to sub-sub-sub…)
  - Privacy Rule requirements (use/disclosure, violations)

- Policies and Procedures
  - Retain for at least six years

The Breach Notification Rule - General

- General Rule: must notify of any "breach"
- Breach = unauthorized acquisition, use, access, or disclosure of [unsecured] PHI that "compromises" privacy/security of that information
- Breach ≠
  - Unintentional access by workforce member if in good faith and no further disclosure
  - Disclosure to individual that cannot retain PHI

Elimination of De Minimis "Risk of Harm" Test

- Previous standard:
  - Individual notification required IF there is a "significant risk of financial, reputational, or other harm to the individual"

- New standard:
  - Presumption that any impermissible use or disclosure is a breach that compromises the security or privacy of the information

California Breach Notification

- California breach notification law (Civil Code § 1798.82) has no specific harm threshold.
  - However, statute defines breach as:
    - "unauthorized acquisition"
    - "compromises the security, confidentiality, or integrity of personal information"

Four Factors to Determine Whether to Notify

- The nature and extent of PHI involved
- To whom the disclosure was made
- Whether PHI was actually acquired or viewed
- Extent to which risk to PHI has been mitigated

Who Needs to Be Notified?

- Individuals
- HHS/OCR (timing depends on size of breach)
- Media (for substitute notice and larger breaches)
- If BA has breach, must notify CE
  - Contract typically allocates individual notification burden

Notification Mechanics

- Timing: Without unreasonable delay (60 day max)
  - Discovery rule (actual or constructive knowledge)
  - Law enforcement delay
  - California: OPP guidance: 10 business days!

- Method: first class mail (electronic may be ok)
  - Substitute notice possible (out-of-date info)

- Content – must be in plain writing
  - What happened?
  - What information was involved?
  - Mitigation steps

Encryption Safe Harbor

- Notification only required for a breach of "unsecured" PHI (i.e., unencrypted)
  - Most state laws (including California) also have encryption safe harbor

- HHS has set forth approved encryption technology on its website (must meet NIST standards

HIPAA Enforcement

- Criminal penalties possible
- HHS/OCR main enforcer for civil penalties
- State AGs also have enforcement power

Interplay Between Laws

- OCR can displace AG actions for HIPAA violations, investigate concurrently, or wait for state to finish investigation/prosecution

- State actions premised on laws other than HIPAA not subject to OCR displacement

- Multiple laws potentially permit multiple penalties arising out of same incident and individual lawsuits

State Security Breach Laws

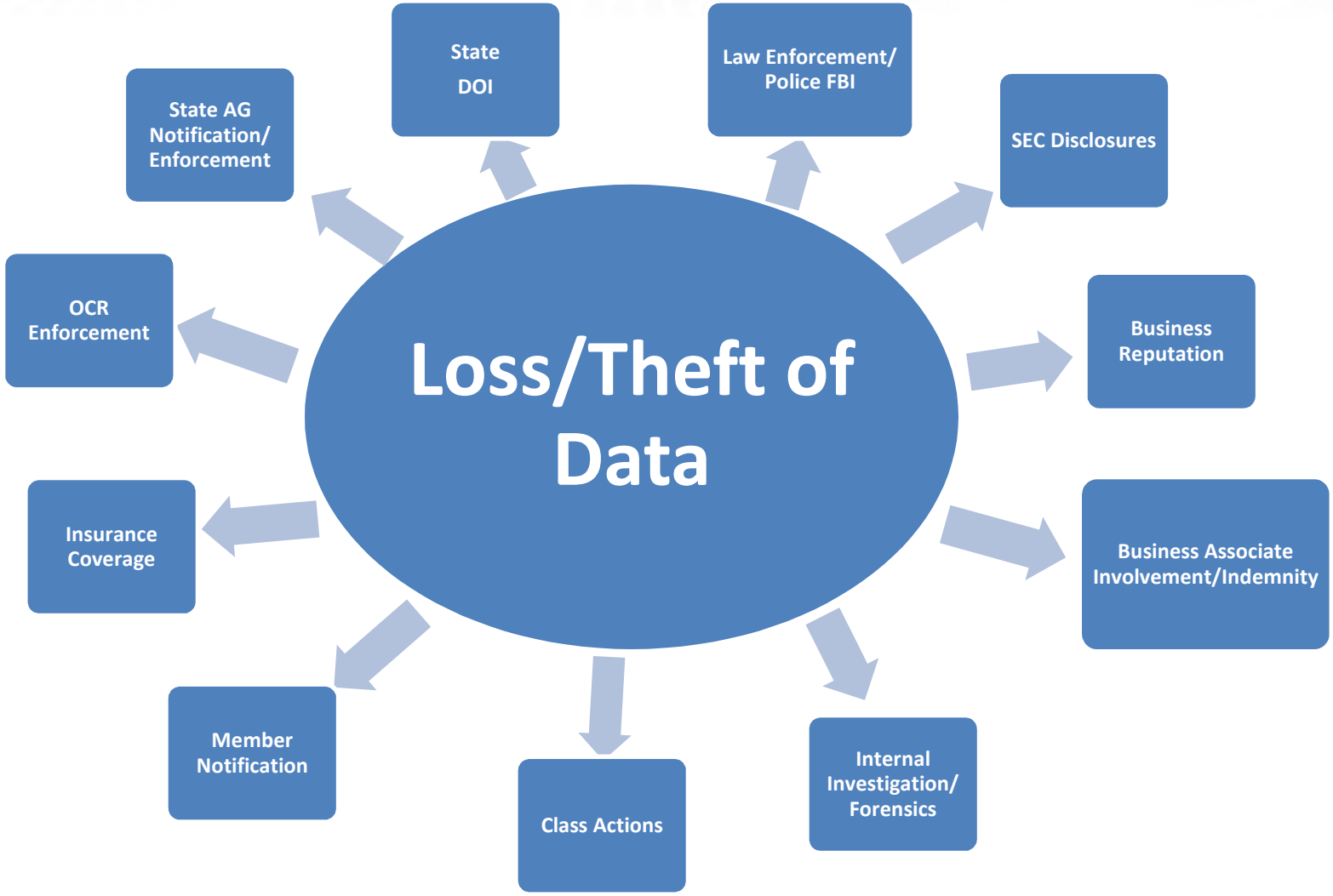
- 47 States (including California) + DC have Breach Notification Laws

- States are stepping up enforcement
  - 7/19/12—CA AG Privacy Enforcement and Protection Unit

- Many variations
  - Security requirements
  - Type of information covered
  - Notification "harm trigger" and timing

Breach Response Tips

- Act promptly
  - Untimely/incomplete notice=independent state law claims
  - Untimely/incomplete notice=sign of vulnerability, may attract litigation
- Breach Response Team
  - General Counsel's Office
  - Privacy Office
  - IT Department
  - Media Relations
  - Be proactive with regulators
  - Outside Counsel
    - Can assert privilege to maximum extent possible
    - Assert privilege over outside consultants
- Maintain a consistent message
- Anticipate Litigation/Investigation


Loss/Theft of Data
State DOI
Law Enforcement/ Police FBI
SEC Disclosures
Business Reputation
Business Associate Involvement/Indemnity
Internal Investigation/ Forensics
Class Actions
Member Notification
Insurance Coverage
OCR Enforcement
State AG Notification/ Enforcement

Breach Scenarios

- Loss of data
- Employee steals data
- Stolen data or hacking
- Vendor Activities (all of the above)

Business Associate Issues

- Joint Defense Agreement
- Investigation/Forensics Notification
- CE Liability for BA Conduct
- Class litigation
- Indemnity
  - Timing of claim
  - Tolling Agreement

Insurance Issues

- Report incident to commence/preserve claim
- What kind of policy?
  - All Risk
  - CGL
  - Standalone Cyber Policy

CGL Policies

- Traditional CGL
  - Physical loss
  - Tangible property
  - Personal and advertising injury
- Hacking and data breaches not contemplated when standard CGL policies first written
- Exclusions for privacy-related action, e.g., TCPA claims are getting tighter and more explicit

Insurers Contesting Data Breach Coverage Under CGL

- *Zurich American Insurance Company v. Sony Corporation* (N.Y. Supreme Ct., February 21, 2014)
  - Zurich contested coverage under a general liability policy for losses due to data hacking, which impacted 77 million user accounts
  - Zurich argued CGL did not cover losses because they were not "property damage" or "bodily injury"
  - New York Court held that policies did not cover breach costs because they covered only confidential material published directly by Sony – not by hackers

Insurers Contest Coverage Under CGL

- *Hartford Casualty Insurance Company v. Corcino & Associates* (C.D. Cal. 10/7/13)
  - Court grants MTD, ruling that CGL policy covers indemnity of claims under California Confidentiality of Medical Information Act ("CMIA") in spite of exclusion disclaiming coverage arising from a right of privacy "created by state or federal act"

Cyber Risk– Common Exclusions

- Coverage territory restrictions
- Losses from “named viruses”
- Failure to take reasonable security measures
- Blogs
- Hostilities & warlike operations

Emerging Litigation Issues

- Typical Claims
  - Negligence
  - Breach of Contract
  - Unfair Competition Law (Section 17200)
  - Breach of Privacy
  - State Statutes, e.g., CMIA

CMIA

- Civil Code 56.10: health care service plan shall not *disclose* medical information without obtaining the patient's authorization (unless exceptions apply)
- Civil Code 56.101: "any health care service plan . . . who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36."

CMIA - Remedies

- Civil Code 56.36: ". . . any individual may bring an action against any person or entity who has negligently *released* confidential information concerning him or her in violation of this part, for either or both of the following:

  (1). . . Nominal damages of one thousand dollars ($1,000). In order to recover under this paragraph, it shall not be necessary that the plaintiff suffered or was threatened with actual damages.

  (2)The amount of actual damages, if any, sustained by the patient."

CMIA – UC v. Superior Court (Platter) (Cal. Ct. App., October 15, 2013)

- Facts
  - Hard drive containing information on 16,000 patients stolen
  - Index card with password to access the data went missing at the same time
  - No evidence that patient data was accessed or misused

- Multiple class actions filed
  - One cause of action - violation of CMIA
  - UC allegedly "negligently lost possession of the hard drive and encryption passwords"
  - Plaintiff sought $1000 statutory damages per patient
  - Superior Court overruled demurrer

CMIA – UC v. Superior Court (Platter)

- Court of Appeal Granted Writ, Held:
  - Although CMIA provides a cause of action for negligently maintaining data under Section 56.101, a plaintiff must still prove a "release" of the data for statutory damages under Section 56.36
  - A loss of data is not a "release" under CMIA
  - Plaintiff must prove that someone "breached" the "confidential nature" of the patient's information
  - A claim for "negligent maintenance" of patient data is only permitted "when such negligence results in unauthorized or wrongful access to the information"

CMIA - Sutter Health v. Superior Court (Atkins)

- Facts:
  - A thief broke a window and stole a computer, monitor, keyboard and other equipment from Sutter office
  - Computer had password-protected (unencrypted) database containing demographic/numeric information for 3.3 million members and demographic/numeric information plus medical information for almost 1 million members
- Multiple class actions filed
  - Causes of action for negligent "release" in violation of CMIA, UCL violation, delay in disclosure under Civil Code Section 1798.82
  - Plaintiffs seek $1000 statutory damages per member
  - No allegation of actual damages or that the information was read by the thief

CMIA – Sutter Health v. Superior Court (Atkins)

- Superior Court Decision (October 17, 2013)
  - A "release" can occur without evidence that an unauthorized person has viewed the files
  - Rejected Sutter's argument that CMIA does not permit class actions
- Sutter filed a writ
- Court of Appeal granted review of the trial court's decision regarding "release"
- Oral argument on the appeal is set for June 20, 2014

Questions?

NonDiscrimination under the ACA

- Enrollees and Providers -

Bill Helvestine
(San Francisco Office)
David Johnson
(San Francisco Office)

Enrollee NonDiscrimination

Equality!

Equality?

Pre-ACA Discrimination Law

- Discrimination in healthcare coverage can occur in many ways
  - Point of enrollment
  - Benefit design
  - Administration of benefits
- Pre-ACA laws addressed some discrimination
  - BUT: these were often criticized as being limited in scope – because they often only addressed discrimination in enrollment.
- Parity laws also existed, mandating coverage for certain conditions
  - But these only targeted specific conditions: mental health, certain women's health issues.

HIPAA (1996)

- **Group health plans prohibited from:**
  - Establishing rules on ***eligibility to enroll*** based on "health status-related factors" including: health status, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability.
  - Requiring an individual to ***pay a higher premium*** based on health status factors.
- **BUT**: ***carved out benefits and exclusions***:

. . . these requirements "***shall not be construed***"

(A) to require a group health plan, or group health insurance coverage, ***to provide particular benefits*** other than those provided under the terms of such plan or coverage, or

(B) ***to prevent*** such a plan or coverage from establishing ***limitations or restrictions on*** the amount, level, extent, or nature of the ***benefits*** or coverage for similarly situated individuals enrolled in the plan or coverage.

-- Pub. L. 104-191, 1996 HR 3103

ACA: Establishes non-discrimination rules for plans required to offer EHBs

- **ACA requires non-grandfathered small group, individual, Medicaid benchmark, and state basic health insurance coverage to offer "*essential health benefits*". 45 C.F.R. 12834 (Feb. 23, 2013); 42 U.S.C. § 18022(b)(1)(G).**
- **Benefits must include coverage in nine broad categories. 42 USC § 18022.**
  - **Ambulatory patient services.**
  - **Emergency services.**
  - **Hospitalization.**
  - **Maternity and newborn care.**
  - **Mental health and substance use disorder services, including behavioral health treatment.**
  - **Prescription drugs.**
  - **Rehabilitative and habilitative services and devices.**
  - **Laboratory services.**
  - **Preventive and wellness services and chronic disease management.**
  - **Pediatric services, including oral and vision care**

EHB requirements not an "all services" mandate

- **Statute only requires that covered benefits include some benefits in each EHB general category.**
  - **"the Secretary shall define the essential health benefits, except that such benefits shall include the following *general categories* . . ." 42 U.S.C. § 18022(b)(1).**
- **Statute only requires coverage of benefits that are "equal to the scope of benefits provided under a *typical employer plan*." 42 U.S.C. § 18022(b)(2)(A).**
  - **Typical employer plans do not include all possible services within each EHB category.**

But: EHB Rules Have Strong NonDiscrimination Standards – The §(4)(A)-(D) Requirements

- **Balance required among the mandatory EHB categories**
- **Cannot make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their *age, disability, or expected length of life*.**
- **Must account for health care needs of *diverse segments* of the population including *women, children, persons with disabilities*, and other groups.**
- **EHBs are not subject to denial on basis of *age, expected length of life, present or predicted disability, degree of medical dependency, or quality of life*.**

HHS Regulations Stiffen Discrimination Rules

- 45 CFR § 156.125:

  An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

- 42 CFR § 156.200(e)

  Non-discrimination. A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation.

WARNING – state benchmark plans may not comply with nondiscrimination rules

- CMS delegated establishing benefits to be provided under EHB rules to states. 42 CFR 156.100 et seq.
- States were to pick "benchmark" plans to define coverage required by plans in the stated
  - If an EHB category of services was not covered, states were to augment their benchmark plan.
- However: commentators indicated that state benchmark plans appeared to violate the anti-discrimination rules.

Examples: benchmark plan coverage for habilitative services

- **Indiana benchmark plan – physical therapy coverage *excludes*:**
  - **maintenance therapy to *delay or minimize* muscular deterioration in patients suffering from a chronic disease or illness; repetitive exercise to improve movement, maintain strength and increase endurance (including assistance with walking for weak and unstable patients); range of motion and passive exercises that are not related to restoration of a specific loss of function . . . .**
  - **appears to exclude coverage for chronic or progressive diseases, such as cerebral palsy or multiple sclerosis**
- **New Jersey benchmark plan -- cognitive rehabilitation therapy *limited to*:**
  - **the retraining of the brain to perform intellectual skills which it was *able to perform prior to disease*, trauma, surgery or previous therapeutic process; or the training of the brain to perform intellectual skills it should have been able to perform if there were not a *congenital* anomaly.**
  - **appears to exclude therapy for chronic progressive diseases like Alzheimer's.**

CMS: Benchmark plan defects are no excuse

- States had until December 31, 2012 to pick a benchmark plan (or have HHS select it for them).
  - Benchmark plans could be augmented with any state-mandated services enacted by December 31, 2011.
  - Summaries of benchmark plans are located at www.cms.gov/CC110/Resources/Data-Resources/ehb.html
- Regulators recognized that many benchmark plans contain discriminatory provisions.
  - Example: some B/M plans limit benefits based on age, or only provide benefits for particular diseases.

CMS: Benchmark plan defects are no excuse

- **<u>But</u>: HHS states that plans are still expected to comply with the non-discrimination rules:**
  - ***Comment*: Several commentators express concern over state benchmarks that they believed contained discriminatory benefit designs and worried that issues in those states would be required to copy those designs.**
  - ***Response*: To the extent that a state benchmark plan includes a discriminatory design, *non-discrimination regulations* at §156.110(d) and §156.125 *require <u>issuers</u> to meet the benchmark requirements in a nondiscriminatory manner*.**

75 CFR 12834, 12846 (Feb. 25, 2013)

ACA § 1557

SEC. 1557. NONDISCRIMINATION

(a) IN GENERAL.—***Except as otherwise provided for in this title*** (or an amendment made by this title), ***an individual shall not***, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), ***be excluded from participation in***, be ***denied the benefits of***, or be ***subjected to discrimination under***, any ***health program or activity***, any part of which is receiving ***Federal financial assistance***, including credits, subsidies, or contracts of insurance, or under any program ***or activity that is administered by an Executive Agency or any entity established under this title*** (or amendments). ***The enforcement mechanisms*** provided for and available ***under such title VI, title IX, section 504, or such Age Discrimination Act shall apply*** for purposes of violations of this subsection.

Elements of ACA Section 1557

- Prohibits discrimination "on the grounds prohibited" in civil rights laws.
  - Title VI — race, color, or national origin
  - Title IX — sex
  - Section 504 disability
  - Age Discrimination Act — age
- Discrimination prohibited for benefit design, not just participation in plan.
  - "Participation in, be denied the benefits of, or be subjected to discrimination under".
- Authorizes private rights of action for discrimination.
  - "The enforcement mechanisms provided for and available under such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection."

Who are § 1557 covered entities?

- **Covered entities defined broadly.**
  - **"any *health program or activity*, any part of which is *receiving Federal financial assistance*, including credits, subsidies, or contracts of insurance, or under *any program or activity that is administered by an Executive Agency* or any *entity established under this title*."**
- **Likely covers:**
  - ***Insurers that offer exchange products*: most commentators: "program or activity that is administered by an Executive Agency or any entity established under this title" specifically contemplates exchange products.**
  - **Insurers *and providers* who receive funds from federally-supported health insurance programs such as Medicaid or Medicare.**
  - ***Possibility*: group plans sponsored by health-related institutions that receive federal funds for health programs and activities, such as universities.**

Exception for discrimination permitted by other ACA provisions

- Section 1157 contains exclusion from its terms: "except as otherwise provided for in this title"
- EHB rules actually permit some forms of discrimination.
  - Example: premiums can vary based on age.

HHS Enforcement of § 1557

- **Regulations**
  - **HHS currently engaged in rulemaking.**
  - **Issued RFI to inform its rulemaking in August 2013**
- **HHS Office of Civil Rights enforcing § 1557 even in the absence of regulations.**
  - **Written complaint must be filed within 180 days of when complainant knew that the act or omission occurred.**
  - **OCR performs initial case review within 30 days after complaint filed.**
  - **If possible civil rights violation, OCR issues Civil Rights Recommendation for Action letter (CR-RFA).**
  - **OCR conducts investigation.**
  - **If OCR finds a violation, its preferred outcome is to reach a voluntary resolution with the covered entity.**
  - **If no voluntary compliance: HHS can refer to DOJ or take steps to terminate federal financial assistance.**

OCR complaints: *National Women's Law Center Cases* against five institutions

- 5 OCR complaints filed by National Women's Health Center against:
  - Auburn University
  - Batelle Memorial Institute
  - Beacon Health System
  - Gonzaga University
  - Pennsylvania State System of Higher Education
- Filed June 2013

NWLC v. Beacon Health System

- **Sex discrimination claim: hospital system fails to provide full coverage for gynecological and maternity care in its employee health plan.**
- **Why allegedly covered by § 1557?**
  - **Beacon is allegedly a "health program or activity" because it is a Michigan hospital system.**
  - **Receives Federal financial assistance in the form of Medicare & Medicaid funds.**
  - **<u>Status as covered entity possible</u>: *U.S. v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039 (5th Cir. 1984) (health care provider that received reimbursement for services from Medicaid deemed to have received federal financial assistance).**

NWLC v. Auburn University

- **Suit claimed sex discrimination in benefits: employee benefits plans covered children of subscribers, but excluded coverage for pregnancy of subscriber's children.**
- **Why was University allegedly covered by § 1557?**
  - **receives FFA in the form of tuition from students including nursing students that is partially paid with federal funds.**
  - **so employee health benefits plan (a health program or activity) is covered by § 1157.**
- **<u>Status as covered entity questionable</u>: § 1157 applies to "health programs or activities that receive FFA" <u>not to *all* institutions</u> that receive FFA**

OCR complaints: National Women's Law Center Cases Against LTCI Carriers

- Ten OCR complaints against four Long-Term Care Insurance carriers
  - Genworth, John Hancock, Mututal of Omaha, Transamerica
- Claim discrimination based on the use of gender in rates for LCTI policies purchased under Long Term Care Partnership programs.
  - LTCI Partnership programs permit individuals to exempt more assets for Medicaid eligibility determinations.
    - They do not provide funds to help purchase of LTCI policies.
  - If an LTCI carrier adopts gender rating, a female enrollee could pay more for the same level of coverage and asset protection as a male enrollee.
- <u>Status as covered entities highly questionable</u>: No direct FFA goes to the Partnership programs, and the program is not aimed at helping carriers, but Medicaid beneficiaries.
- Filed January 2014

OCR report on results of other complaints (December 2013)

- **Complaint against Touro Infirmary in New Orleans**
  - **Claimed sex discrimination: Male victim of domestic violence alleged that he was subjected to rude comments from hospital staff because of his gender.**
  - **Resolution: Touro revised its abuse protocol to provide gender-neutral procedures for reporting domestic abuse and provided training to staff on identifying and assessing victims of domestic abuse.**
- **Complaint against St. Bernard Med. Ctr. in Jonesboro, Arkansas**
  - **Claimed sex discrimination: Hospital automatically assigned male spouse financial responsibility when a female spouse received services, but did not assign a female spouse financial responsibility when a male spouse received services.**
  - **Resolution: Hospital changed practices to ensure equal treatment.**
- **<u>Why were these institutions covered entities?</u>**
  - **Likely because of their receipt of Medicaid/Medicare funds**

§ 1557 Class Action: *East v. BCBS of Louisiana*

- **Allegations:**
  - BCBS received "Ryan White Funds" premium support for enrollees with AIDS.
  - Nov. 2013: CMS issues guidance discouraging third-party premium payments.
  - Feb. 2014: BCBS announces it would no longer accept Ryan White Funds.
  - Lead plaintiff: made his insurance unaffordable, even if purchased in the state exchange, excluding him from participation in health coverage.
- **Section 1557 Claim:**
  - Section 1557 prohibits discrimination based on a disability. AIDS is disability.
  - BCBS's actions caused plaintiff to be excluded from a health program.
  - Why was BCBS covered by § 1157: no ruling yet, but could be
    - Its past receipt of Ryan White Funds?
    - Its sale of insurance on the exchange?
- **TRO Issued on February 14, 2014:**
  - Defendants enjoined from changing their policies of accepting Ryan White Funds.
  - Plaintiff made the required showing that he was likely to succeed on his §1557 claim.

The Future of Section 1557?

- Providers: expect challenges to traditional gender-preferential practices.

- Plans: expect challenges to plan exclusions and benefit designs.

Provider NonDiscrimination

The "Harkin Amendment"

- § 2706(a) of Public Health Service Act, created by § 1201 of Patient Protection and Affordable Care Act ("PPACA") (42 U.S.C. §300gg-5(a))
  - "A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law.
  - This section shall not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer.
  - Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures."
- Also incorporated into § 715(a)(1) of ERISA and § 9815(a)(1) of the Internal Revenue Code

To what plans does it apply?

- "Group health plans" and "health insurance issuers offering group or individual health insurance coverage"
  - Self-insured employee health benefit plans
  - Group health insurance
  - Individual health insurance
  - Likely includes Federal Employees Health Benefits Program
  - Will apply to products sold via the new health insurance "Exchanges"

- Effective the beginning of the applicable plan year on or after January 1, 2014, except for "grandfathered plans"

To what plans does it not apply?

- **Does not include Medicare, Medicare Advantage, Medicare Supplement or Medicaid**
  - **Medicare Advantage plans already are prohibited from discriminating, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under state law, solely on the basis of the license or certification.**
  - **Workers compensation, credit-only insurance, on-site medical clinics coverage, automobile medical payment insurance, liability insurance, or supplements to liability insurance**

To what plans does it not apply?

- Appears not to apply to "limited scope dental or vision benefits" or long-tem care, home health care, or nursing home care offered in connection with a group health plan (42 U.S.C. 300gg-21c, -91(c)(2))
  - If provided under a separate policy, certificate or insurance contract; and
  - Not otherwise "an integral part of the plan"
- Does not apply to specified disease or illness insurance or hospital indemnity or other fixed indemnity insurance if provided under a separate policy or contract and there is no "coordination" between those benefits and any exclusion of benefits under a group health plan of the same plan sponsor

What are providers saying?

- AMA vowed to seek repeal
- Chiropractors
  - Hailed it as "the most significant piece of federal legislation in many years" and declared that "we have pierced the shield of ERISA with this provision. It's huge."
  - Predicted it "won't be warmly embraced by the insurance industry – at best, it will be grudgingly accepted."
  - Have written to HHS Secretary asking that HHS consider adherence to § 2706(a) in evaluating states' benchmark plans
- American Counseling Association
  - Predicted that "the provision should stop health plans from having a blanket policy of not covering counselors"
- PCMHs evolving to "PCMNs"

Provider Non-Discrimination

- **Prohibits discrimination against a provider acting within the scope of license**
  - **Prohibits discrimination on the basis of participation or coverage**
    - **Reference to "coverage" reaches benefit plan design, e.g., services covered, benefit limits, and enrollee cost-sharing.**
  - **Does NOT require plan to contract with "any willing provider"**
  - **Does NOT prevent the plan from varying reimbursement rates based on quality or performance measures**

Provider Non-Discrimination

- By rejecting "any willing provider," the law recognizes that a Plan may refuse to contract with individual providers. The refusal of an individual contract should not be improper discrimination.
- What, then, is prohibited discrimination?
  - The exclusion of or discrimination against classes of providers.
  - Naturopaths
  - Naprapaths
  - Podiatrists
  - Chiropractors
  - Optometrists
  - Acupuncturists
  - Massage Therapists
- Colorado DOI: Disapproved the existing exclusion for "chiropractic services" in that state's EHB Benchmark Plan
- What else will be prohibited discrimination?

Examples of NonDiscrimination Issues

- Discrimination based on different negotiated rates?
  - Resulting from different market power?
  - The "marquee practice" problem
- Must the same "service" always be paid the same?
  - Paying optometrist less than ophthalmologist for the same service?
  - Physicians vs Nurses vs Physician Assistants?
  - Is this "varying reimbursement rates based on quality or performance measures"?
- Having a "closed panel" benefit for optometrists, podiatrists or chiropractors but an "open access" benefit for ophthalmologists and orthopedists?

Other potential battlegrounds

- **Treatment Limitations**
  - **FEHBP BCBS removed restrictions of one visit and one set of xrays per year on chiropractic services.**
- **Explicit discrimination vs. discriminatory effect?**
  - **Facially neutral practices that have a "discriminatory effect"**
  - **Requiring particular certification, training or experience that are theoretically available to non-MD practitioners, but that in practice are more difficult for non-MDs to satisfy?**
  - **Imposing new credentialing criteria that are hard for non-MDs to meet, but grandfathers the existing network which includes few non-MDs?**
- **Pay-for-Performance Programs**
  - **Reimbursement can vary based on "quality or performance measures," but are existing performance measures statistically valid measures of quality or performance, or will they be challenged as a "subterfuge" for discrimination?**
- **Chiropractors or Naturopaths as Primary Care Providers?**

"Horizontal" Provider Non-Discrimination

- **Federal Mental Health Parity & Equity Act:**
  - **"Non Quantitative Treatment Limitations"**
  - **Standards for Provider Admission into Network**
    - **"Including provider reimbursement rates"**
- **Psychiatrists versus Other MDs**
  - **CPT Codes and their Reimbursement Rates**
  - **Psychiatrist as Primary Care Physician**

American Chiropractic Association v American Specialty Health Networks and Cigna (E.D.Pa. No. , filed Dec. 28, 2012)

- Lawsuit based primarily on alleged ERISA violations.
- Alleges, among other things:
  - False and misleading EOBs
  - Overly restrictive UR on chiropractors
  - Excessive co-pays for chiropractors
  - Discriminatory restrictions on services that fall within the scope of the chiropractic license
- Motions to Dismiss and to Strike, pending.

The Agencies' 2013 Guidance

- **Q2: Will the Departments be issuing regulations addressing PHS Act section 2706(a) prior to its effective date?**
  - **No. The statutory language of PHS Act section 2706(a) is self-implementing and the Departments do not expect to issue regulations in the near future.**
  - **Health plans and insurers are expected to implement the requirements of PHS Act section 2706(a) using a good faith, reasonable interpretation of the law.**
  - **To the extent a service is a covered benefit under the plan, and consistent with reasonable medical management techniques with respect to the frequency, method, treatment or setting, a plan shall not discriminate based on a provider's license or certification, to the extent the provider is acting within the scope of the provider's license under applicable state law.**
  - **This provision does not require plans or issuers to accept all types of providers into a network.**
  - **This provision also does not govern provider reimbursement rates, which may be subject to quality, performance, or market standards and considerations.**

CCIIO, ACA Implementation FAQs, Set 15, April 29, 2013)

Congress Responds to the FAQ

- **The FAQ allows insurers "to exclude from participation whole categories of providers operating under a State license or certification. In addition, the FAQ … allows discrimination in reimbursement rates based on broad "market considerations" rather than the more limited exception cited in the law for performance and quality measures. Section 2706 was intended to prohibit exactly these types of discrimination.**
- **"The Committee directs HHS to work with DOL and the Department of Treasury to correct the FAQ to reflect the law and congressional intent within 30 days of enactment of this act."**

[Consolidated Appropriations Act of 2014]

The Agencies Respond with an RFI

- **The FAQ Agencies (HHS, Labor & Treasury) issued a Request for Information calling for public comment by June 10, 2014.**

Questions?

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HOOPS WEST 2014

The Coordinated Care Initiative: Are We Really Ready?

Marisa Adelson

Ryan Oliver

Peter Roan

What is the Coordinated Care Initiative?

- July 2012 legislation passed to reform Medi-Cal delivery system in in CA in eight counties
- Basis in ACA
- Two parts:
  - Cal MediConnect, a three-year demonstration to integrate care for dual eligibles
  - Incorporation of Medi-Cal Managed Long-Term Supports and Services (LTSS) into Medi-Cal Managed Care Plans

What is the Coordinated Care Initiative?

- Uncharted (and changing) territory for Plans and the Department of Managed Health Care

Timeline of Coordinated Care Initiative

County	LTSS Expansion Start Date	Duals Plan Start Date
Riverside	4/1/2014	5/1/2014
San Bernardino	4/1/2014	5/1/2014
San Mateo	4/1/2014	4/1/2014
Los Angeles	4/1/2014	7/1/2014
San Diego	7/1/2014	5/1/2014
Santa Clara	7/1/2014	1/1/2015
Alameda	1/1/2015	1/1/2015
Orange	1/1/2015	1/1/2015

Cal MediConnect

- Cal MediConnect plans are testing innovative capitation method and service delivery model
- Replaces silos of Medicare and Medi-Cal with single integrated plan
- Includes additional care coordination, vision, and transportation benefits

Medicare vs. Medi-Cal Services

Medicare	Medi-Cal
Who: 65+, under 65 with certain disabilities including ESRD	**Who: Low-income Californians**
Part A: • Hospital care • Short-term skilled nursing facility care • Home health care • Hospice **Part B:** • Physician & ancillary services • Durable medical equipment (DME) **Part D:** Prescription drugs	• Medicare cost sharing • Long-term nursing home (after exhaustion of Medicare) • Long-term supports and services (LTSS) – CBAS, MSSP, IHHS, HCBS waivers • Prescriptions, DME, and supplies not covered by Medicare

Cal MediConnect Implementation for Plans: Major Steps

- MOU followed by Three-Way Contracts between Primary Plans, CMS, and DHCS
- Completion of Readiness Review prior to enrollment
- DMHC filing and approval of material modification

CCI changes to LTSS

- Managed Medi-Cal Long-Term Supports and Services (LTSS)
  - *apparently "MM-CL-TS&S" didn't have a nice ring to it*
- Benefits that were previously administered by counties.
- Now integrated into and administered by Medi-Cal managed care plans.
- Independent of Cal MediConnect Program

LTSS Services

- Same services that Medi-Cal beneficiaries currently receive:
  - **Multipurpose Senior Services Program** (MSSP): social and health care management services for Medi-Cal recipients aged 65 and older who meet eligibility requirements for a skilled nursing facility.
  - **In-Home Supportive Services** (IHHS): in-home care for people who cannot safely remain in their own homes without assistance; to qualify, recipient must be aged, blind, or disabled, and low income.
  - **Community-Based Adult Services** (CBAS): outpatient, facility-based service program that delivers skilled nursing care, social services, therapies, personal care, family and caregiver training and support, meals, and transportation.
  - **Skilled Nursing Facilities** (SNFs): nursing homes and rehabilitation facilities that provide nursing, rehabilitive, and medical care.
  - **Non-Emergency Medical Transport**.
- Benefits now administered by Medi-Cal managed care plans

LTSS Enrollment Timeline

County	LTSS Expansion Start Date
Los Angeles	4/1/14
Riverside	4/1/14
San Mateo	4/1/14
San Bernardino	4/1/14
San Diego	7/1/14
Santa Clara	7/1/14
Orange	1/1/15
Alameda	1/1/15

How is it going? (As artfully stated in a recent filing):

"We have received the draft DHCS LTSS amendment. The terms of the amendment are currently under negotiations, however, we are actively providing LTSS services."

Cal MediConnect Implementation Issues

Ambiguities in Three-Way Contract

- "All providers must have good standing in the Medicare and Medi-Cal programs and a valid NPI number, as applicable." (Section 2.9.8.1)

- Significance of incorporation of DHCS Medi-Cal Contract and other sources into Three-Way Contract (Section 5.7.1)

What does the DMHC want in CCI filings?

According to their Checklist…

- DMHC focused on understanding:
  - LTSS network
  - Plan-to-plan arrangements of services and delegation
- DMHC is less familiar with Medi-Cal terminology and Medicare because of preemption

What does the DMHC want in CCI filings? LTSS Network Adequacy

- Increased detail required in DMHC filings concerning LTSS network adequacy:
  - Lists and maps detailing provider location on a per benefit basis
    - CBAS, HCBS, MSSP, and SNF
  - Previously, such providers were part of the catch-all Exhibit I-3 “Other Providers”

Goals of the CCI

- "Coordinate Medi-Cal and Medicare benefits across health care settings and improve the continuity of care, long-term care, behavioral health, including mental health and substance use disorder services, and home- and community-based services settings using a person oriented approach."
- Coordinate access to acute and long-term care services for duals.

Goals of the CCI

- Maximize ability of duals to remain in their homes with supportive services in lieu of institutional care.
- Increase access to home and community-based services.
- Coordinate access to necessary and appropriate behavioral health services.
- Improve quality of care. W&I § 14132.275(f).


WHAT COULD POSSIBLY GO WRONG?
ICANHASCHEEZBURGER.COM

Utilization Management for LTSS

- Includes IHSS, CBAS, MSSP and SNF and Subacute Care. W&I § 14186.1(b).
- Potential problem because the current law doesn't appear to permit the plans to do much UM for IHSS or for SNF and Subacute Services.

SNF and Subacute Services

- Plans shall authorize SNF and subacute facility services.
- Plans shall maintain the standards for determining levels of care and authorization of services for both Medicare and Medi-Cal services consistent with existing CMS and Medi-Cal standards.
- Plans must recognize existing treatment plans and authorizations for at least 6 mos.

SNF and Subacute Services (cont'd)

- Medicare standards apply to level of care assessments made by the facilities for the 100-day period covered by Medicare.
- Payments based on assessments made on the 5th, 14th, 30th, 60th and 90th day even though levels of care may have changed.
- Authorization determinations under Medi-Cal will continue to based on the Manual of Criteria for Medi-Cal Authorization.

SNF and Subacute Services (cont'd)

- Plans must continue to pay not less than the recognized Medicare and Medi-Cal FFS rates. W&I § 14132.276(c)
- Plans cannot accept discounts or rebates as inducement for referral of patients.
- Plans may pay bonuses for meeting quality and utilization goals for re-hospitalizations and shorter lengths of stay.

IHSS

- IHSS is an entitlement program that serves 450,000 Medi-Cal beneficiaries, of whom 75 percent are dual eligible beneficiaries.
- California spends 53.7 percent of its Medicaid LTSS funding on IHSS.
- County social services agencies will continue to perform current IHSS functions, including assessment, authorization, and IHSS hours determinations. W&I § 14186(b)(6)(A).

IHSS (cont'd)

- Plans may authorize IHSS hours above those authorized by the county, as well as additional home- and community-based services, using the funding provided under the capitation payment.
- There would be no county share of cost for these additional IHSS hours or services.

IHSS (cont'd)

- The fair hearing process currently in place for IHSS consumer appeals will remain for hours authorized by counties.
- SB 1036 created the IHSS Statewide Authority to conduct collective bargaining with IHSS employee organizations to set wages, hours and conditions of employment.
- Plans have financial risk and little control.

Adequacy of Capitation Payments

Capitation Payments

- Federal and state law requires DHCS to pay "actuarially sound" rates using data specific to the dual eligible population. 42 U.S.C. § 1396b(m)(2)(A)(iii); W&I §§ 14182.6(j), 14301(a).
- Discussions continue with State actuary, Mercer, about the rate setting process.
- Rate Components:

  Medicare Parts A and B

  Medicare Part D

  State Payment for Medi-Cal Benefits

Capitation Payments (cont'd)

- Model does not adjust adequately for outliers from certain sub-sets of MA population.
- Duals are typically sicker, with chronic multiple conditions or are in long-term care or receiving IHSS.
- Underfunded for AB because of the methodology used.
- Part D funding based on National Average Bid Amount (42 CFR § 423.279) looks to be sufficient

Capitation Payments (cont'd)

- Medi-Cal Benefit Funding for Cal MediConnect has increased from that first proposed (10-12%).
- Large concerns about IHSS funding.
- Plans have little control and are required to pay FFS rates as determined through collective bargaining.
- Risk that plans will be left holding the bag.

Capitation Payments (cont'd)

- Opt outs that keep their FFS Medicare benefits will still be enrolled in the demonstration counties into managed care plans for Medi-Cal benefits.
- No control over numbers of enrollees who opt out.
- Lack of UM for opt outs using existing Medicare providers.
- May 1, 2014 DHCS policy that MA enrollees in a non-Cal MediConnect DSNP will not be passively enrolled into a Cal MediConnect plan in CCI counties.

Capitation Payments (cont'd)

- Only have "final" rates for full duals under Cal MediConnect.
- Still don't have rates for partial Medi-Cal Duals (Part B only), Medi-Cal only and SPDs.
- Significant risk that final rates will be inadequate.
- Rate challenges by plans are subject to cumbersome dispute resolution processes and exhaustion requirements under the Administrative Procedures Act.

Any Questions?

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HOOPS WEST 2014

Medicare Advantage and Part D Developments

Kevin Kroeker
Christine Clements

Los Angeles, CA
May 13, 2014

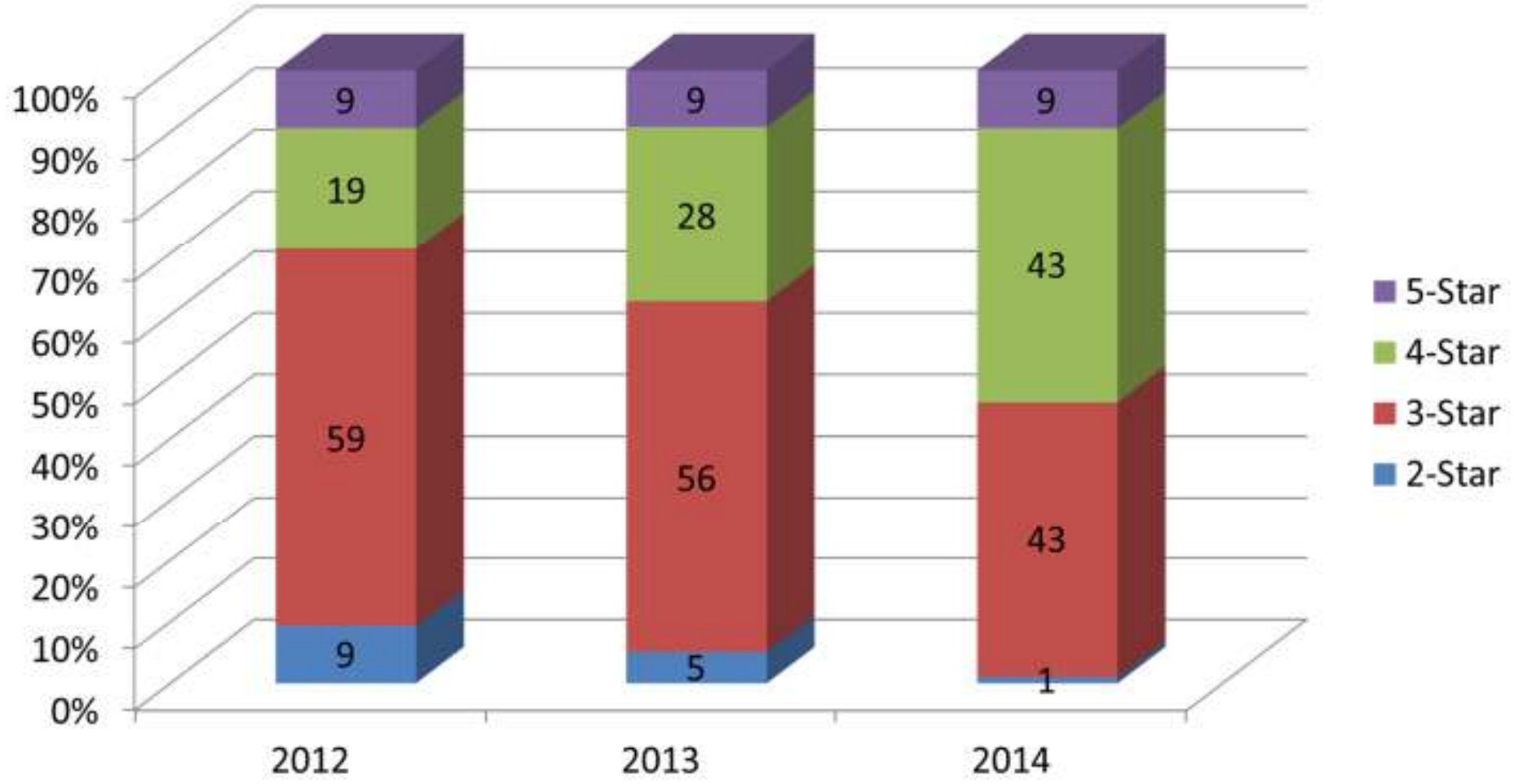
What's Hot in 2014 and Beyond

- Star Ratings
- First Tier, Downstream and Related Entities (FDRs)
- RADV audits – Let's all extrapolate!
- Audits – They're not just for risk adjustment!
- January 10, 2014 proposed rule
- 2015 Call Letter

Star Ratings

- Star Ratings and Quality Bonus Payments indicate that MA quality continues to improve
- Average Star Rating increased for both MA plans and MA-PDs
- 2014 Star Ratings—
  - More than 1/3 of MA contracts have 4 or more stars
  - More than ½ of all MA enrollees have selected contracts with 4 or more stars
  - Fewer enrollees select contracts with below average ratings

Star Ratings Increase Year-Over-Year



Star-Rating Based Terminations

- CMS may terminate an MAO or PDP sponsor if it fails to achieve at least a 3-star summary plan performance rating for 3 consecutive years.
- Three year transition period ends with release of star measures in fall of 2014.
- CMS can terminate poor performers effective December 31, 2014.

Star-Rating Based Terminations – cont'd

- CMS will terminate MA-PD contracts that scored
  - Part C summary rating of less than three stars in each of the most recent three consecutive rating periods (2013-2015) regardless of their Part D summary rating performance during that period;
  - Part D summary rating of less than three stars in that period regardless of Part C score during that period.
- Proposed rule would allow CMS to terminate MA–PD organizations that do not achieve at least 3 stars in both their Part C and D ratings in the same year for 3 consecutive years.

FDRs

- Are you my FDR?
- Additional guidance from CMS has not resolved the question
- MAOs and PDPs are accountable for their FDRs
- CMS-required terms must be in FDR contracts
- Audits and oversight of FDRs are required
- Comply with Compliance Guidelines including Fraud, Waste and Abuse Training
- When is an offshore subcontractor an FDR?

RADV Audits – Back with a Vengeance

- CMS is conducting medical record reviews to validate the accuracy of the CY 2011 Part C risk adjustment data and payments.
- The 30 MAOs selected for audit were notified November 5, 2013.
  - Not randomly selected
- The Proposed Rule – as if RADV wasn't bad already.

CMS RADV Methodology

- Published on February 24, 2012
- Payment year 2011 is the first year for which payment recovery will be based on extrapolated estimates
- CMS will select up to 201 enrollees for medical record review from each contract selected for a contract-level audit

CMS RADV Methodology

- Enrollee-based stratification to be employed
- MA organizations may submit multiple medical records for each hierarchical condition category (HCC) being validated, although all diagnoses will be abstracted from the first medical record that validates the HCC under review.
- 99% confidence interval for estimated payment error
- FFS Adjuster to be applied (yet to be published)

Other Audits and Monitoring

- Program Audits
  - Organization Determinations, Appeals and Grievances
  - Compliance Program Effectiveness
  - Agents and Brokers
- One-third financial audits
- Data Validation
- Recovery Audit Contractor (RAC)
- Call Center Monitoring

RAC Audits

- ACA amendments to 1893(h) of the Act provide CMS with general authority to enter into contracts with RACs to identify overpayments and underpayments and recoup overpayments in Medicare Advantage and Part D.
- Excluded provider audits under Part D

Proposed Rule (79 Fed. Reg. 1918)

- Risk Adjustment Data Requirements and RADV Appeals
- Reporting and Returning Overpayments
- Direct Access to FDRs
- Minimum Requirements for New Applicants and/or their FDRs
- Simplification of Agent and Broker Compensation

CMS Backs Down

- On March 10th, CMS announced that it would not finalize Proposed Rule provisions on:
  - Protected class drug definitions
  - Standards for Part D preferred pharmacy networks
  - Reducing the number of plans offered by Part D sponsors
  - "*Clarifying*" non-interference provisions, i.e., scope of CMS authority

Risk Adjustment Data Requirements

- Any medical record reviews conducted by MAO must be designed to determine the accuracy of diagnoses submitted and can't be designed only to identify diagnoses that would trigger additional payments to MAO.
- Medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments.
- Revise the deadline for risk adjustment data submissions to explicitly permit late submissions only to correct overpayments; not to submit diagnoses for additional payment.

RADV Appeals

- Three step administrative appeal for both medical record review-determination appeals and RADV payment error calculation appeals.
- Issues that are and are not eligible for RADV appeal
  - Failure to follow RADV audit and appeal procedures and requirements will render appeal request invalid.
  - Must specify disputed HCC finding and provide justification. Appeal limited to the one best medical record and it must have been audited.
  - Appeal cannot include HCCs, medical records or other documents beyond the audited HCC.

Reporting and Returning Overpayments

- Would implement § 6402 of ACA
- Overpayment exists when, after "applicable reconciliation" MAO or Part D sponsor is not entitled to "funds" it has received or retained.
- MAOs and Part D sponsors would be required to report and return overpayments that they identify within the 6 most recently completed payment years.

Reporting and Returning Overpayments (cont'd)

- "Funds" are payments an MAO or Part D sponsor received that are based on data that they submitted to CMS for payment purposes and for which they are responsible for accuracy, completeness and truthfulness.
  - Part C data includes enrollment data under § 422.308(f) and risk adjustment data under § 422.310
  - Part D data includes drug claims submitted for risk adjustment, cost data submitted for risk adjustment, data submitted for retroactive adjustments action reconciliations including reinsurance, and data submitted to determine allowable costs including direct and indirect remuneration.

Reporting and Returning Overpayments (cont'd)

- "Applicable reconciliation" is the event(s) after which an overpayment can exist.
- For Part C, applicable reconciliation occurs after the final deadline for risk adjustment data submission.
- For Part D sponsors applicable reconciliation is the later of: the annual deadline for submitting PDE data for annual Part D payment reconciliation, or the annual deadline for submitting DIR data.

Reporting and Returning Overpayments (cont'd)

- CMS proposes that MAO or Part D sponsor must report and return an overpayment when it identifies an overpayment.
- Identification of an overpayment is having actual knowledge of the existence of the overpayment or acting in reckless disregard or deliberate ignorance of the existence of the overpayment.
- Actual process for reporting and returning the overpayment will be set forth in later guidance from CMS.

Direct Access to FDRs

- Proposed rule would amend § 422.504(i)(2)(ii) and § 423.505(i)(2)(ii) to provide that HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records by obtaining them directly from any FDR.
- No more waiting for FDR records.
- Eliminate the middleman – the MAO or PDP.

Minimum Requirements for New Applicants and/or their FDRs

- For entity seeking to contract as a Part D plan sponsor (as a stand alone PDP or MA-PD sponsor), either it or one of its FDRs must have one full year prior experience serving as a Part D plan sponsor or performing key Part D functions for another Part D plan sponsor.
- Prior experience obtained within the two years preceding the Part D sponsor application submission.
- Prior experience of parent or another subsidiary of that parent counts.

Minimum Requirements for New Applicants and/or their FDRs (cont'd)

- Prior Part D experience required in:
  - Authorization, adjudication and processing of pharmacy claims at the point of sale;
  - Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and
  - Operation of an enrollee appeals and grievance process.

Agent and Broker Compensation

- Current scheme:
  - Initial payment not to exceed annually established FMV amount
  - Renewal payment of 50% of initial amount for years 2 – 6
  - Renewal payments can extend beyond year 6

Agent and Broker Compensation (cont'd)

- Simplified scheme
  - Initial payment not to exceed annually established FMV amount
  - Renewal payments of up to 35% of current FMV for that year
  - Removes 6-year cap on compensation cycle

Agent and Broker Compensation (cont'd)

- Simplified scheme
  - Payments must be tied to plan years (January 1 – December 31) and cannot cross calendar years
  - Payments may not be made until January 1 of the compensation year and must be paid in full by December 31 of the compensation year
  - Plans should recover agent/broker compensation only for the months that the beneficiary is not enrolled other than the first 3 months
    - If beneficiary disenrolled in first 3 months and the disenrollment did not result from agent/broker action, plan sponsor not required to recoup compensation

2015 Call Letter - Highlights

- Implications of Inaccurate and Incomplete Bid Submissions and Plan Corrections
- Termination of Poor Performers
- Provider Terminations
- Tiered Cost-Sharing for Medical Benefits

CMS Gets Tough

- Incomplete or Inaccurate Bids
  - Incomplete bids will not be accepted
  - "Clearly" inaccurate bids will result in compliance letter and corrective action plan. Revisions may not be allowed.
- Plan Corrections
  - Submitters will receive compliance letter and will be suppressed in Medicare Plan Finder until November update.
  - Submitters that are repeat offenders may receive more severe compliance action.

Provider Terminations

- MAOs must notify CMS at least 90 days prior to network changes for any no cause termination that they deem "significant".
- CMS will determine whether terminations are substantial and require the granting of a Special Election Period.
- Criteria for allowing an SEP include:
  - Number of enrollees affected;
  - Size of affected service area;
  - Timing of the termination;
  - Whether adequate and timely notice is provided to enrollees; and
  - Any other information that may be relevant to the particular circumstance(s).

Additional SEP considerations

- Enrollee must demonstrate that he/she has been affected by the change.
- SEPs will not be granted when network changes are effective on January 1 of the following contract year, as long as affected enrollees are notified of the changes prior to the start of the Annual Election Period.
- Best practice is give enrollees more than the required 30 days prior notice of significant network changes for no cause.

Significant Network Changes

- CMS expects MAOs to take a conservative approach in determining whether a network change is significant and notify CMS if there is any doubt as to whether planned contract termination represents significant change to the network.
- CMS encourages MAOs to provide more than 60 days prior notice to providers whose contracts are being terminated without cause to allow for a complete appeals process prior to beneficiaries being notified.

Tiered Cost-Sharing of Medical Benefits

- MAOs may charge different cost sharing amounts for physicians or groups of physicians to encourage members to seek care from providers the MAO identifies based on quality and efficiency criteria.
- Tiered cost sharing may apply to primary and/or specialty care physicians.
- The cost sharing must be applied so that all plan members are charged the same cost sharing amount for any specific physician and all physicians are available and accessible to all members in the plan.

Preemption, as applied by DMHC

- MA standards set forth in 42 CFR 422 supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans, with the exception of licensing laws and regulations and laws and regulations relating to plan solvency.
- DMHC seeks to regulate on financial solvency and administrative capacity.
- DMHC doesn't review provider contracts, except for financial terms to evaluate compensation.
- DMHC does review administrative services agreements.
- RBO laws are arguably not preempted.

Provider Risk Arrangements and PIP Rules

- ACOs and Stars have resulted in many new and creative physician risk arrangements
- Federal Physician Incentive Plan rules are often implicated
- PIP Rules apply to incentive plans that place physicians or physician groups at risk for referral services
- Plans should be careful to ensure that stop loss requirements are included in PIP arrangements
- Pooling of membership amongst plans might avoid the need for stop-loss, but that shouldn't be assumed
- Knox-Keene jurisdictional issues can also be implicated in new incentive arrangements